Table of Contents

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

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	**83-0751369**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10955 Alexandria Way, Suite 100, San Diego, CA	**92121**
(Address of principal executive offices)	**(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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $18.0 million on the last business day of the registrant's most recently completed second fiscal quarter based on the closing price of $1.01 per share, which was the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on such date. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant on such date have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

The number of shares of registrant's Common Stock outstanding as of March 2, 2026 was 22,407,251.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for the 2026 annual meeting of stockholders to be filed with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year covered by this report are incorporated by reference into Part III of this report.

Table of Contents

		Page
PART I		
Item 1.	Business	4
Item 1A.	Risk Factors	40
Item 1B.	Unresolved Staff Comments	88
Item 1C.	Cybersecurity	88
Item 2.	Properties	89
Item 3.	Legal Proceedings	89
Item 4.	Mine Safety Disclosures	90
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	91
Item 6.	[Reserved]	91
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	92
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	102
Item 8.	Financial Statements and Supplementary Data	102
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	103
Item 9A.	Controls and Procedures	103
Item 9B.	Other Information	103
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	104
PART III		
Item 10.	Directors, Executive Officers, and Corporate Governance	105
Item 11.	Executive Compensation	105
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	105
Item 13.	Certain Relationships and Related Transactions, and Director Independence	105
Item 14.	Principal Accountant Fees and Services	105
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	106
Item 16.	Form 10-K Summary	107

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND MARKET AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this report are forward-looking statements, including statements regarding our future results of operations and financial position, our 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 candidate (ecDTx), our use of the net proceeds from the initial public offering (IPO) of our common stock, the period over which we estimate our cash position will be sufficient to fund our operations, the sufficiency of our cash position to fund achievement of milestones, including initial clinical data readout, the expected benefits of the portfolio prioritizations we recently implemented, the timing and likelihood of success, plans, and objectives of management for future operations, the potential to enter into strategic collaborations, the timing of expected clinical data readout for our ecDTx, the potential safety and therapeutic benefits of our ecDTx, the potential addressable patient populations for our ecDTx, the potential to identify additional development opportunities for our ecDTx or expand our therapeutic pipeline, the timing and likelihood of regulatory submissions, filings and approvals for our ecDTx, expected regulatory approval pathways for our ecDTx, our ability to commercialize our ecDTx, if approved, the pricing and reimbursement of our ecDTx, if approved, potential competition for our ecDTx, our intellectual property and other market exclusivity strategies, our intent regarding any strategic collaborations, licenses, or similar arrangements and the potential benefits of any such arrangements.

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,” “would,” “target,” or “will” or the negative of these terms or other similar expressions. Our forward-looking statements are only predictions. We have based our 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 based upon information available to us as of the date of this report. Such information may be limited or incomplete. Forward-looking statements in this report speak only as of the date of this report and are subject to several risks, uncertainties, and assumptions, including those described in Part I, Item 1, “Business,” and Item 1A, “Risk Factors,” and Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and, our actual results, performance, or achievements could differ materially from those expressed or implied by our forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not place undue reliance on any forward-looking statement. 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.

In addition, statements that “we believe” and similarly qualified statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to rely unduly upon them.

We obtained the industry, market, and competitive position data used in this report from our own internal estimates and research, as well as from independent market research, industry, and general publications and surveys, governmental agencies, and publicly available information in addition to research, surveys, and studies conducted by third parties. The content of these third-party sources, except to the extent specifically set forth in this report, does not constitute a portion of this report and is not incorporated herein. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research, and our industry experience and are based on assumptions made by us using such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

In addition, while we are responsible for all of the disclosure contained in this report and we believe the industry, market, and competitive position data included in this report is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed below under the section titled “Risk Factors

Summary" and in Part I, Item 1A, "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

RISK FACTORS SUMMARY

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factors summary, and other risks that we face, can be found in Part I, Item 1A., "Risk Factors," of this Annual Report on Form 10-K, and should be carefully considered, together with other information in this report and our other filings with the U.S. Securities and Exchange Commission (SEC) before making investment decisions regarding our common stock.

- 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 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.
- We are early in our development efforts and have only one ecDTx in development. If we are unable to successfully develop, obtain regulatory approval, and ultimately commercialize our 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 novel and 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 ongoing or future 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, cause us to 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 identify predictive biomarkers to identify patient populations most likely to benefit from our ecDTx, or develop a 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.
- 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.
- We rely on third parties to conduct our clinical trials and preclinical studies, manufacture our ecDTx, package, label, ship, store, and distribute our ecDTx, and supply products used as combination agents in our clinical trials, and these third parties may not perform satisfactorily or at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.
- Disruptions or changes at the U.S. Food and Drug Administration (FDA), the U.S. Securities and Exchange Commission (SEC), and other government agencies, including due to government shutdowns, other funding shortages, policy changes, leadership changes, layoffs or significant personnel turnover, or public health concerns could impede development and potential marketing approval of our ecDTx and our ability to raise capital.
- 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.

- 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.
- We occupy our corporate headquarters under a long-term non-cancellable lease which may limit our operating flexibility and could adversely affect our liquidity and results of operations.
- We may engage in strategic transactions that could impact our liquidity, increase our expenses, and divert management's attention from other business priorities.
- If we are unable to obtain, maintain, defend, and enforce patent or other intellectual property protection for our ecDTx 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.
- 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.
- The trading volume and price of our common stock have been and may continue to be highly volatile, and purchasers of our common stock could incur substantial losses.
- If we fail in the future to satisfy the applicable continued listing requirements of The Nasdaq Stock Market LLC, Nasdaq may take steps to delist our common stock.
- Macroeconomic and geopolitical events and conditions outside of our control, including market volatility, high interest rates, inflation, tariffs and other trade barriers, retaliatory measures taken by foreign countries, slowed economic growth or recession, uncertainty with respect to the federal budget and debt ceiling, potential or prolonged government shutdowns, liquidity concerns at financial institutions, supply chain disruptions, military conflicts, and other geopolitical events and instability in market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, and stock price.

Item 1. Business.

The terms "we," "us," "our," "our company," "Boundless Bio," "Boundless," or the "Company" refer to Boundless Bio, Inc. unless otherwise stated or the context otherwise requires. All information in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months, or periods refer to our fiscal years ending December 31 and the associated quarters, months, and periods of those fiscal years.

Overview

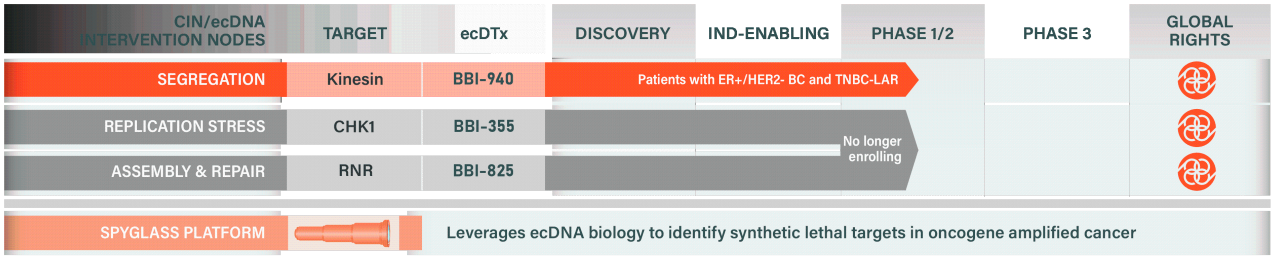
We are a clinical-stage oncology company dedicated to unlocking a new paradigm in cancer therapeutics that addresses the significant unmet need in patients with oncogene amplified tumors by interrogating extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in 14 to 17% of cancer patients. Our mission is to be the foremost biopharma company interrogating ecDNA biology to deliver transformative therapies that improve and extend the lives of patients with previously intractable oncogene amplified cancers.

ecDNA are large circular units of nuclear DNA that are a primary mechanism of gene amplification and are detected only in cancer cells, not in healthy cells. Despite tremendous advancements in treating cancer broadly, patients with oncogene amplified cancers generally derive little benefit from existing therapies, such as molecular targeted therapies or immunotherapies, and have worse survival rates than patients without oncogene amplification. Using our proprietary Spyglass platform, we identify targets essential for ecDNA functionality in oncogene amplified cancer cells, then design and develop small molecule drugs called ecDNA-directed therapeutic candidates (ecDTx) to inhibit those targets, with the aim to prevent cancer cells from using chromosomal instability (CIN) and ecDNA amplification biology to grow, adapt, and become resistant to existing therapies. Instead of directly targeting the proteins produced by amplified oncogenes, which is the approach of traditional targeted therapies, our ecDTx are intended to be synthetic lethal in tumor cells reliant on ecDNA amplification biology. In the context of drug development, synthetic lethality is a therapeutic approach wherein using a drug to inhibit one target is lethal to cancer cells harboring a specific genetic alteration to a second target, but not lethal to healthy cells that lack the genetic alteration to the second target. Accordingly, our ecDTx are designed to preferentially kill ecDNA-enabled cancer cells, but not healthy cells. They are engineered to disrupt the underlying cellular machinery that enables ecDNA or functional amplification.

Our lead ecDTx, BBI-940, is a novel, oral, selective degrader that targets a previously undrugged kinesin involved in DNA segregation, including ecDNA segregation during mitosis. BBI-940 has demonstrated potent anti-tumor activity across a range of cancer cell lines and mouse xenograft models, including single-agent tumor regressions. In February 2026, we initiated a Phase 1, open-label, multicenter, first-in-human clinical trial of BBI-940 in patients with estrogen receptor positive and human epidermal growth factor receptor 2 negative, or ER+/HER2-, breast cancer who have progressed following treatment with a cyclin-dependent kinase 4 and/or 6 inhibitor, or CDK4/6 inhibitor, plus endocrine therapy, as well as patients with triple-negative breast cancer luminal androgen receptor subtype, or TNBC-LAR (clinicaltrials.gov identifier NCT07408089). We refer to this trial as KOMODO-1 (for Kinesin Oral Molecular Degrader for Oncology-1). In the KOMODO-1 trial, we contemplate two distinct biomarkers for patient selection, and we will retrospectively assess ecDNA status using multiple techniques for inferring ecDNA in tumor samples. We expect to have initial proof-of-concept safety and efficacy clinical data from the KOMODO-1 trial of BBI-940 within our existing cash runway timeline discussed in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," of this Annual Report on Form 10-K.

We have been investigating BBI-355, a novel, oral, selective inhibitor of checkpoint kinase 1 (CHK1) designed to target replication stress in oncogene amplified cancers in a first-in-human Phase 1/2 clinical trial in patients with oncogene amplified cancers that we refer to as POTENTIATE (for Precision Oncology Trial Evaluating Novel Therapeutic Interrupting Amplifications Tied to ecDNA) (clinicaltrials.gov identifier NCT05827614). In the POTENTIATE trial, we used an internally developed ecDNA diagnostic clinical trial assay, which we refer to as ECHO (ecDNA Harboring Oncogenes), to detect ecDNA in patient tumor samples by analyzing genomic data from routine next generation sequencing (NGS) tests. In May 2025, we announced that we discontinued the monotherapy arm and combination arms of BBI-355 with third-party targeted therapies in the POTENTIATE trial based on initial trial data. During 2025, we have been winding down those initial arms of the POTENTIATE trial. We had been continuing to investigate BBI-355 in combination with BBI-825, a novel oral, selective inhibitor of ribonucleotide reductase (RNR) designed to target ecDNA assembly and repair; however, in January 2026, following a strategic portfolio review, we elected to cease enrollment of the POTENTIATE trial due to market considerations, clinical data, and prioritization of our BBI-940 program.

Our Pipeline and Platform



ER+: ER positive; HER2-: HER2 negative; BC: breast cancer; TNBC: triple-negative breast cancer; LAR: luminal androgen receptor; ecDTx: ecDNA-directed therapeutic candidates

Spyglass is our proprietary platform that leverages ecDNA biology to identify new cancer drug targets. These targets span multiple, diverse synthetic lethal nodes in oncogene amplified cancers. In addition to the ecDTx programs described above, we have preclinically validated multiple additional targets and conducted ecDTx drug discovery efforts to identify candidates against certain targets.

We believe our unique development approach has several potential benefits for patients, including:

- addressing oncogene amplified cancers, a type of cancer without effective treatment options;
- identifying patient populations most likely to benefit from our ecDTx by using a biomarker-driven approach; and
- employing a tumor-agnostic development strategy, as appropriate, focusing on oncogene amplified cancers across a broad range of tumor types and amplified oncogene drivers.

We consider ourselves to be the world's leading ecDNA company. To our knowledge, we are the first company developing new cancer medicines directed at amplification biology and ecDNA function and the only company to date to bring an ecDTx into the clinic. All of our ecDTx have been discovered internally, and we retain global rights for all of our programs. Our efforts build on the work of our scientific founders and advisors, including Dr. Paul Mischel, who is a globally recognized leader in the ecDNA field, having authored more than 30 peer-reviewed publications on ecDNA and the team leader for the National Institute of Health's (NIH) and Cancer Research United Kingdom's (CRUK) Cancer Grand Challenges team devoted to ecDNA and its role in cancer. Dr. Mischel is the Chairman of our Scientific Advisory Board.

Our Strategy

Our mission is to be the foremost biopharma company interrogating ecDNA biology to deliver transformative therapies that improve and extend the lives of patients with previously intractable oncogene amplified cancers. To accomplish this mission, our strategy is to leverage our unique expertise in ecDNA biology and its role in oncogene amplified cancer to pioneer the discovery, development, and commercialization of novel ecDTx for these patients who are not successfully treated by existing therapeutic options. The principal components of our strategy are to:

- ***Advance our lead ecDTx, BBI-940, a novel, oral kinesin degrader through clinical development and regulatory approval in patients with metastatic breast cancer.*** Through Spyglass, we have gained a deeper understanding of unique ecDNA segregation mechanisms during cell division and identified a kinesin target essential for ecDNA segregation and inheritance, whose inhibition is synthetic lethal to certain chromosomally unstable and ecDNA enabled cancer cells. This program is directed to this kinesin, which is a member of a family of known druggable proteins, but for which there are no approved drugs and to our knowledge no other publicly disclosed drug discovery efforts. In February 2026, we initiated the first-in-human KOMODO-1 trial of BBI-940 in patients with ER+/HER2- breast cancer who have progressed following treatment with a CDK4/6 inhibitor, plus endocrine therapy, as well as patients with TNBC-LAR, and we expect to have initial proof-of-concept safety and efficacy clinical data within our existing cash runway.
- ***Leverage Spyglass to potentially identify additional development opportunities for BBI-940 and expand our therapeutic pipeline.*** We utilize Spyglass to identify and interrogate targets that exploit cellular vulnerabilities of oncogene amplified cancers. Our target identification efforts have revealed multiple distinct nodes of vulnerability within the lifecycle of ecDNA. We continuously incorporate new models, tools, and technologies into our Spyglass platform to identify novel points of synthetic lethality in oncogene amplified cancers. In addition to our programs described above, we have preclinically validated multiple additional targets and have historically initiated ecDTx drug discovery efforts to identify potential candidates against such targets. We continue to deploy Spyglass to inform development of BBI-940 and potential complementary targets or assets that we may wish to acquire or internally develop in the future.
- ***Opportunistically pursue strategic collaborations to accelerate development timelines and maximize the commercial potential of our ecDTx.*** The large number of potential intervention points in the ecDNA life cycle identified by our Spyglass platform has the potential to provide us with more targets, ecDTx, and clinical development strategies than we may be able to pursue on our own. We believe this abundance of potential treatment opportunities may provide an opportunity for potential strategic collaborations involving our targets, our ecDTx, or our Spyglass platform to maximize the patient benefit and long-term value of our research and development portfolio.

Our History and Team

Our company was founded in 2018 by a leading healthcare investor, ARCH Venture Partners, and the world's leading academic researchers in the burgeoning field of ecDNA. One of our scientific co-founders, Paul Mischel, M.D., Institute Scholar ChEM-H and Vice Chair of Research and Professor for the Department of Pathology at Stanford University, and member of the National Academy of Medicine, is internationally recognized for his expertise in ecDNA and cancer biology. Dr. Mischel serves as the Chairman of our Scientific Advisory Board.

Our other scientific co-founders include:

- Vineet Bafna, Ph.D., Professor of Computer Science & Engineering at the University of California, San Diego; co-founder of Digital Proteomics; current member of our Scientific Advisory Board.
- Howard Chang, M.D., Ph.D., Senior Vice President of Research and Chief Scientific Officer at Amgen, former Director of the Center for Personal Dynamic Regulomes and the Virginia and D.K. Ludwig Professor of Cancer Genomics at Stanford University; co-founder of Accent Therapeutics, Cartography Biosciences, Epinomics, and Orbital Therapeutics; former Howard Hughes Medical Investigator; member of the National Academy of Sciences.
- Ben Cravatt, Ph.D., Professor and Gilula Chair in Biology and Chemistry at The Scripps Research Institute; co-founder of Abide Therapeutics, ActiveX Biosciences, Belharra Therapeutics, and Vividion Therapeutics; recipient of the 2022 Wolf Prize for chemistry; member of the National Academy of Sciences; current member of our Scientific Advisory Board.
- Prashant Mali, Ph.D., Professor of Bioengineering at the University of California, San Diego; co-founder of Navega Therapeutics and Shape Therapeutics.
- Roel Verhaak, Ph.D., Harvey and Kate Cushing Professor in the Department of Neurosurgery at Yale University School of Medicine.

One of our industry co-founders is Jonathan Lim, M.D., Co-founder, CEO, and Chairman of Erasca, Venture Partner at ARCH Venture Partners, and former Co-founder and CEO of Ignyta. Dr. Lim serves as the Chairman of our Board of Directors.

In support of our mission to deliver the world's first ecDTx to patients with oncogene amplified cancers, we have assembled a highly qualified management team with deep experience in precision oncology, drug discovery and development, diagnostic development, company building, capital raising, and strategic partnerships and acquisitions. This team hails from leading oncology-focused organizations such as Ignyta, Sierra Oncology, Halozyme Therapeutics, and Rain Oncology and from leading pharmaceutical companies such as Genentech/Roche.

Our management team is led by our President and Chief Executive Officer, Zachary Hornby, who formerly served as Chief Operating Officer and Chief Financial Officer at Ignyta (acquired by Roche/Genentech). At Ignyta, he led the operational team that developed Rozlytrek®, which is globally approved and commercialized for patients with *NTRK*+ solid tumors and *ROS1*+ non-small cell lung cancer. Our Chief Scientific Officer, Chris Hassig, Ph.D., brings over 20 years of oncology research, target discovery, and drug development experience to Boundless Bio. Dr. Hassig was most recently Chief Scientific Officer at Sierra Oncology (acquired by GlaxoSmithKline) where he spearheaded research efforts for the company's pipeline against several oncology and hematology targets. Our Chief Medical Officer, Robert Doebele, M.D., Ph.D., is a medical oncologist and previously served as Chief Medical Officer and Chief Scientific Officer at Rain Oncology, where he led the early and late-stage development of multiple oncology programs using biomarker-based, tumor-agnostic strategies.

Evolution of Precision Oncology

Cancer is the second leading cause of mortality in the United States, accounting for approximately 1,900,000 new diagnoses and 600,000 deaths on an annual basis. There are many genetic aberrations, including mutations, fusions, and amplifications that lead to the malignant cellular growth that results in cancer.

The first approved precision oncology drugs were predominately directed at the proteins produced by oncogenes hyperactivated by gene mutations or gene fusions. These drugs targeted specific types of receptor tyrosine kinases such as BCR-ABL, HER2, EGFR, ALK, and others. Since 2001, the FDA has approved more than 50 tyrosine kinase inhibitors for the treatment of cancer. This initial class of precision oncology drugs, also known as targeted therapies, generated more than $30 billion of worldwide sales in 2023. Much of the commercial success of these targeted therapies is due to their capacity to drive deeper and more durable responses than conventional chemotherapy regimens while minimizing unwanted side effects and damage to normal healthy tissues.

An evolution in the understanding of tumor biology coupled with an improved ability to segment subsets of tumors based on genomic alterations has led to the development of new therapies that transcend single tumor or organ-targeted cancers. This improved molecular understanding of cancer resulted in the approval of therapies that address specific genomic features of tumors but are tumor type agnostic; some examples are the TRK inhibitors, including entrectinib and larotrectinib, for the treatment of tumors with *NTRK* gene fusions. This trend for tumor-agnostic indications represented a breakthrough in patient identification, drug development, clinical trial designs, and speed to market approvals, albeit benefiting relatively modest sized patient populations.

Despite these advances of the precision oncology field, treatment resistance is still an unfortunate inevitability in cancer. The predominant resistance mechanisms to targeted therapies are secondary mutations of the treatment target (e.g., *EGFRT790M*, *ALKG1202R*), other means of pathway activation, and oncogene or resistance gene amplifications. The quest to address resistance has given rise to a newer generation of targeted therapies and treatment modalities, mostly directed at secondary mutations and alternative pathways. However, there are still very few approved or investigational therapies in development for patients with gene amplifications.

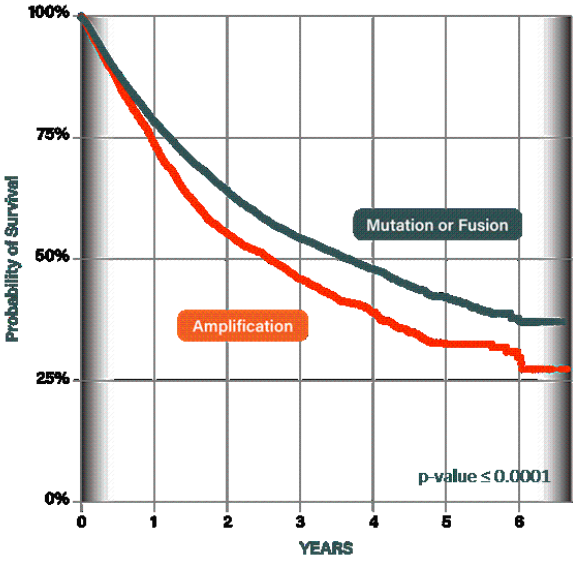
Significant Unmet Medical Need in Oncogene Amplified Cancers

While progress in treating cancers with other forms of oncogenic driver alterations continues to advance, patients whose cancers harbor oncogene amplifications remain a high unmet medical need. Cancers with gene amplifications are characterized by the abnormal presence of more than two copies of any gene within the human genome; when more than eight copies of a gene are present, this is often referred to as high copy number gene amplification. Genes whose activating mutation or amplification are associated with cancer are referred to as oncogenes. According to analyses of large cancer patient databases, greater than 25% of all cancer cases involve oncogene

amplifications, suggesting that in the U.S. alone the oncogene amplified cancer population may represent more than 400,000 new patients each year across multiple tumor types.

Patients whose tumors harbor oncogene amplification have significantly worse survival compared to the broader cancer population. As seen in the figure below, patients with oncogene amplifications also have significantly worse survival compared to patients with other genetic alterations of the same oncogenes.

Cancer Patients with Oncogene Amplifications Have Worse Survival Than Those with Oncogene Mutations or Fusions



Patients with primary or metastatic cancers with amplifications, point mutations, skipping deletions or fusions of these genes: AR, ALK, ARAF, BRAF, CCND1, CDK4, CDK6, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, MAP2K4, MDM2, MET, MYC, NF1, NRAS, NTRK1, NTRK2, NTRK3, PDGFB, PDGFRA, PDGFRB, PIK3CA, RAF1, RET, ROS1

cBioPortal analysis using MSK-MET (N=14,674 patients) and MSK-IMPACT (N= 1,115 patients), p-value =< 0.0001)

A p-value is the probability that the reported result was achieved purely by chance, such that a p-value of less than or equal to 0.05 means that there is a less than or equal to 5% probability that the difference between the control group and the treatment group is purely due to chance. A p-value of 0.05 or less typically represents a statistically significant result. The FDA's evidentiary standard of efficacy when evaluating the results of a clinical trial generally relies on a p-value of less than or equal to 0.05.

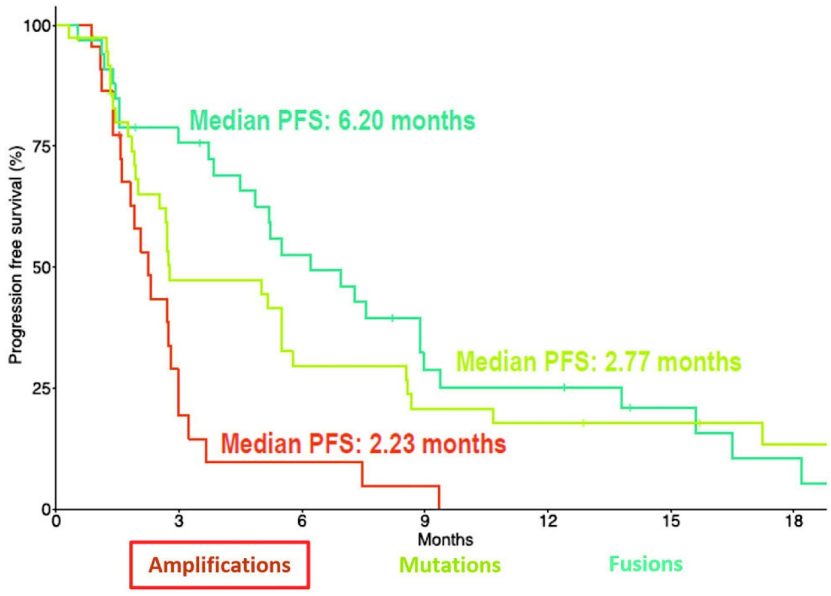
Despite the advancements in precision medicine and targeted therapies for these other forms of driver oncogene alterations, as well as immunotherapies for patients whose cancers lack driver oncogenes, both targeted therapies and immunotherapies have proven largely ineffective in oncogene amplified cancers.

Examples of Commercial Targeted Therapies Not Approved for Oncogene Amplifications

TARGETED THERAPY	TARGET	APPROVED	NO APPROVAL
palbociclib ribociclib abemaciclib	CDK4/6	HR+/HER2- breast cancer	Amplification
gefitinib afatinib erlotinib osimertinib	EGFR	Exon 19 deletion NSCLC L858R NSCLC T790M NSCLC	Amplification
erdafitinib pemigatinib infigratinib futibatinib	FGFR	*FGFR3* mutation bladder cancer *FGFR2/3* fusion cholangiocarcinoma	Amplification
capmatinib tepotinib	MET	EXON 14 skipping NSCLC	Amplification

Targeted agents that have shown efficacy in patients whose cancers are driven by other oncogene alterations, including point mutations, gene fusions, or skipping deletions, have generally failed to demonstrate robust efficacy in patients whose tumors are driven by oncogene amplification. The lack of approved therapies targeting oncogene amplified tumors exists despite extensive clinical testing of targeted agents in oncogene amplified cancer populations. Clinical studies have shown limited success in treating patients with *EGFR*, *FGFR*, and *CDK4* amplified solid tumors with matching molecular targeted therapies. For example, approved and clinical-stage CDK4/6 inhibitors showed only a collective 2% overall response rate (ORR) in *CDK4* amplified tumors, and FGFR inhibitors showed only a collective 13% ORR in patients with *FGFR* amplified tumors. This unfortunate trend has been observed across several classes of targeted agents when tested in oncogene amplified tumors. In fact, despite continuous advancement of the precision oncology field, of the more than 200 FDA approved targeted therapies to date, only HER2 inhibitors and a MET antibody drug conjugate (ADC) have ever been approved for oncogene amplified or overexpressed cancer populations.

FGFR Inhibitors Demonstrated Less Clinical Benefit in Patients with FGFR Amplifications Than in Patients with Other FGFR Alterations (Mutations, Fusions)



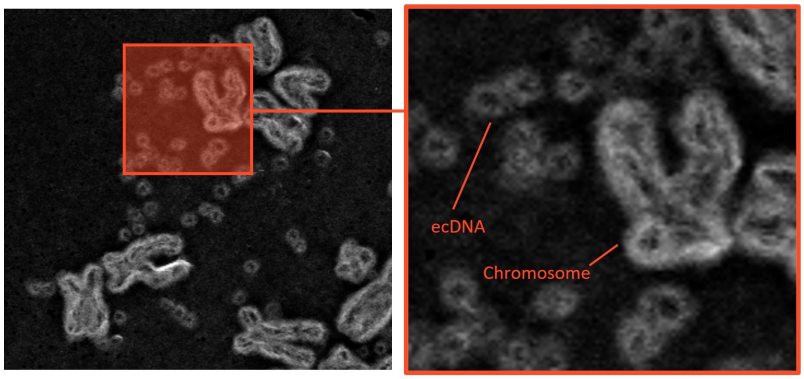
The presence of oncogene amplification is also associated with a lack of response when patients are treated with immunotherapies, for instance immune checkpoint inhibitors such as pembrolizumab. Furthermore, immune checkpoint inhibitors have been associated with rapid clinical worsening, known as hyper-progression, in patients with oncogene amplified tumors. There is growing evidence that oncogene amplifications could be one of the mechanisms that cancers use to escape immune surveillance or alter the tumor immune environment to avoid being eliminated by the immune system.

Role of extrachromosomal DNA in Oncogene Amplified Cancers

Chromosomal instability and tumor variability, or heterogeneity, account for many failures of targeted therapies in patients with cancer. Oncogene amplification is a consequence of chromosomal instability, arising through either numerical and/or structural alterations in chromosomes including the formation of ecDNA. It has long been recognized that oncogenes can be amplified not only on chromosomes but also on ecDNA. However, the frequency, importance, and specific role of ecDNA in cancer biology has not been well understood until recently. We believe the emerging science of ecDNA, first elucidated by our scientific founders and now the core focus of our Company, brings a new understanding of oncogene amplifications in cancer.

ecDNA are cancer-specific, circular fragments of genomic DNA that often encode full-length genes and regulatory regions such as promoters. ecDNA are physically separate from chromosomes, but still reside in the nucleus, and have unique properties that make them a common cellular mechanism for oncogene amplification. ecDNA often range in size from 2-5 megabase pairs in length and are visible through various forms of microscopy, as seen in the figure below. They have been observed in cancer cells by pathologists for more than 60 years, but until recently their function was unclear.

Microscopy Images of Chromosomes and ecDNA



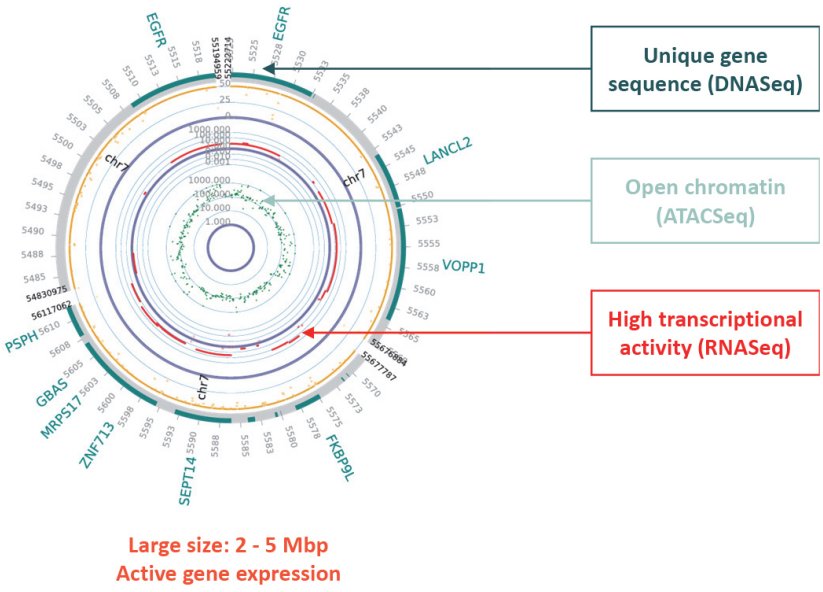
Low magnification *High magnification*

Some of the most common driver oncogenes, such as *EGFR*, *MYC*, *KRAS*, *FGFR*, etc., are found to be amplified on ecDNA and can confer a selective fitness advantage to cancer cells. Oncogenes amplified on ecDNA have several features that distinguish them from amplifications located on chromosomes, including:

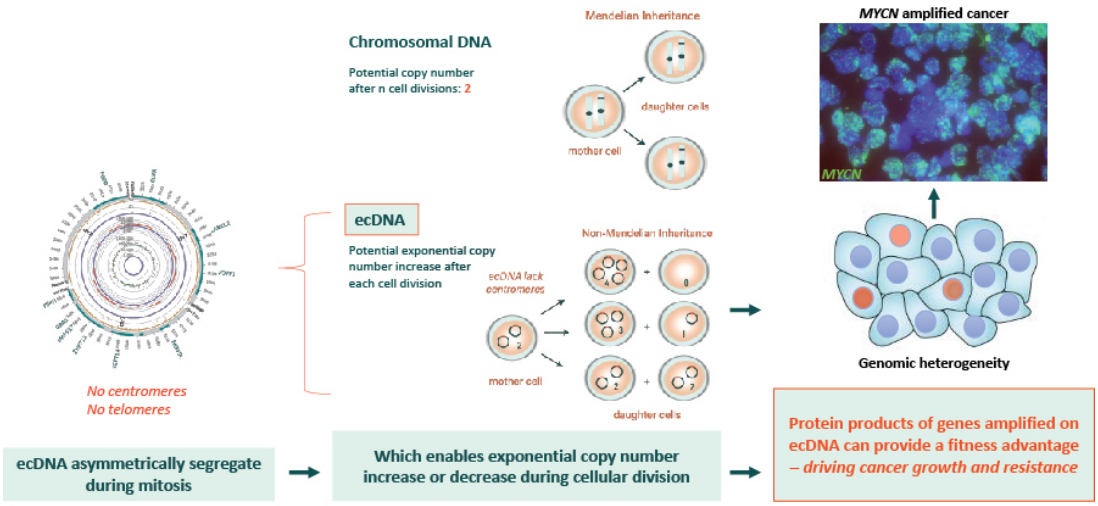
- ***Overexpression*** – Genes on ecDNA behave differently from genes on chromosomes because ecDNA are not properly regulated at the epigenetic level. ecDNA have a circular structure that is less tightly compacted compared to chromosomes, allowing easier access to their DNA. Easier access of the DNA to the cellular transcriptional machinery results in highly transcriptionally active genes that are often more actively expressed than genes located on chromosomes.
- ***Heterogeneity*** – ecDNA lack centromeres, a critical regulatory component of chromosomal segregation in cell division. Thus, in contrast to chromosomes, ecDNA can segregate unequally during cell division. This property supports a non-Mendelian inheritance pattern for ecDNA, enabling extreme gene copy number changes in relatively few cell divisions and extensive copy number heterogeneity, thereby driving rapid adaptability and tumor evolution.

These features distinguish oncogene amplification on ecDNA from other forms of oncogenic alterations and uniquely enable amplification-dependent, ecDNA-enabled tumors to rapidly adapt and evade therapeutics such as targeted therapies.

Circular Shape of ecDNA Enhances Transcriptional Activity, Leading to High Oncogene Expression

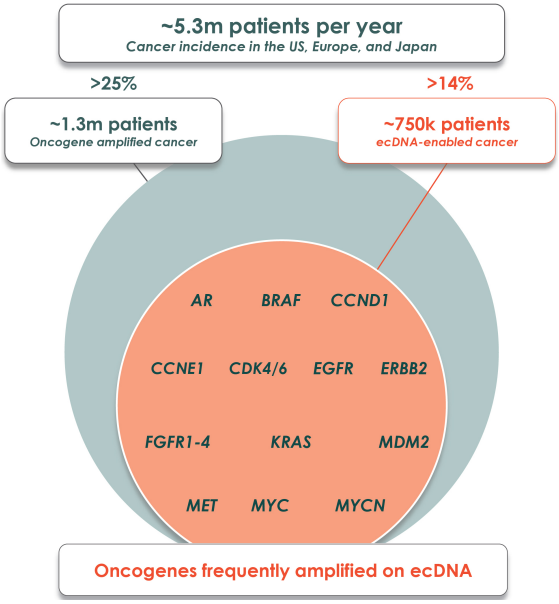


ecDNA Are Inherited via a Non-Mendelian Pattern, Leading to Genomic Heterogeneity



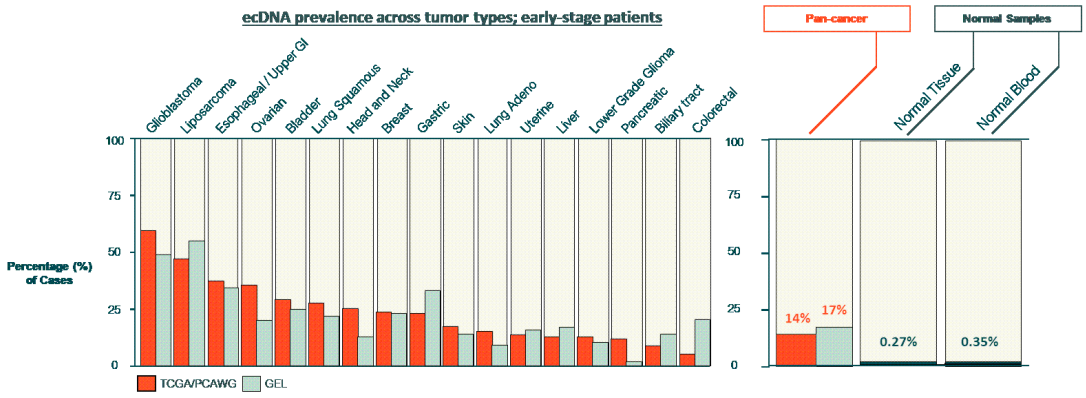
Until recently, the presence of ecDNA in cancer was thought to be a rare event of unclear significance. Then, in 2014, it was demonstrated that ecDNA-enabled gene amplifications are a primary driver of oncogenesis and play a critical role in driving tumor heterogeneity and enabling resistance to targeted therapies. In 2017, it was further demonstrated that ecDNA-enabled gene amplifications were observed in many human cancer types but almost never found in normal cells. More recent publications have shown ecDNA-enabled gene amplifications to be present in 14 to 17% of cancer patients, suggesting an incident population of approximately 750,000 new patients each year in the major addressable markets of the United States, European Union, and Japan, of which approximately 200,000 new patients are in the United States each year. More than half of all cancer cases with high-copy number gene amplification (copy number value >8) have been observed to be in association with ecDNA.

Incident Population of Cancer Patients with ecDNA in the United States, European Union, and Japan is Estimated to be 750,000 Each Year



As seen in the figure below, many of the most aggressive tumor types contain the highest prevalence of ecDNA, including approximately 60% of glioblastomas and approximately 50% of liposarcomas. In fact, based on an analysis of several data sets including The Cancer Genome Atlas (TCGA), Pan-Cancer Analysis of Whole Genomes (PCAWG), and Genomics England (GEL), ecDNA was observed in more than 25% of cases from many different tumor types including: glioblastoma, liposarcoma, esophageal/upper gastrointestinal cancer, ovarian cancer, bladder cancer, lung squamous cancer, head and neck cancer, breast cancer, and gastric cancer.

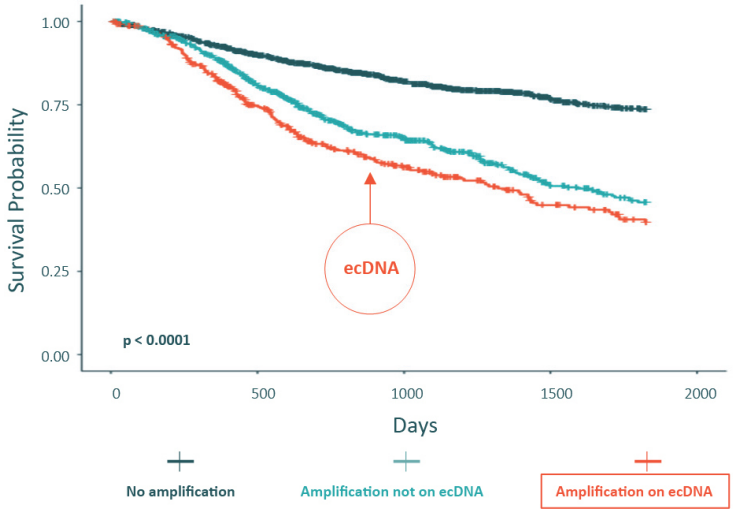
ecDNA Occur Broadly Across Tumor Types but Not in Normal Healthy Tissue



Analysis of WGS data from >3,000 tumor and matched normal samples TCGA and PCAWG; ~15,000 tumor samples from GEL

Unfortunately, as seen in the figure below, patients whose cancers harbor oncogene amplifications experience significantly shorter survival than cancer patients whose tumors are driven by other molecular alterations, such as mutations or fusions. Due to ecDNA's unique properties in cancer cells, patients with ecDNA-enabled oncogene amplification experience even worse survival than patients whose cancers harbor other forms of oncogene amplifications. This data strongly indicate that patients with oncogene amplified cancers, including those with ecDNA, are in dire need of a new therapeutic paradigm.

Patients with Oncogene Amplification on ecDNA Have Worse Survival

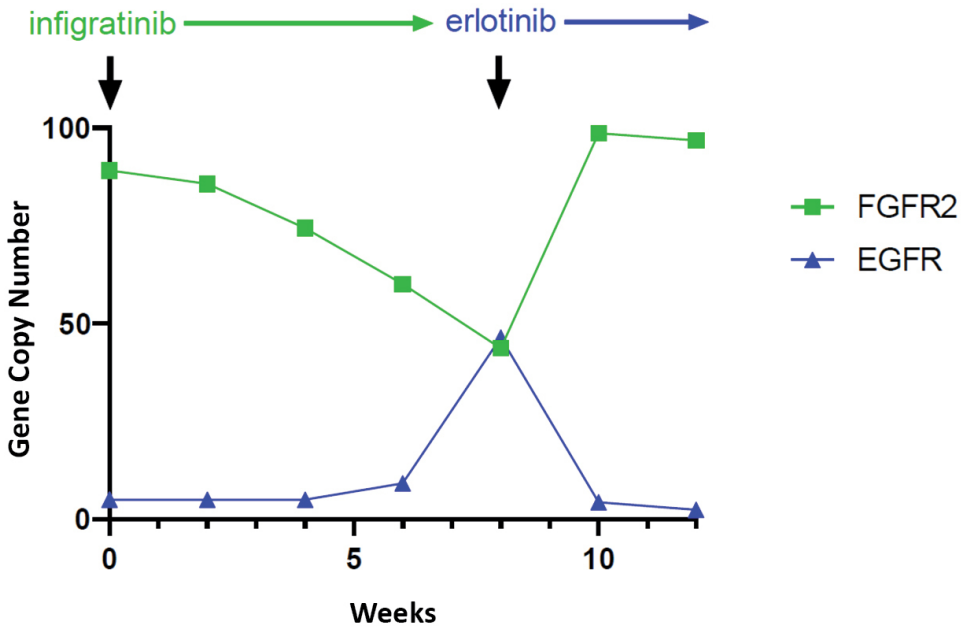


Role of ecDNA in Cancer's Resistance to Therapy

The remarkable genomic plasticity of ecDNA-enabled tumors enables cancers to resist therapies by rapidly adapting their oncogene levels, or by switching their oncogenic drivers all together.

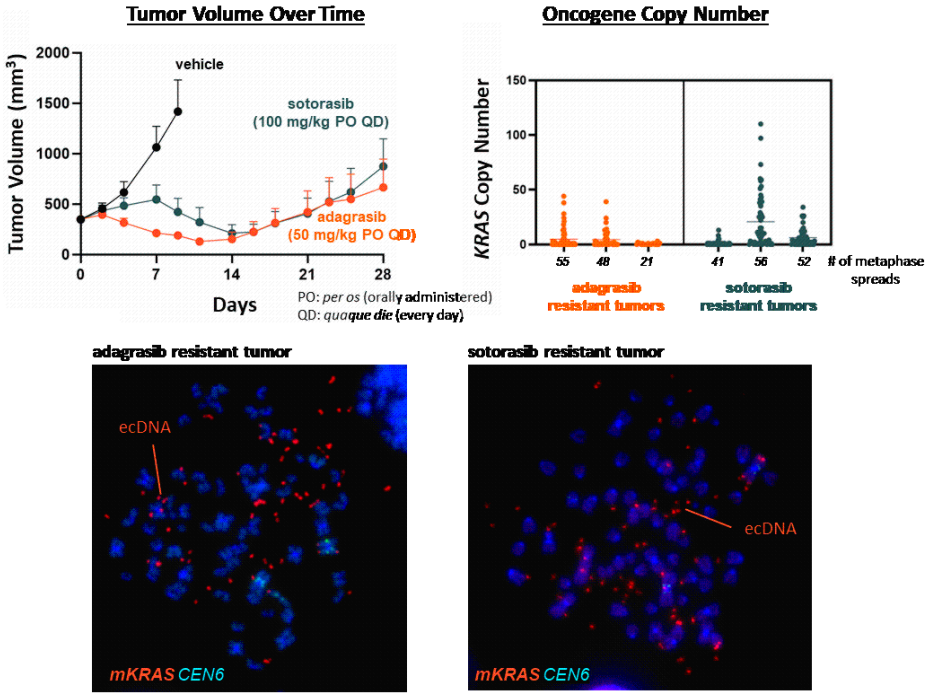
ecDNA's role in enabling resistance to molecular targeted therapies has become better understood through recent preclinical studies. For instance, as seen in the figure below, preclinical studies in a gastric cancer cell line containing *FGFR2* amplified on ecDNA demonstrated that cellular resistance to the pan-FGFR inhibitor infigratinib could be driven by oncogene dependency switching from *FGFR2* amplification on ecDNA to a new, rapid amplification of *EGFR* on ecDNA. Strikingly, this dependency was reversed back to *FGFR2* amplification on ecDNA under EGFR inhibitory pressure via erlotinib. In each case, the initial cell population was sensitive to the respective targeted therapy, resulting in short lived anti-proliferative effects lasting several weeks. Regrowth and resistance to the targeted therapies occurred coincident with switching of the oncogenes amplified on ecDNA.

Dynamic Changes in Average Oncogene Copy Number on ecDNA in Gastric Cancer Cells in Response to Sequential Targeted Therapeutic Pressure



Similarly, mutant oncogenes, such as $BRAF^{V600E}$, $KRAS^{G12C}$, etc., can be amplified on ecDNA as a resistance mechanism to corresponding targeted therapies, such as BRAF or KRAS inhibitors. For example, a mutant $BRAF^{V600E}$ melanoma cell line developed ecDNA-enabled amplification of $BRAF^{V600E}$ after exposure to dual BRAF/MEK inhibition. This phenomenon has also been documented in clinical cases of melanoma patients treated with an approved BRAF/MEK inhibitor regimen. Relatedly, amplification of $KRAS^{G12C}$ on ecDNA has been reported as a clinical resistance mechanism to the $KRAS^{G12C}$ inhibitor adagrasib and to the $KRAS^{G12C}$ inhibitor sotorasib in combination with EGFR inhibitors; this ecDNA enabled amplification was observed *in vitro* and *in vivo* to confer resistance to both of these clinically validated $KRAS^{G12C}$ inhibitors.

Treatment of Colorectal Cancer Cells with KRAS^{G12C} Inhibitors Generated Resistance via Amplification of *KRASG12C* on ecDNA



In other models, evasion of therapeutic response to the EGFR inhibitor erlotinib was facilitated by rapid loss of the population of *EGFRvIII* amplifications on ecDNA in patient-derived glioblastoma cells, contemporaneous with occurrence of a new cell population containing *MDM2* amplification on ecDNA; this observed effect was consistent with an equivalent lack of response to EGFR inhibitors in *EGFR* amplified cancer patients.

ecDNA can also facilitate resistance to therapeutic classes outside of targeted therapies. ecDNA-enabled resistance to chemotherapy was first demonstrated in a mouse cancer cell line whereby methotrexate treatment led to high amplification of *DHFR* on ecDNA, which was lost upon removal of methotrexate. Similar instances of *DHFR* ecDNA amplification have been recapitulated in multiple human cancer cell lines. Furthermore, amplification of drug efflux pump genes on ecDNA, including the family of ABC transporters, has been observed to facilitate resistance to various chemotherapies and other modalities.

Collectively, these data highlight the striking genomic plasticity and precipitous rise and fall of ecDNA-enabled gene amplification that both drives oncogenesis and enables cancer cells to adapt to various therapeutic pressures, leading to rapid resistance. The rapid adaptability afforded by ecDNA-enabled genomic plasticity, including oncogene switching, helps account for the failure of targeted therapies against oncogene amplification-driven tumors, as well as amplification-driven resistance, resulting in a futile, clinical ‘whack-a-mole’ phenomenon. Despite the development and approvals of more potent and selective targeted therapies, rates of resistance via oncogene amplification continue to increase and remain a large unmet need for patients, agnostic to tumor type or molecular driver, as seen in the table below.

Increased Rates of Resistance via Oncogene Amplification in Next-Generation Cancer Drugs

Patients with ≥ 1 amplification at resistance

Indication	Previous-gen inhibitors	Next-gen inhibitors	References
EGFR-mutated non-small cell lung cancer (NSCLC)	erlotinib or gefitinib **15/145 (10%)**	osimertinib **24/109 (22%)**	Chmielecki et al., *Nat Comm* (2023)
ALK+ NSCLC	crizotinib **6/90 (7%)**	lorlatinib **9/31 (29%)**	Solomon et al., *JCO* (2024)
ROS1 fusion NSCLC	crizotinib **7/42 (17%)**	crizotinib → lorlatinib **8/28 (29%)**	Lin et al., *Clin Cancer Res* (2021)
KRAS^{G12C} colorectal cancer (CRC)	adagrasib + cetuximab **13/34 (38%)**	divarasib + cetuximab **11/14 (79%)**	Desai et al., *Nat Med* (2023); Yaeger et al., *Canc Disc* (2024)
BRAF^{V600E} CRC	chemo + cetuximab **0/94 (0%)**	encorafenib + binimetinib + cetuximab **22/112 (20%)**	Kopetz et al., *Nat Med* (2024)
Pancreatic ductal adenocarcinoma (PDAC)	adagrasib or sotorasib (in KRAS^{G12C}) **6/22 (27%)**	daraxonrasib **18/44 (41%)**	Dilly, et al., *Cancer Discovery* (2024); Aronchik, et al., *ANE poster* (2025)

We believe a new and differentiated strategy is needed to interfere with the underlying ecDNA biology that engenders tumor adaptability, heterogeneity, and therapeutic resistance.

Our Approach to Treating ecDNA-Enabled Cancer

We aspire to improve clinical outcomes for patients with oncogene amplified cancer by identifying targets essential for the formation and function of ecDNA in cancer cells, then designing and developing drugs to inhibit those targets. As described above, ecDNA contribute to oncogenesis by facilitating high copy number gene amplification and expression and to therapeutic resistance by providing rapid genomic plasticity. While cancer cells can use chromosomal instability and ecDNA-enabled amplification for certain advantages, their reliance on ecDNA can also expose them to potential vulnerabilities. We use our proprietary Spyglass platform to interrogate ecDNA biology in cancer with the goal of identifying these vulnerabilities in the form of cellular targets that are essential for oncogene amplified tumor cell survival.

We explore the ecDNA lifecycle to identify nodes of synthetic lethality in cancers reliant on amplification biology. In contrast to current precision medicine approaches that focus on targeting proteins that result directly from mutations or fusions of oncogenes such as *EGFR*, *BRAF*, and *ALK*, our precision medicine approach centers on disrupting ecDNA functionality in the cancer cells of patients who are genomically selected based on the presence of ecDNA-enabled amplification in their tumors. Instead of targeting the specific protein products of the oncogenes encoded by ecDNA, our novel small molecule ecDTx are designed to inhibit cellular machinery proteins that enable ecDNA to function properly, such as those critical for ecDNA formation, expression, replication, repair, and segregation.

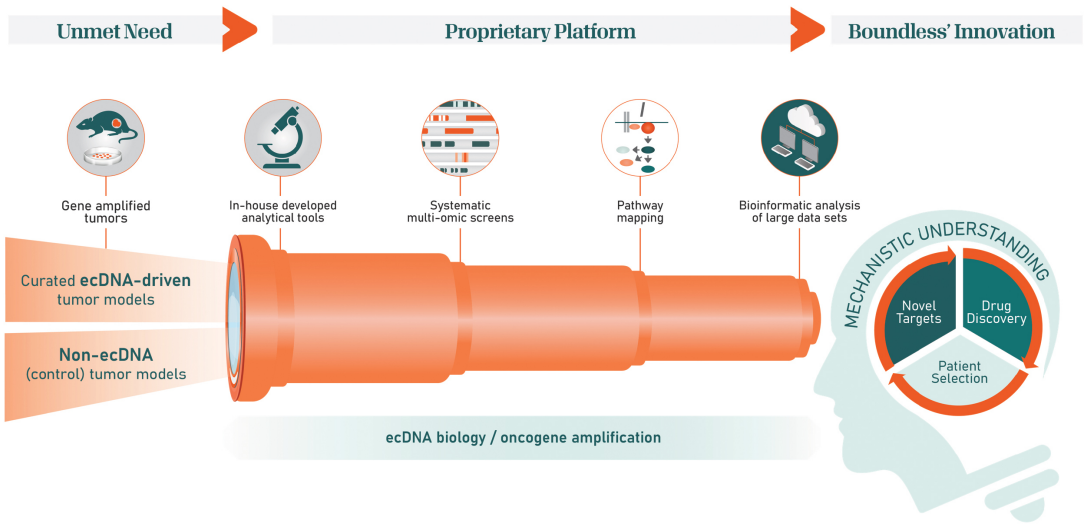
We are developing our ecDTx to be administered as a single agent and in combination with other therapies. The rationale for a combination approach is based on the observation described above that applying targeted therapy, or other therapeutic pressure, to cancer cells can cause them to respond and adapt via increased reliance on ecDNA. We believe this increased reliance on ecDNA for survival makes the cancer cells more susceptible to our ecDTx. We liken this phenomenon to a cellular vice grip concept, as the targeted therapy pushes the surviving cancer cell population to higher reliance on ecDNA, and the ecDTx kills the cancer cells that most rely on ecDNA to survive. Our therapeutic approach is based on the concept of synthetic lethality and uses a strategy to interfere with cancer's ability to employ amplification biology to grow, adapt, and survive.

While targeting ecDNA biology is a novel approach to cancer treatment, our ecDTx drug discovery and development process is rooted in traditional small molecule drug discovery methodology.

Spyglass Platform

We have built our proprietary Spyglass platform to identify specific, druggable targets essential to ecDNA formation and function in cancer cells. To our knowledge, Spyglass is the only platform for identifying ecDNA-enabled vulnerabilities in cancer. We preclinically validate each drug target through our purpose-built validation funnel consisting of multiple oncogene amplified cancer models. The targets that we identify and preclinically validate represent synthetic lethalities for oncogene amplified or other chromosomally unstable tumors.

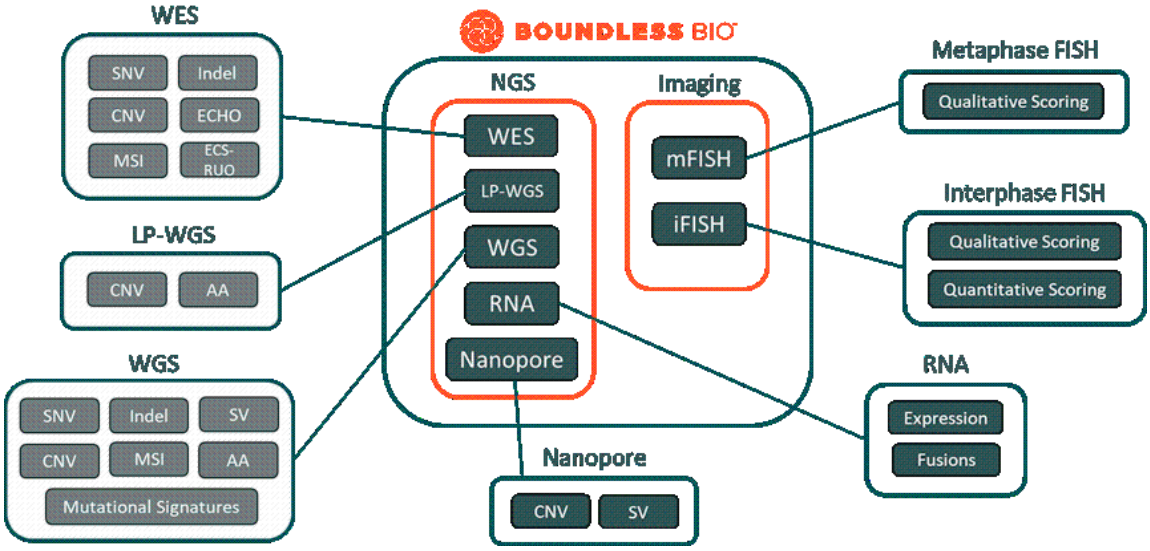
Spyglass Platform



Spyglass consists of the following elements:

- ***Model Systems*–** A heavily curated library of oncogene amplified cancer model systems, including ecDNA-enabled models, and control models. This library consists of approximately 2,000 well characterized cancer models (*in vitro* and *in vivo*), of which approximately 300 are in-house, including:
  - a panel of ecDNA-enabled models, representing multiple different tumor types, such as breast, colorectal, gastric, prostate cancer, and sarcoma and multiple different oncodriver amplifications such as *AR*, CCND1, *CCNE1*, *EGFR*, *FGFR1*, *FGFR2*, *CDK4*, *KRAS*, and *MYC*;
  - a panel of matched control lines of various other states of chromosomal instability and gene amplification ranging from no amplification to chromosomal forms of amplification;
  - the ecDNA-enabled models consist of both "driver oncogene amplified systems" where ecDNA is a primary driver of oncogenesis and "treatment induced resistance systems" where ecDNA becomes the dominant resistance mechanism under therapeutic pressure, such as targeted therapy or chemotherapy; and
  - *in vivo* models, including cell derived (CDX) and patient derived (PDX) tumor xenografts.
- ***Analytical Tools* –** A suite of custom-built analytical tools designed to detect, quantify, characterize, monitor, and perturb ecDNA, including:
  - imaging tools for visual detection and monitoring of ecDNA;
  - off-the-shelf sequencing tools coupled to our proprietary analytical methods to detect, quantify, and characterize ecDNA; and
  - whole genome and custom built CRISPR libraries and shRNA to analyze the biology of oncogene and resistance gene amplified cancer cells.
- ***Bioinformatics Data* –** Large databases to understand amplification biology, including:
  - preclinical databases to support target identification, target validation, biological pathway mapping, model library expansion, biomarker discovery, and preliminary indication finding; and
  - clinical databases of cancer patient genomic data and clinical outcome data to validate preclinical findings and help us identify tumor indications representing the largest opportunity and highest unmet need for our novel ecDTx

Analytical Tools for Model Characterization



WES – whole exome sequencing; SNV – single nucleotide variant; CNV – copy number variation; MSI – microsatellite instability; Indel – insertion and deletion; ECHO – propriety ecDNA diagnostic; ECS – ecDNA solution; RUO – research use only; LP: low-pass; WGS – whole genome sequencing; AA – amplicon architect; SV – structural variation; mFISH – metaphase fluorescence in situ hybridization; iFISH – interphase fluorescence in situ hybridization

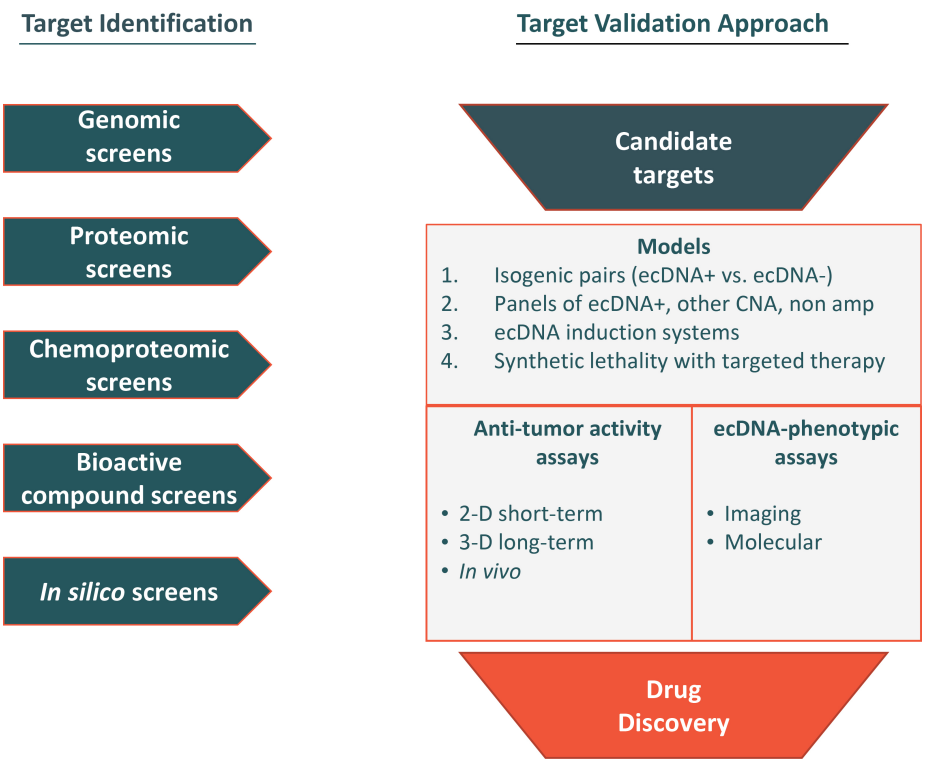
Target Identification and Validation

Through Spyglass, we have developed a sophisticated understanding of amplification biology, including ecDNA biology, and key cellular mechanisms that facilitate tumor growth and development of resistance to therapeutic treatments. This understanding has given us new insight on how to disrupt amplification biology and cancer cell growth. Through multiple screening methods, we have identified several potential targets that differ not only by class, but also in the role the target plays in the formation and function of ecDNA in cancer cells.

To complement our target identification approach, we have established a robust target validation funnel through which all our candidate targets must pass before we declare them as targets suitable for initiation of drug discovery efforts. This target validation funnel consists of:

- differential single agent sensitivity in multi cell line panels of matched ecDNA positive (ecDNA+) and ecDNA negative (ecDNA-) cancer cell lines;
- genetic, such as CRISPR, or pharmacologic inhibition of candidate targets in ecDNA-enabled cancer cells *in vitro* and/or *in vivo*;
- phenotypic assessment of ecDNA function in ecDNA-enabled cancer cells *in vitro* and/or *in vivo;*
- phenotypic assessment of ecDNA location and distribution in cancer cells;
- synthetic lethality assessment, in combination with various therapeutic classes, in inducible ecDNA assays *in vitro* and/or *in vivo*; and
- *in vivo* assessments performed in multiple CDX and PDX xenograft models representing various cancer types such as breast, colorectal, gastric, prostate cancer, and sarcoma and multiple different oncodriver amplifications such as *AR*, *CCNE1*, *EGFR*, *FGFR1*, *FGFR2*, *CDK4*, *KRAS*, and *MYC*.

Target Identification and Validation Process

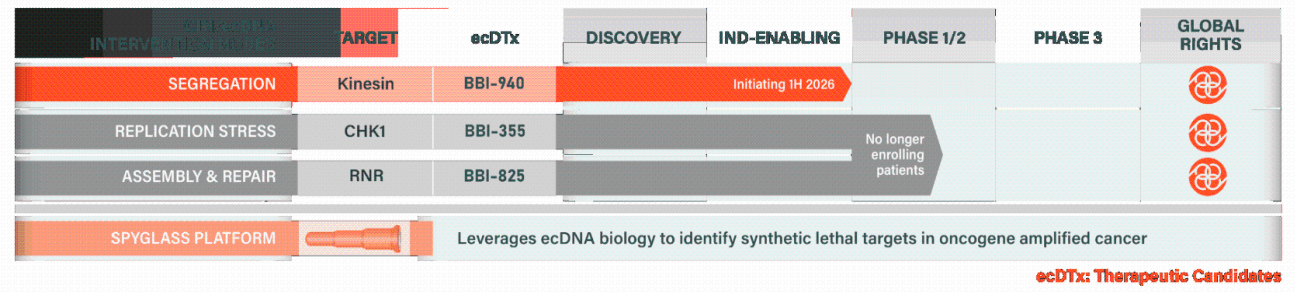


The targets that our platform has identified as suitable for drug discovery efforts consist of targets that are either novel, previously clinically validated but lacking approved drugs, or have approved pharmaceutical agents but nonselective to the target. There appears to be a wide range of potential targets whose inhibition impact distinct aspects of the ecDNA life cycle, including enzymatic machinery responsible for segregation, replication, transcription, and repair. Each category of targets may have differentiated benefits in terms of optimal treatment setting, efficacy, tolerability, therapeutic index, and single agent versus combination approach. In addition to targets against which we have previously initiated drug discovery efforts, we also have multiple additional preclinically validated targets that could be candidates for future drug discovery efforts. We believe that our ability to identify and pursue ecDNA-essential targets represents a unique capability for novel target identification, drug discovery, and value creation.

Our Pipeline and Platform

We are pioneering a new and differentiated approach to precision medicine focused on developing ecDTx. Our ecDTx are novel, small molecules that target specific biological pathways believed to be essential to ecDNA function in cancer cells. Through Spyglass, we are able to better understand the lifecycle of ecDNA, including ecDNA formation, segregation, maintenance, replication, transcription, and degradation. We have identified several vulnerability nodes of ecDNA biology for therapeutic intervention.

Our ecDTx pipeline currently consists of three clinical stage small molecules, one of which, BBI-940, we have prioritized for ongoing development. In addition, our Spyglass platform has yielded multiple preclinically validated novel targets that could represent candidate targets for potential future drug discovery efforts.



Our Lead ecDTx: BBI-940 Kinesin Degrader

Our lead ecDTx, BBI-940, is a novel, oral, selective kinesin degrader being developed for the treatment of patients with ER+/HER2-breast cancer who have progressed following treatment with a CDK4/6 inhibitor plus endocrine therapy, as well as patients with TNBC-LAR. BBI-940 targets a specific kinesin protein, referred to here as Kinesin, that functions in chromosome alignment and proper cell division. BBI-940 is designed to exploit the heightened dependence of ecDNA-positive tumors on mitotic machinery by degrading Kinesin to induce mitotic catastrophe and cell death.

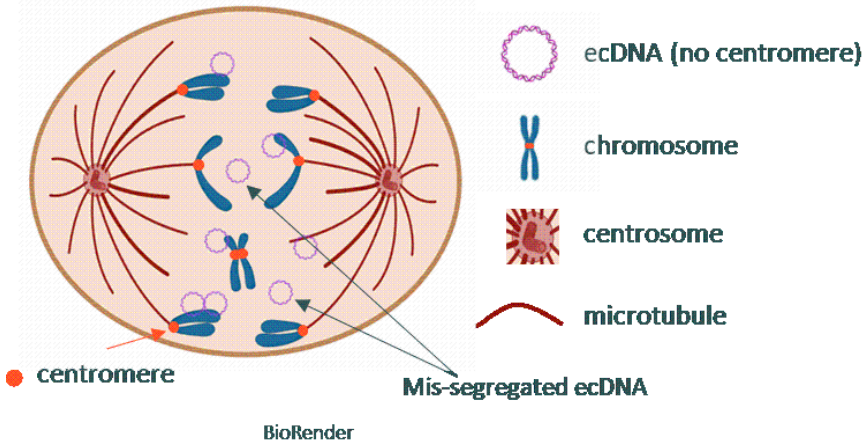
BBI-940 is a targeted protein degrader that uses a heterobifunctional degrader mechanism to selectively eliminate Kinesin. BBI-940 works by linking Kinesin to the cell's protein-degradation machinery, which is intended to result in removal of the target protein. Specifically, BBI-940 binds both Kinesin and the E3 ubiquitin ligase cereblon, facilitating ubiquitination and subsequent proteasomal degradation of Kinesin. In preclinical models, BBI-940 achieved potent, selective Kinesin degradation at low nanomolar concentrations and demonstrated greater than 200-fold selectivity versus other kinesin family members.

Kinesin Synthetic Lethality in ecDNA-Enabled Cancer Cells

During each mammalian cell division, chromosomes must be precisely and evenly segregated to ensure proper distribution of genetic material. Errors in this process can result in chromosomal instability, or CIN, and, if unregulated, cell death. Cancer cells harboring ecDNA frequently exhibit CIN. The presence of ecDNA and associated focal amplifications, such as *FGFR1, CCND1*, and *MYC*, increases cancer cells' reliance on certain mitotic machinery to enable proper segregation during cell division of DNA elements that lack centromeres.

Kinesin is a non-essential cellular kinesin protein that functions during mitosis by facilitating chromosome positioning at the metaphase plate, a process critical for proper segregation of genetic material during cell division. Inhibition or degradation of Kinesin in CIN cancer cells with ecDNA has been shown in pre-clinical models to result in prolonged mitosis, mis-segregation of DNA and cell death, potentially through mitotic catastrophe. We believe that targeting Kinesin in ecDNA-positive tumors may preferentially induce mitotic errors and cell death in these cancer cells while sparing normal tissues, representing a potential synthetic lethal vulnerability unique to ecDNA-positive cancer cells. To our knowledge, there are no other disclosed drug development efforts specifically targeting Kinesin.

Chromosomally Unstable ecDNA-Enabled Cancer Cells Rely on Kinesin for Inheritance of Acentric DNA, Including ecDNA

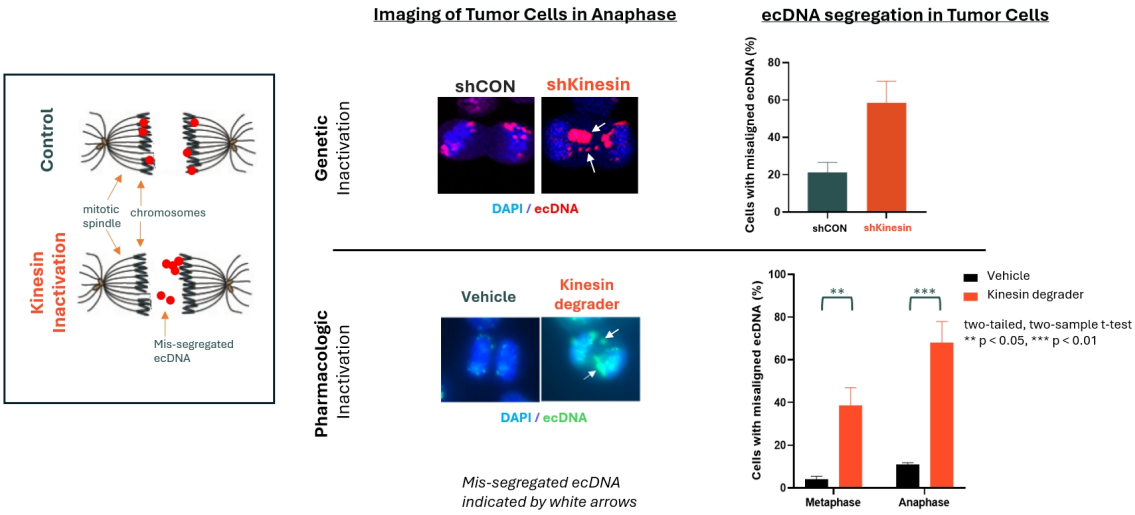


Kinesin is a Druggable Target for ecDNA-Enabled Tumors

Our preclinical research indicated that sensitivity to Kinesin degraders correlated with the presence of certain oncogene amplifications and the presence of ecDNA. In these ecDNA-positive tumor models, Kinesin played a critical role in enabling proper segregation of genetic material during cell division, making it a potential therapeutic target for tumors reliant on ecDNA-enabled oncogene amplifications. Consistent with this hypothesis, both genetic and pharmacological inactivation of Kinesin in preclinical models resulted in mis-segregation of ecDNA during metaphase and a reduction in ecDNA levels, accompanied by antiproliferative effects and cytotoxicity.

In the figure below, both genetic knock-down of Kinesin using short hairpin RNA, or shRNA (top row) and pharmacologic degradation of Kinesin using a BBI-940 analog (bottom row) resulted in aggregation of ecDNA (stained with red or green FISH probes, respectively) at the metaphase plate while chromosomes (stained with blue DAPI) were segregated evenly into the two daughter cells . This effect is quantified in graphs to the right of each representative micrograph.

Kinesin is Essential for Proper Segregation of ecDNA During Cell Division



BBI-940 Kinesin Degrader Profile

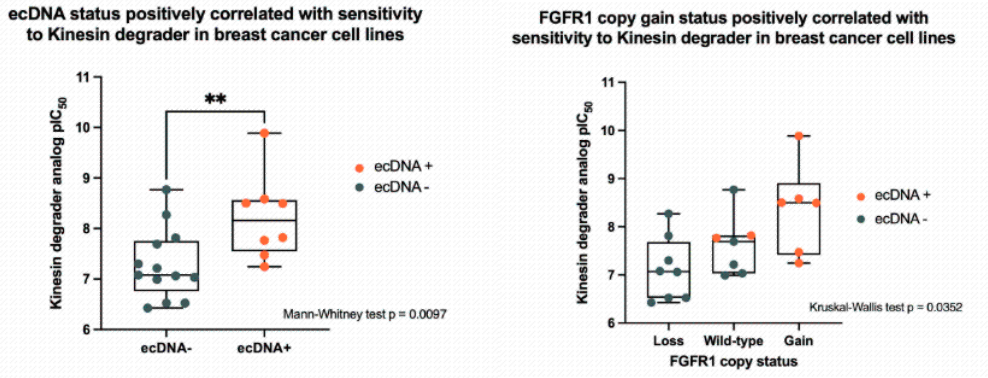
Through extensive testing in preclinical cancer models with ecDNA-enabled oncogene amplifications, we identified what we believe to be an optimal Kinesin degrader profile for targeting ecDNA-positive tumors and designed our lead ecDTx, BBI-940, accordingly. Notably, BBI-940 inhibited the enzymatic activity of Kinesin with a half-maximal inhibitory concentration, or $IC_{50,}$ of approximately 200 nM and achieved robust cellular Kinesin degradation with a half-maximal degradation concentration, or $DC_{50,}$ of approximately 1 nM, demonstrating catalytic degradation activity consistent with a heterobifunctional degrader mechanism of action. BBI-940 is highly specific for Kinesin, and demonstrated greater than 100-fold selectivity over other kinesins tested. BBI-940 also demonstrated favorable pharmacokinetic properties including oral bioavailability ranging between 28% to 49% across multiple preclinical species.

BBI-940 Kinesin Degrader In Vitro Preclinical Studies

Both genetic inactivation and pharmacological degradation of Kinesin in preclinical models resulted in enhanced cytotoxicity in ecDNA positive cells compared to cells lacking ecDNA, consistent with a synthetic lethal relationship between Kinesin dependence and ecDNA positivity. This synthetic lethal relationship was observed across multiple preclinical cancer models and provides the mechanistic basis for BBI-940's therapeutic rationale.

As seen in the figure below, a structural analog of BBI-940 demonstrated potent antiproliferative activity across a panel of breast cancer cell lines. Approximately one-third (1/3) of breast cancer cell lines tested showed sensitivity, defined as IC_{50} ≤100 nM, to this Kinesin degrader. Sensitivity within these breast cancer cell lines correlated with ecDNA positivity. Moreover, within the ER+/HER2- cell lines, sensitivity correlated with *FGFR1* amplification status, and within the TNBC cell lines, sensitivity correlated with androgen receptor, or AR, positivity (referred to as the LAR subtype). Taken together, these results support development of BBI-940 as a targeted therapy for selected ecDNA-positive breast cancers characterized by ER+/HER2-/*FGFR1* amplification or the TNBC-LAR subtype.

Kinesin Degrader Sensitivity in Breast Cancer Cell Lines Correlates with ecDNA and *FGFR1* Copy Number Status

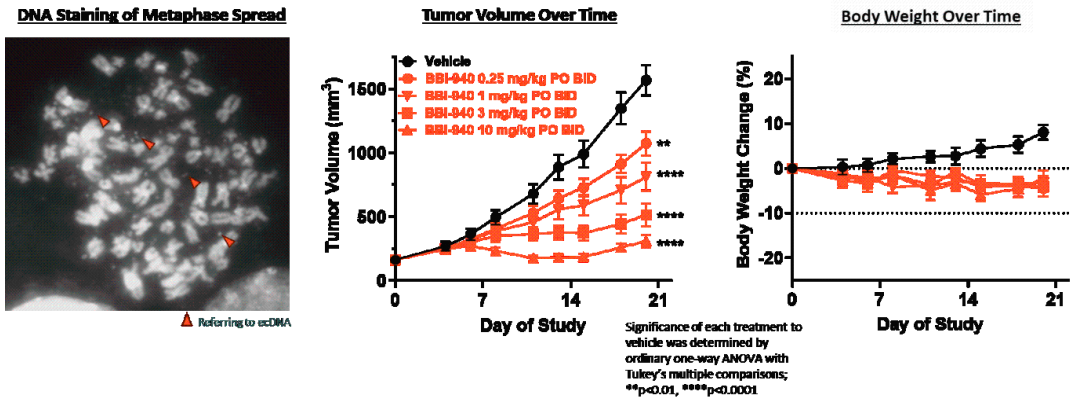


BBI-940 Kinesin Degrader In Vivo Antitumor Activity

In preclinical xenograft models of ecDNA-positive breast cancer, Kinesin degradation, both as a single agent and in combination with endocrine therapy, resulted in tumor growth inhibition and tumor regressions.

For example, as seen in the figure below, in a TNBC-LAR xenograft model, treatment with BBI-940 demonstrated significant antitumor activity, including regressions, compared to vehicle control.

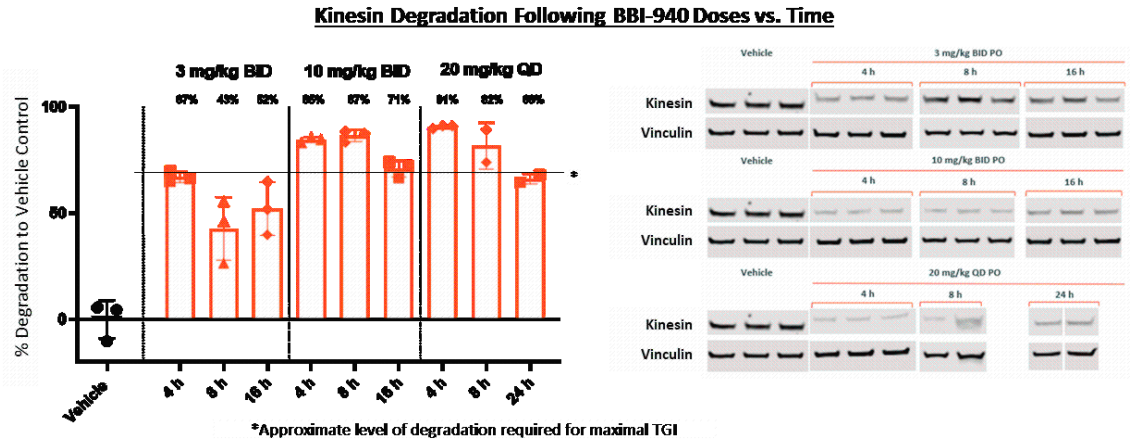
BBI-940 Demonstrated Single Agent *In Vivo* Antitumor Activity in TNBC-LAR Xenograft Model



As seen in the figure above, oral administration of BBI-940 resulted in dose-dependent tumor growth inhibition compared to vehicle control in an ecDNA-enabled TNBC-LAR xenograft model.

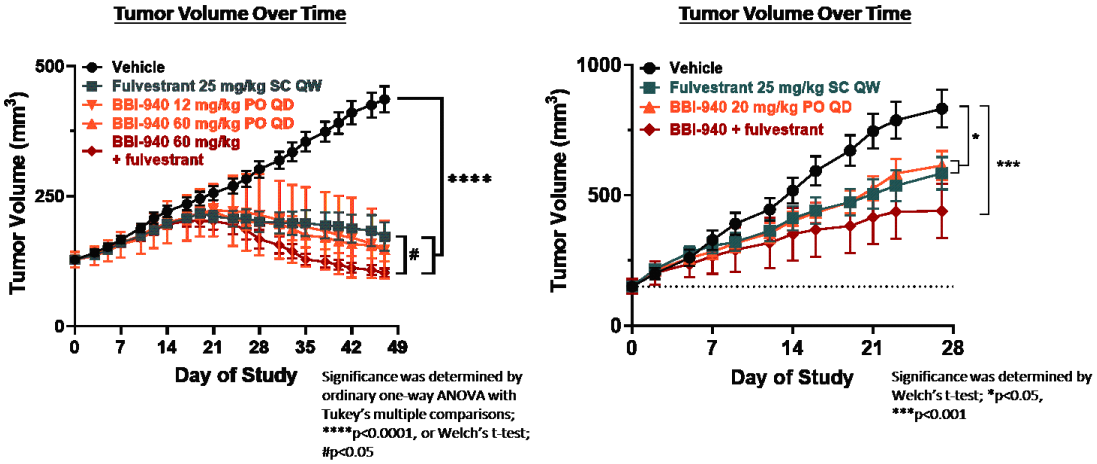
As seen in the figure below, treatment with BBI-940 also resulted in significant Kinesin degradation in tumor tissue at pharmacologically relevant doses, supporting target engagement consistent with the proposed mechanism of action.

In vivo Kinesin Degradation Following Administration of BBI-940 in TNBC-LAR Xenograft Model



Moreover, as seen in the figure below, combination treatment with BBI-940 plus fulvestrant resulted in enhanced tumor growth inhibition compared to either agent alone in ER+/HER2- breast cancer xenograft models. These findings support the evaluation of BBI-940 in combination with endocrine therapy as part of our clinical development strategy for patients with ER+/HER2- breast cancer.

BBI-940 In Vivo Antitumor Activity in Combination with Fulvestrant in ER+/HER2- Breast Cancer Xenograft Models



BBI-940 Nonclinical Toxicology Studies

We have completed good laboratory practice, or GLP, 28-day repeat-dose toxicology studies in rats and dogs to support the first-in-human KOMODO-1 trial of BBI-940. These studies evaluated the nonclinical safety profile of BBI-940 following oral administration, including assessment of treatment-related findings in target organs and reversibility of findings following cessation of dosing. The results of these studies supported the submission of the investigational new drug (IND) application for the KOMODO-1 trial of BBI-940, which was cleared by the U.S. Food and Drug Administration (FDA) in January 2026.

BBI-940 Clinical Development Plan

In February 2026, we initiated the KOMODO-1 trial, a Phase 1, open-label, multicenter, first-in-human clinical trial of BBI-940 in patients with ER+/HER2- metastatic breast cancer who have progressed following treatment with a CDK4/6 inhibitor plus endocrine therapy, as well as in patients with metastatic TNBC-LAR. We expect to have initial proof-of-concept safety and efficacy clinical data within our existing cash runway timeline discussed in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," of this Annual Report on Form 10-K.

The trial is designed to evaluate the safety and tolerability of BBI-940, characterize human pharmacokinetics, or PK, and pharmacodynamic, or PD, biomarkers, and assess preliminary antitumor activity. The trial is also intended to identify the maximum tolerated dose, or MTD, and the recommended phase 2 dose, or RP2D, of BBI-940 administered as a single agent or in combination with fulvestrant. In the trial, BBI-940 is administered orally. The trial is non-randomized and consists of two parts:

Part 1 (Dose Escalation)

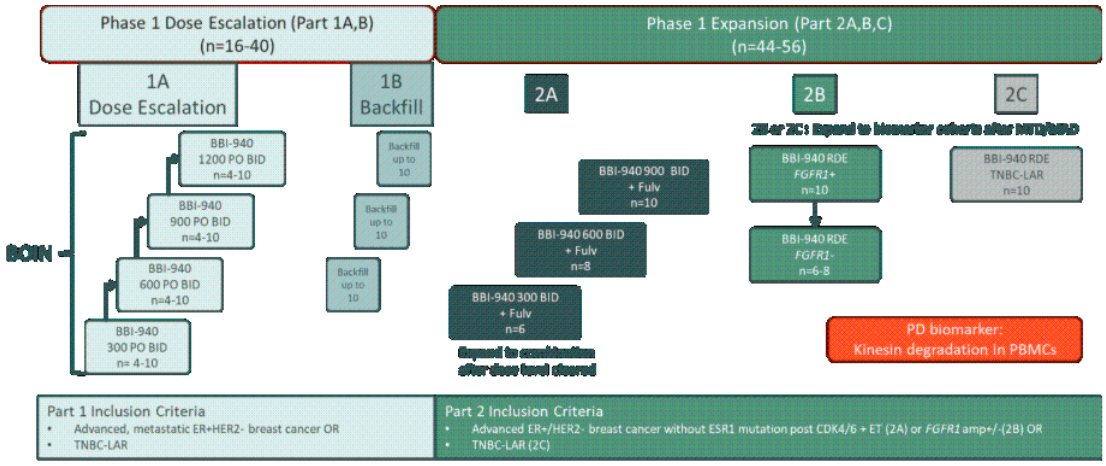
- Part 1A – Dose Escalation: Evaluation of BBI-940 monotherapy in dose-escalating cohorts to characterize safety and tolerability, and to identify the MTD and/or RP2D.
- Part 1B – Backfill Cohorts: Enrollment of additional patients at doses cleared in Part 1A to further evaluate safety, PK, and PD biomarkers, including evaluation in patients with *FGFR1*-amplified tumors.

Part 2 (Dose Expansion)

- Part 2A – Combination Expansion: Evaluation of BBI-940 in combination with fulvestrant in patients with ER+/HER2- metastatic breast cancer lacking *ESR1* mutations, with the objective of assessing safety and preliminary antitumor activity of the combination.
- Parts 2B and 2C – Monotherapy Expansion: Expansion cohorts evaluating BBI-940 monotherapy at the RP2D in patients with *FGFR1*-amplified tumors (Part 2B) and in patients with TNBC-LAR (Part 2C).

Across all applicable cohorts, two distinct biomarker populations will be assessed, FGFR1 gene amplification in ER+/HER2- breast cancer and AR expression in TNBC, and ecDNA status will be assessed retrospectively in tumor samples using multiple techniques. We anticipate enrolling approximately 60 to 96 patients in total across all parts of the trial. If one or more cohorts demonstrate evidence of clinically meaningful antitumor activity with an acceptable safety and tolerability profile, we intend to engage with the FDA and other global regulatory authorities to discuss potential future clinical development and registrational paths.

Design of BBI-940 Phase 1 KOMODO-1 Clinical Trial



Significant Unmet Medical Need in ER+/HER2- Breast Cancer and TNBC-LAR

Despite advances in treatment for ER+/HER2- metastatic breast cancer, significant unmet medical need remains. Approximately 30% of patients treated with CDK4/6 inhibitors in combination with endocrine therapy experience disease progression within the first year of treatment. Patients whose tumors harbor *FGFR1* amplification, which is reported in approximately 10-15% of ER+ breast cancers, generally have particularly poor outcomes with currently available therapies and no approved therapies specifically directed to this alteration.

Focal amplifications including *FGFR1*, *CCND1*, and *MYC* are more frequently observed in treatment-resistant disease settings, and are enriched in tumors harboring ecDNA. Tumors characterized by ecDNA-driven genomic instability have been associated with increased risk of disease progression and distant recurrence, with up to 45% of such patients experiencing metastatic disease progression.

TNBC-LAR represents approximately 10-15% of triple-negative breast cancers and is characterized by androgen receptor expression and a luminal gene expression profile. This subtype has limited therapeutic options and generally demonstrates poor response to standard chemotherapy, representing an additional area of significant unmet need.

We believe BBI-940, which is designed to degrade a novel kinesin protein critical to ecDNA segregation, has the potential to address significant unmet medical need in ecDNA-positive tumors, including *FGFR1* amplified ER+/HER2- breast cancer and TNBC-LAR. By targeting a mechanism central to ecDNA-driven oncogene amplification, BBI-940 may offer a differentiated therapeutic approach for patient populations with limited options and poor outcomes on currently available therapies.

Other Programs

We have been investigating BBI-355, a novel, oral, selective inhibitor of checkpoint kinase 1 (CHK1) designed to target replication stress in oncogene amplified cancers, in a first-in-human Phase 1/2 clinical trial in patients with oncogene amplified cancers that we refer to as POTENTIATE (for Precision Oncology Trial Evaluating Novel Therapeutic Interrupting Amplifications Tied to ecDNA). In May 2025, we announced that we discontinued the monotherapy arm and combination arms of BBI-355 with third-party targeted therapies in the POTENTIATE trial based on initial trial data. During 2025, we have been winding down those initial arms of the trial. We had been continuing to investigate BBI-355 in combination with BBI-825, a novel oral, selective inhibitor of ribonucleotide reductase (RNR) designed to target ecDNA assembly and repair; however, in January 2026, following a strategic portfolio review, we elected to cease enrollment of this last arm of the POTENTIATE trial due to market considerations, clinical data, and to prioritize our BBI-940 program.

Previously, in December 2024, following an assessment of preliminary PK data, we made the strategic decision not to proceed with evaluation of BBI-825 in a first-in-human, open-label, non-randomized, 3-part, Phase 1/2 clinical trial of BBI-825 we refer to as STARMAP (for Study Treating Acquired Resistance: MAPK Amplifications). In STARMAP, BBI-825 was being evaluated in patients with solid tumors, including those with $BRAF^{V600E}$ or $KRAS^{G12C}$mutated colorectal cancer that developed resistance oncogene amplifications. We completed the winddown of the STARMAP trial in 2025.

Spyglass Drug Discovery Platform

Spyglass is our internal proprietary platform used to identify new targets. We utilized Spyglass to identify targets that exploit cellular vulnerabilities of oncogene amplified cancers. Our target identification efforts have revealed multiple distinct nodes of vulnerability within the lifecycle of ecDNA. We continuously incorporate new models, tools, and technologies into our Spyglass platform to identify novel points of synthetic lethality in oncogene amplified cancers. In addition to our programs described above, we have preclinically validated multiple additional targets and have historically initiated ecDTx drug discovery efforts to identify potential candidates against such targets. We continue to deploy Spyglass to inform development of BBI-940 and potential complementary targets or assets that we may wish to acquire or internally develop in the future.

Our Precision Medicine Approach

Precision medicine aims to identify and treat patients with specific biomarkers to maximize the likelihood of therapeutic benefit while minimizing side effects. Each of our ecDTx advanced into the clinic to date has incorporated biomarker hypotheses, sometimes including ecDNA status, for patient selection as part of the trial design. Our KOMODO-1 trial of BBI-940 contemplates two distinct biomarkers for prospective patient selection in the Part 2 dose expansion phases and will retrospectively assess ecDNA status in tumor samples. As data from the KOMODO-1 or other potential future clinical studies mature, we intend to discuss with the FDA whether a diagnostic, including potential assessment of ecDNA status, would be appropriate or required to enable commercialization of BBI-940, if approved.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies and understanding of disease etiology, intense development and commercial competition, and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how, and experience, particularly in the fields of ecDNA and precision oncology, provide us with competitive advantages. Nonetheless, we expect competition from multiple sources, including major biopharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions, governmental agencies, and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have or will have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may be or may become interested in developing ecDNA-directed therapeutic candidates and may rapidly develop programs that compete with ours by studying ecDNA at scale in the context of oncogene amplified cancer. Even if they do not advance programs with the same mechanism(s) of action as ours, these companies could develop products or product candidates that are competitive with ours or that have a superior product profile and may do so at a rapid pace. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license, or commercialize products before or more successfully than we do.

We face competition from segments of the pharmaceutical, biotechnology, and other related markets that pursue development of precision oncology therapies for patients with genetically defined cancers. In addition, we may face competition from companies developing product candidates that are based on synthetic lethality in cancer.

Furthermore, we also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are 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. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our ecDTx, if any are approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our ecDTx may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our ecDTx that we successfully introduce to the market may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

For BBI-940, we are unaware of any therapeutic programs developing compounds directed against the Kinesin target.

We could see a reduction or elimination in our potential commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive, or have more favorable commercial labeling than our ecDTx, regardless of whether they target ecDNA as a mechanism of action. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of our ecDTx, if approved, are likely to be their efficacy, safety, route of administration, convenience, price, level of generic competition, and availability of reimbursement from government and other third-party payors.

Intellectual Property

We strive to protect the intellectual property and proprietary technology that we consider important to our business through a variety of methods. We seek to obtain domestic and international patent protection and endeavor to promptly file patent applications for new commercially valuable inventions as they arise to expand our intellectual property portfolio. We also rely on proprietary know-how and trade secrets to protect certain innovations that may be important to our business and to benefit from their confidential status.

As of March 9, 2026, our intellectual property portfolio included 24 patent families solely owned by us, which include 7 pending U.S. provisional applications, 18 pending U.S. non-provisional patent applications, 5 issued U.S. patents, pending applications in China, Europe, Hong Kong, Japan, and Taiwan, as well as 3 pending applications filed pursuant to the Patent Cooperation Treaty (PCT).

We continually assess and refine our intellectual property strategy. To that end, we are prepared to file additional patent applications as appropriate to support our intellectual property strategy, or where we seek to adapt to competition or seize business opportunities.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any patents we may own or license in the future will be useful in protecting our technology. Please see "Risk Factors—Risks Related to Our Intellectual Property" for additional information on the risks associated with our intellectual property strategy and portfolio.

Intellectual Property Relating to Our Kinesin Program

With regard to our Kinesin program, including BBI-940, as of March 9, 2026, we owned 4 patent families, including 4 pending U.S. provisional applications, 1 pending U.S. non-provisional patent application, 2 pending applications in Taiwan, as well as 2 pending applications filed pursuant to the PCT. These patent rights relate to compositions of matter, as well as methods of treating diseases using Kinesin inhibitors and degraders. We expect these patents and patents issued from these applications, if any, to expire in 2042-2047 without accounting for any patent term adjustment or extension that may be available.

Other Intellectual Property

With regard to our CHK1 program, including BBI-355, as of March 9, 2026, we owned 10 patent families, for which we are currently pursuing 3 pending U.S. provisional applications, 8 pending U.S. non-provisional patent applications, 4 issued U.S. patents, as well as pending applications in China, Europe, Hong Kong, and Japan. These patent rights relate to compositions of matter, as well as methods of treating diseases using CHK1 inhibitors. We expect these patents and patents issued from these applications, if any, to expire in 2041-2046 without accounting for any patent term adjustment or extension that may be available.

With regard to our RNR program, including BBI-825, as of March 9, 2026, we owned 9 families (3 of which also cover our CHK1 program), for which we are currently pursuing 3 pending U.S. provisional applications, 7 pending U.S. non-provisional patent applications, 1 issued U.S. patent, pending applications in China, Europe, Hong Kong, and Japan, as well as 1 pending application filed pursuant to the PCT. These patent rights relate to the compositions of matter, as well as methods of treating diseases using RNR inhibitors. We expect patents issues from these applications, if any, to expire in 2041-2046 without accounting for any patent term adjustment or extension that may be available.

With regard to our precision medicine approach, we developed a proprietary diagnostic to detect ecDNA based on the data outputs from next generation sequencing, or NGS, tests routinely used to profile patient tumor samples. As of March 9, 2026, we owned 1 patent family related to methods of detecting ecDNA signatures in cancers and 1 pending U.S. non-provisional patent application related to our diagnostic. We expect patents issued from these applications, if any, to expire in 2041-2044 without accounting for any patent term adjustment or extension that may be available. We also protect the intellectual property related to ecDNA detection as a trade secret.

Scope and Duration of Intellectual Property Protection

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent. Under certain circumstances, the term of U.S. patents may be adjusted for delays encountered during prosecution that are caused by the USPTO. Additionally, the term of a patent as it specifically relates to an FDA regulated product may be extended. For example, for drugs that are regulated by the FDA under the Hatch-Waxman Act, the FDA is permitted to extend the exclusivity term that covers such drug for up to five years beyond the normal expiration date of the patent, depending on the timing of the issuance of the patent, the IND filing, the NDA filing and the approval date, and provided that the term of the patent does not extend beyond 14 years from the NDA approval date. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions to any of our issued patents in jurisdictions where these are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology therapy has emerged in the U.S. The patent situation outside of the U.S. is even more uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the U.S. and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making,

using, selling, offering to sell, importing, or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending, and enforcing patent claims that cover our technology, inventions, and improvements. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our patents that may be granted to us in the future will be commercially useful in protecting our product candidates and the methods used to manufacture them.

The area of patent and other intellectual property rights in the biopharmaceutical industry is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology. Our patents that may issue in the future may be challenged, narrowed, circumvented, or invalidated, which could limit our ability to stop competitors from marketing related product candidates. In addition, our competitors may independently develop similar technologies, and the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. For these and other reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that before any product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any protection afforded by the patent. For this and other risks related to our proprietary technology, inventions, improvements, and product candidates, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our technology as trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to execute confidentiality agreements under the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our agreements with consultants, outside scientific collaborators, sponsored researchers, and other advisors require them to assign or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches.

We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in relation to the resulting know-how or inventions.

We seek trademark protection in the United States and in certain other jurisdictions where available and when we deem appropriate. We currently have registrations for our “Boundless Bio” mark in the United States as well as in certain foreign jurisdictions, including the European Union. We have registrations for our “UNBOUND BY CONVENTION, BOUND TO SAVE LIVES” mark in the United States. We have also filed a trademark application in the United States for registration of our “ECHO” mark, and we have registrations for our “ECHO” mark in certain foreign jurisdictions, including the European Union. For more information, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Manufacturing

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 our ecDTx obtains marketing approval. We work with our current manufacturers to ensure that we will be able to scale up our manufacturing capabilities to support our clinical plans. We also plan to continue to evaluate additional manufacturers to build redundancies into our supply chain. 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 design and development of our ecDTx.

Commercialization

We intend to retain significant development and commercial rights to our ecDTx and, if marketing approval is obtained, to commercialize our ecDTx on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing, or commercial product distribution capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our ecDTx. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure, and manufacturing needs may all influence or alter our commercialization plans.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and post-approval activities of drug and biological product candidates, such as those we are developing.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. Drugs are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a new drug may be marketed in the United States generally involves the following:

- completion of nonclinical or preclinical laboratory tests, animal studies, and formulation studies, with certain studies conducted in accordance with Good Laboratory Practice (GLP) regulations, and other applicable regulations;
- submission to the FDA of an Investigational New Drug Application (IND), which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations (GCPs) to evaluate the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice requirements (cGMPs) to assure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality, and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. An IND sponsor must submit, among other things, the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for allowance from the FDA to administer an investigational drug product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about ongoing or proposed clinical trials or non-compliance with specific FDA requirements, and in such case, the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. FDA may also place a trial on a partial clinical hold. A partial clinical hold is a delay or suspension of only part of the clinical work requested or ongoing under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold.

Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only begin or resume after the FDA has notified the sponsor that the investigation may proceed.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. The sponsor must report to the FDA any suspected adverse reaction that is both serious and unexpected within fifteen days after the sponsor's initial receipt of the information. The sponsor must also report to the FDA any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Furthermore, an independent IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the trial until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the registration of certain clinical trials and reporting of ongoing clinical studies and clinical trial results to public registries, including clinicaltrials.gov.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion, and, if possible, to gain an early indication of its effectiveness, identify any adverse effects, and determine maximal dosage.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy, purity, and potency, and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

In February 2026, via an editorial published the *New England Journal of Medicine*, the FDA Commissioner and the director of the FDA's Center for Biologics Evaluation and Research announced a policy shift whereby, going forward, the FDA's default position will be a "a one-trial requirement," meaning that one adequate and well-controlled study, combined with confirmatory evidence, will serve as the basis of marketing authorization of novel product candidates. Confirmatory evidence can include mechanistic science, data from a related indication, animal models, information from other drugs of the same class, real-world evidence, or a second adequate and well-controlled study. The announcement represents a major shift from the FDA's historical default requirement of two pivotal clinical trials. However, as indicated by FDA representatives during informal interviews and other media appearances, if FDA shifts to only requiring a single trial, it may heighten the standard for these trials in terms of quality. For example, the FDA indicated it will carefully examine all aspects of study design with particular focus on controls, end points, effect size, and statistical protocols. The FDA may still require additional adequate and well-controlled studies if a product candidate has a nebulous, pluripotent, or nonspecific mechanism of action; if it affects a labile, short-term, or surrogate outcome; or if a trial has some underlying limitation or deficiency. The editorial also referenced a new postmarket initiative being rolled out synchronously to collect robust data on all drugs and devices. The FDA has not published formal guidance regarding the new one-trial default option or postmarket surveillance initiative.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

The results of product development, preclinical and other non-clinical studies, and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness, or safety, purity, and potency of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective, or safe, pure, and potent. The sponsor may request or the FDA may grant a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or fails to submit a request for approval of a pediatric formulation.

Once an NDA has been submitted, the FDA conducts a preliminary review of the application within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of an NDA for a new molecular entity to complete a standard review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides recommendations as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured to assure compliance with cGMPs. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs. After the FDA evaluates an NDA and conducts any required inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle for the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, including additional clinical trials or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the resubmitted NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require that contraindications, warnings or precautions be included in the product's labeling; require that post-approval studies be conducted to

further assess the drug's safety or effectiveness; require testing and surveillance programs to monitor the safety of the commercialized product; or impose other conditions, including distribution restrictions or other risk management mechanisms, including a risk evaluation and mitigation strategy (REMS) to assure safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA will not approve the NDA without an approved REMS, if required. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. However, competitors may receive approval of different products for the disease or condition for which the orphan product has exclusivity or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the "same drug," as defined by the FDA, or if the active moiety of the product candidate is determined to be contained within the competitor's product for the same disease or condition. In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

In February 2026, Congress passed the 2026 Consolidated Appropriations Act, which included the 2026 appropriations legislation for the Department of Health and Human Services (HHS). The HHS appropriations bill included a package of FDA reform legislation better known as the Mikaela Naylon Give Kids a Chance Act. The bill reauthorized the Rare Pediatric Disease Priority Review Voucher program, created new pediatric testing obligations for sponsors of certain molecularly targeted combination oncology products, changed a legal definition impacting how the agency grants orphan drug exclusivity, imposed new requirements on companies to complete pediatric study requirements, and required the FDA to open a new foreign office in a country that signed the Abraham Accords. Additionally, as part of the 2026 Consolidated Appropriations Act, Congress enacted provisions revising how patent exclusivity is applied to orphan-designated drugs. This provision modifies the standard for orphan drug patent protection so that it applies to the same approved use or indication within a rare disease or condition.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more

intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

An NDA may also be eligible for priority review if the product candidate is designed to treat a serious condition and, if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Specifically, drugs intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials and may require that such confirmatory trials be underway prior to granting accelerated approval. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In June 2025, the FDA launched the Commissioner's National Priority Voucher (CNPV) pilot program, offering drug manufacturers an expedited 30 to 60-day review by proposing plans to advance five stated priorities, which include addressing public health crises, delivering innovative cures, meeting unmet medical needs, strengthening supply chains through onshore drug manufacturing, and increasing affordability. The FDA cites examples that include developing novel medicines for obesity, PTSD, other chronic diseases, or creating universal flu vaccines. Proposals may also include domestic manufacturing expansions and commitments for the firm to implement "most favored nation" pricing models on some of their drugs. Proposals are not required to address all five priority areas, but more comprehensive plans are likely to be favored in the selection process.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time for FDA review or approval will not be shortened.

Post-Approval Requirements

Any drug manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, or additional labeling claims, are subject to further FDA review and approval. There also are continuing, annual program fees for any marketed products. As noted above, in February 2026, the FDA announced a new postmarket data-collection initiative applicable to all drugs and devices, but the FDA has not yet published guidance specific to this new program.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain procedural and documentation requirements upon NDA holders and their third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;

- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A sponsor can only make those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally-available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Increased scrutiny over direct-to-consumer (DTC) drug advertising has been a priority of the current administration. In September 2025, the FDA announced a crackdown on deceptive drug advertising, sending thousands of letters warning pharmaceutical companies to remove misleading ads, and issuing many enforcement letters to companies with deceptive ads.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA), or an NDA submitted under Section 505(b)(2) (505(b)(2) NDA) submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval based on the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to an existing period of regulatory exclusivity or available patent term if a sponsor conducts clinical trials in children in response to a "written request" from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials, and the FDA's grant of pediatric exclusivity does not require the FDA to approve labeling containing information on pediatric use based on the studies conducted.

FDA Regulation of Companion Diagnostics

We believe that certain of our ecDTx may require an *in vitro* diagnostic to identify appropriate patient populations for investigation and/or use of our ecDTx. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things,

medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval (PMA). Most companion diagnostics for oncology product candidates, such as those we are developing, utilize the PMA pathway.

If use of a companion diagnostic is deemed essential to the safe and effective use of a drug product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. In August 2014, the FDA issued a final guidance document addressing the development and approval process for "*In Vitro* Companion Diagnostic Devices." According to the guidance, for novel product candidates, a companion diagnostic device and its corresponding drug candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device may be considered a significant risk device under the FDA's Investigational Device Exemption (IDE) regulations. In which case, the sponsor of the diagnostic device will be required to submit and obtain approval of an IDE application and subsequently comply with the IDE regulations. However, according to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of applicable IDE regulations and the IND regulations. The guidance provides that, depending on the details of the study plan and degree of risk posed to subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

In April 2020, the FDA released a guidance titled "Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products," which expands on the policy statement in the 2014 guidance by recommending that companion diagnostic developers consider a number of factors when determining whether their test could be developed, or the labeling for approved companion diagnostics could be revised through a supplement, to support a broader labeling claim such as use with a specific group of oncology therapeutic products, rather than listing an individual therapeutic product(s).

The FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously with approval of the therapeutic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation (QSR), which currently imposes elaborate testing, control, documentation, and other quality assurance requirements.

If the FDA's evaluation of the PMA application is favorable, the FDA may issue an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If and when the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale, and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

After a device is commercialized, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which currently cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

In November 2025, the FDA proposed a rule to reclassify certain class III nucleic acid-based test systems indicated for use with a corresponding approved oncology therapeutic product from class III into class II, subject to premarket notification. The FDA also proposed a new device classification regulation, along with the special controls that the FDA believes are necessary to provide a reasonable assurance of safety and effectiveness for these devices. If this proposed rule were enacted, these nucleic acid-based companion diagnostic tests would become class II devices subject to 510(k) premarket notification requirements, which could delay availability of these tests to be used with oncology therapeutics.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, and physician payment transparency laws and regulations regarding drug pricing and payments or other transfers of value made to physicians and other licensed healthcare professionals as well as similar foreign laws in the jurisdictions outside the United States. Violation of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement fines, additional reporting requirements and oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/ or imprisonment.

Coverage and Reimbursement

Successful sales of our ecDTx in the U.S. market, if approved, will depend, in part, on the extent to which our ecDTx will be covered and eligible for adequate reimbursement by third-party payors, including government health programs, such as Medicare and Medicaid, and private health insurance (including managed care plans). Patients generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. Even if coverage is provided, the approved reimbursement amount may not be adequate to support pricing sufficient to realize a return on our investment. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly. Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs such as requiring prior authorization or step therapy for coverage, among other things. For products administered under the supervision of a physician or other healthcare professional, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used or delivered may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party payor reimbursement for our drug candidates, if approved, or a decision by third-party payors to not cover our drug candidates could have a material adverse effect on our sales, results of operations, and financial condition.

General regulatory cost control measures may also affect reimbursement for our products. If we obtain approval to market a drug candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid, or other publicly funded or subsidized health programs and/or any significant taxes or fees.

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

authorities. In the United States, CMS, an agency within the DHHS, determines whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow Medicare policies to a substantial degree. Factors payors frequently consider in determining reimbursement are whether the product is: (a) a covered benefit under its health plan; (b) safe, effective, and medically necessary; (c) appropriate for the specific patient; (d) cost-effective; and (e) neither experimental nor investigational.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any current or future programs to promote the importation of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot provide any assurances that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, whether the level of reimbursement will be adequate. Further, reimbursement for drugs by government healthcare programs may be reduced by mandatory discounts or rebates required by such programs. Certain government healthcare programs impose ceiling prices on products of participating manufacturers.

U.S. Healthcare Reform

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs.

For example, in March 2010, the Affordable Care Act (ACA) was enacted in the United States and substantially changed the way healthcare is financed by both the government and private insurers. The ACA contains provisions that may reduce the profitability of drug products. Among other things, 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 outpatient 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; and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. In June 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 force in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. Enacted in August 2011, the Budget Control Act of 2011 includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken. Enacted in January 2013, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, enacted in March 2021, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. The American Rescue Plan Act also temporarily increased premium tax credit assistance for individuals eligible for subsidies under the ACA for 2021 and 2022 and removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. The Inflation Reduction Act of 2022 (IRA) extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025. This tax credit assistance expired on December 31, 2025, and additional action from Congress would be needed to restore such assistance in the future.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation and regulations designed to, among other things, reduce the cost of prescription drugs under Medicare, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

Most significantly, in August 2022, the IRA was enacted. 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, 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); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance

as these programs are implemented, 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.

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, marketing cost disclosure, drug price reporting, and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which pharmaceutical products and suppliers will be included in their prescription drug and other healthcare programs.

Existing healthcare reform measures, as well as the implementation of additional cost containment measures or other reforms, may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved. These new laws and the regulations and policies implementing them, as well as other healthcare-related measures that may be adopted in the future, could materially reduce our ability to develop and commercialize our product candidates, if approved.

Data Privacy and Security Laws

Numerous state, federal, and foreign laws, regulations and standards govern the collection, use, access to, confidentiality, and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

As of March 8, 2026, we had 28 employees, all of whom are full-time employees. Of these employees, 16 employees are engaged in research and development and 12 are engaged in finance, legal, business development, and general management and administration. A total of 8 of these employees have M.D. or Ph.D. degrees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain, and motivate selected employees, consultants, and directors through the granting of stock-based compensation awards. We value our employees and regularly benchmark total rewards we provide, such as short and long-term compensation, 401(k) contributions, health, welfare, and quality of life benefits, paid time off, and personal leave, against our industry peers to help ensure we remain competitive and attractive to potential new hires.

Corporate Information

We were originally founded as a Delaware corporation on April 10, 2018, under the name Pretzel Therapeutics, Inc. On July 8, 2019, we changed our name to Boundless Bio, Inc.

We use our trademarks in this report as well as trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Available Information

Our website address is www.boundlessbio.com. The investor relations portion of our website is located at https://investors.boundlessbio.com. We make available free of charge on the investor relations portion of our website under “Financials – SEC Filings” certain reports and other information we file with or furnish to the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors’ and officers’ Section 16 reports, and any amendments to those reports, as soon as reasonably practicable after we electronically file such materials with, or furnish them to, the SEC. They are also available for free on the SEC’s website at www.sec.gov.

We intend to use the investor relations portion of our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor our website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included in the investor relations portion of our website. The information found on or accessible through our website and the SEC website is not incorporated into, and is not considered part of, this report. We have included these website addresses as inactive textual references only.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes included elsewhere in this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making a 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 all or part of your investment. The risks described below are not the only ones we face, and additional risks and uncertainties not known to us or that we currently believe to be immaterial may also impair our business, financial condition, results of operations and prospects. Some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us and our common stock in the future. References in this section to past events and conditions are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not the factors discussed below have occurred in the past or their likelihood of occurring in the future.

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 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. We have elected to cease enrollment in the POTENTIATE trial evaluating the combination of BBI-355 and BBI-825, and now have only one ecDTx, BBI-940, proceeding with clinical development. 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 or 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 $58.2 million and $65.4 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $259.7 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 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 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 our ecDTx or any future ecDTx we may develop, 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 will continue to incur additional costs associated with operating as a public company and we have substantial payment obligations under a long-term non-cancellable facility lease.

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 2028. We have based our belief in this regard 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 is not 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, inflation, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. 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.

We currently have a “shelf” registration statement on Form S-3 effective and an existing ATM offering program; however, our ability to raise capital under our shelf registration statement, including through the ATM offering program, may be limited by SEC rules and regulations. Based on our public float as of the filing date of this Annual Report on Form 10-K, as calculated pursuant to SEC rules, we are only permitted to utilize our shelf registration statement, including the prospectus pursuant to which our ATM offering is conducted, subject to Instruction I.B.6 of Form S-3, which is referred to as the “baby shelf” rule. Accordingly, for so long as our public float is less than $75.0 million, we generally may not sell securities registered on our shelf registration statement in a primary offering with a value exceeding more than one-third of our public float during any 12 calendar month period. Although alternative public and private transaction structures may be available to raise additional capital, these may require additional time and cost, may impose operational restrictions on us, and may not be available on acceptable terms.

Our future capital requirements are difficult to predict and 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;
- the costs and timing of manufacturing for our ecDTx, including commercial manufacture at sufficient scale, if our ecDTx is approved;
- the costs and timing of obtaining raw materials for manufacturing sufficient quantities of our ecDTx or obtaining sufficient quantities of any combination agents or other materials needed for use in our clinical trials and preclinical studies;
- the costs and timing of developing diagnostics, if required, and the outcome of their regulatory review;
- the costs, timing, and outcome of regulatory meetings and reviews of our ecDTx;

- changes in regulatory policies or approval pathways;
- disruptions at the FDA that hinder its ability to perform routine activities or function in the normal course;
- the costs, timing, and outcome of seeking to obtain, maintain, expand, enforce, defend, and protect our patents and other intellectual property and proprietary rights, or to challenge third-party patents and other intellectual property rights, if necessary;
- the costs and timing of purchasing laboratory supplies and equipment and pharmacology supplies for our preclinical activities and clinical trials;
- the amount of our variable lease payment obligations under our facility lease;
- the costs associated with hiring additional personnel and consultants, as needed, to support our clinical and preclinical development efforts;
- the costs and timing of establishing or securing sales and marketing capabilities if our 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 we can generate substantial product revenue, 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. 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 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.

We occupy our corporate headquarters under a long-term non-cancellable lease which may limit our operating flexibility and could adversely affect our liquidity and results of operations.

We lease office and lab space under a non-cancellable lease agreement with an initial lease term that expires in October 2034. Due to an abatement period, base rent payments under this lease did not commence until July 2025. We expect our payments under this lease will account for a significant portion of our operating expenses. As of December 31, 2025, future undiscounted lease payment obligations under this lease agreement totaled $69.8 million, which is exclusive of future variable lease payments for our allocated share

of variable lease costs associated with the operation and management of the property, which include utilities, property taxes, common area maintenance, and amenities costs, which may be material and are outside of our control. Our substantial lease obligations could have significant negative consequences, including:

- requiring a significant portion of our cash to be applied to pay our lease obligations, thus reducing cash available for other purposes;
- limiting our ability to obtain additional capital to finance our operations and execute our business plan;
- limiting our flexibility in planning for or reacting to changes in our business or the industry in which we compete; and
- increasing our vulnerability to general adverse economic and industry conditions.

The lease generally requires our landlord's consent to assign the lease or sublease the premises, which may not be granted or may be granted only on unfavorable terms. Even if we are able to assign the lease or sublease the premises, we may incur significant costs, including transaction costs associated with finding and negotiating with potential transferees or sublessees, upfront payments or other inducements, and other costs to exit the property.

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

We are early in our development efforts and have only one ecDTx in development. If we are unable to successfully develop, obtain regulatory approval, and ultimately commercialize our ecDTx, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts. We have elected to cease enrollment in the POTENTIATE trial evaluating the combination of BBI-355 and BBI-825, and now have only one ecDTx, BBI-940, proceeding with development. We have invested substantially all of our efforts to date in developing our ecDTx, developing a diagnostic as a potential patient selection tool, identifying other targets for therapeutic pursuit, and developing our proprietary Spyglass platform. We will need to progress our BBI-940 ecDTx through a first-in-human clinical trial to advance to later phase clinical development. There can be no assurance our ecDTx will demonstrate acceptable or commercially viable clinical trial results. 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 contract research organizations (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 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 novel and 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 our ecDTx in clinical trials or in obtaining regulatory approvals from the FDA or other regulatory authorities or in commercializing such ecDTx. For example, as discussed above, we recently elected to cease enrollment in the POTENTIATE trial evaluating the combination of BBI-355 and BBI-825, our first two ecDTx to be tested in humans, due to market considerations, clinical data, and prioritization of our BBI-940 program. 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 ongoing or future 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. For example, as discussed above, we recently elected to cease enrollment in the POTENTIATE trial evaluating the combination of BBI-355 and BBI-825, due to market considerations, clinical data, and prioritization of our BBI-940 program. 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 our current and any potential future 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, including us, as discussed above, 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. 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 or 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 marketing 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 or amendments 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 ECs or 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 ECs or IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial.

Further, if we conduct clinical trials in foreign countries, 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 a comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval 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 that 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 or enabled by 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, patients in our clinical trials 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 assure you 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 authorities 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, cause us to 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 is combined with standard of care therapies, or when used as a single agent. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials. For example, in the now-discontinued monotherapy arm of the POTENTIATE trial, BBI-355 administered with continuous every other day dosing (Q2D) demonstrated a narrow therapeutic index resulting from hematological toxicity at or near doses associated with clinical activity, and in the now-discontinued combination arms with third-party targeted therapies, the combination of BBI-355 administered with Q2D dosing in combination with these therapies was not well-tolerated at the exposure levels believed to be required for robust, sustained anti-tumor activity. 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. In addition, we have studied, and plan to study, our ecDTx in combination with other therapies, which may exacerbate adverse events associated with such ecDTx.

If we successfully complete early phase clinical studies and establish initial clinical proof-of-concept, 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.

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 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, change the labeling of a product, or 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 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. As discussed above, we elected to cease enrollment in the POTENTIATE trial and have not yet completed any clinical trials for our ecDTx. 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 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 identify predictive biomarkers to identify patient populations most likely to benefit from our ecDTx, or develop a 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 patient populations most likely to benefit from our ecDTx by using a biomarker-driven approach. Identification of these patients will require identification of predictive biomarkers and may require the development and use of a diagnostic assay.

We may not be able to identify predictive biomarkers to identify patients most likely to benefit from our ecDTx. If we identify predictive biomarkers, there are several risks associated with the development of a diagnostic assay to identify the biomarkers. We may not be able to validate a 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 to successfully develop or obtain marketing authorization for a diagnostic assay, or any delays in doing so, may harm the commercial prospects of our ecDTx. Moreover, we may need to work with a third-party diagnostic developer to assist us in developing a diagnostic assay. For example, we developed an ecDNA diagnostic as a clinical trial assay for use during our Phase 1/2 POTENTIATE clinical trial using a third-party *in vitro* diagnostic company. In the future, we may have difficulty identifying or maintaining a relationship with a third-party diagnostic developer, and we may face competition from other companies in establishing these relationships.

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

We intend to develop our ecDTx for use in combination with one or more currently approved cancer therapies. Even if our ecDTx 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 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. For example, until recently, we have focused our efforts and resources in large part on discovering and developing BBI-355 and BBI-825, however, as discussed above, based on market considerations, clinical data, and our prioritization of BBI-940, we elected to cease enrollment in the POTENTIATE trial evaluating the combination of these drugs. Similarly, while we are currently expending significant resources to investigate BBI-940, there can be no assurance that we will complete KOMODO-1, the first-in-human clinical study of BBI-940, or that BBI-940 will demonstrate acceptable or commercially viable safety and efficacy results in that trial or any later clinical study, if any.

In addition, 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 preclinical studies to 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. 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 in connection with approval 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.

If the FDA believes that the safe and effective use of our ecDTx depends on an in vitro 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 a diagnostic is not commercially available in this situation, we may be required to complete the development of a 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 diagnostic we may develop for use with our ecDTx. The approval or clearance of a companion diagnostic as part of the therapeutic product's further 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 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 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, the Food and Drug Omnibus Reform Act of 2022, among other things, provided the FDA with 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 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, the SEC, and other government agencies, including due to government shutdowns, other funding shortages, policy changes, leadership changes, layoffs or significant personnel turnover, or public health concerns, could impede development and potential marketing approval of our ecDTx and our ability to raise capital.

Over the last several years, the U.S. government has shut down several times and certain federal regulatory agencies, such as the FDA and SEC, furloughed or laid off employees and halted non-essential operations due to the failure of Congress to pass a new appropriations bill or continuing resolution to temporarily extend funding. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. A federal government shutdown or other disruption to ordinary course operations could prevent or delay staff at federal agencies from performing key functions that may adversely affect our business, and the more prolonged the disruption, the greater risks it may pose to our business. In addition, considerable uncertainty exists regarding the current U.S. presidential administration's initiatives and how these might impact federal government agencies, including the FDA, their implementation of laws, regulations, policies, and guidance, and their personnel. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our business or operations.

The ability of the FDA to review and approve new product applications or take action with respect to other regulatory matters can be affected by a variety of factors, including funding levels, ability to accept the payment of user fees, ability to hire and retain key personnel, and statutory, regulatory, and policy changes. Government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. For example, the current U.S. presidential administration has issued certain policies and executive orders directed towards reducing, and subsequent reductions have occurred to, the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. Disruptions at the FDA may delay meetings and other communications with agency staff necessary to progress development of our ecDTx and may slow the time necessary for acceptance, review, and approval of applications to commence clinical studies or to market a new product in the U.S., which could also adversely affect our operating results and financial condition.

In addition, disruptions at the SEC could prevent or delay SEC staff from performing key functions, including, for example, granting acceleration requests for registration statements, declaring registration statements or amendments thereto effective and providing interpretive guidance or no-action letters. If a federal government shutdown halts non-essential SEC operations for an extended period, it may negatively impact our ability to raise additional capital through registered offerings of our securities. If a prolonged U.S. government shutdown or other event or condition occurs that prevents or significantly delays the FDA, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, or if an agency is restructured or experiences significant reduction in funding, leadership changes, or employee turnover, it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions, 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, some of which operate outside of the U.S., for the manufacture of our ecDTx and related raw materials and to package, label, ship, store, and distribute our ecDTx for clinical and preclinical development, and we intend to rely on third parties for such services for our commercial products if any marketing approval is obtained. This reliance on third parties increases the risk that timely availability of clinical trial supplies of our ecDTx, and future products, if any, may be delayed, limited, or interrupted, or that their quality or cost is not satisfactory or acceptable. 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.

We currently, and may in the future, rely on foreign CMOs. Such foreign CMOs may be subject to U.S. legislation, sanctions, trade restrictions, and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, in January 2024, there was congressional activity, including the introduction of the BIOSECURE Act ("H.R. 7085") in the House of Representatives and a substantially similar Senate bill ("S.3558"). A version of the BIOSECURE Act was passed by the U.S. House of Representatives in September 2024 ("H.R. 8333"), however, the Senate did not approve that legislation. In October 2025, both the U.S. House of Representatives and Senate passed their respective versions of the National Defense Authorization Act of 2026 ("NDAA"), each including an amendment often referred to as "BIOSECURE 2.0." BIOSECURE 2.0 was reconciled in conference and signed into law on December 18, 2025. BIOSECURE 2.0 establishes federal government contracting, grant, and loan restrictions similar in effect to previously introduced bills. BIOSECURE 2.0 implements a process-based designation system through which biotechnology companies "of concern" are identified based on whether such companies fall within statutorily defined categories, including entities identified on the Department of Defense's Section 1260H list of "Chinese military companies" and other entities that are subject to the administrative governance structure, direction, control, or jurisdiction of a foreign adversary's government which pose national security risks based on specified criteria. The prohibitions of BIOSECURE 2.0 will become effective approximately three years after the enactment of BIOSECURE 2.0 (i.e., December 2028). BIOSECURE 2.0 has the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase products or services from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our Chinese CMOs and other Chinese vendors, could be impacted by this legislation.

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;
- obligation to pay tariffs for products or the related raw materials imported from other countries;
- heightened exposure to supply chain complexities and disruptions; 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 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 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 a diagnostic assay, 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 its competitiveness if it reaches 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 our ecDTx receives regulatory approval, it may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. The commercial success of our 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 adequate levels of reimbursement for our ecDTx by third-party payors will have a material effect on our ability to successfully commercialize our 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. Reimbursement for drugs by government healthcare programs may be reduced by mandatory discounts or rebates required by such programs. Certain government healthcare programs impose ceiling prices on products of participating manufacturers.

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 not adequate to enable us to realize an appropriate return on our investment in ecDTx development. If reimbursement is not available or is available only at inadequate 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 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, 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 time consuming and costly and may 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. Reimbursement practices are also subject to rules and regulations that may change frequently, and, in some cases, at short notice.

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 our ecDTx due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. There is increasing downward pressure on healthcare costs in general, and prescription drugs, surgical procedures, and other treatments in particular. 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, biotechnological, 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 our ecDTx is approved, it 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.

For our current ecDTx, BBI-940, the kinesin target is novel and we are unaware of any therapeutic programs developing compounds directed against this kinesin target; however, potential competition could arise from established companies as well as emerging biotechnology companies that may launch programs against the novel target once it is disclosed publicly, or against targets similar to this novel target. Additionally, we are not aware of any companies with programs in clinical development for ecDNA-enabled cancer or a related patient selection strategy for ecDNA. We are aware of one early-stage private company that is focused on research in ecDNA, Econic 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 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 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 our ecDTx before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for 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.

We have a relatively small number of employees which may constrain our ability to accomplish our business objectives. Our long-term success is dependent on our ability to retain and attract highly qualified management and other clinical and scientific personnel.

As of March 8, 2026, we had 28 full-time employees. Due to our relatively small workforce, we may experience constraints that impede the achievement of our business objectives. Further, if multiple employees were to become unable to work for a prolonged period, or if they were to resign at roughly the same time, our ability to effectively manage and operate our business could become significantly impaired.

Our long-term success depends in part on our 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 or offer letters 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. For example, the employment of our Chief Business Officer with us terminated in January 2025. 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 retain highly skilled employees may be negatively impacted by any significant appreciation or depreciation in our stock price relative to the exercise price of outstanding stock options.

In the future, 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. 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 we continue development and pursue the potential commercialization of our ecDTx, 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 (FCA), 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 knowingly making or causing to be made a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. The government can bring claims directly or through a civil whistleblower or *qui tam* action, and potential liability includes mandatory treble damages and significant per-claim penalties. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Pharmaceutical and other healthcare companies have been, and continue to be, prosecuted under these laws, among other things, for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, off-label, and thus generally non-reimbursable uses. 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. 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 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. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, which impose privacy, security, and breach reporting obligations with respect to individually identifiable health information upon covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates and covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Similar to the federal Anti-Kickback Statute and federal false claims laws, 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 our 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, in March 2010, the Affordable Care Act (ACA) was enacted in the United States and substantially changed the way healthcare is financed by both the government and private insurers. The ACA contains provisions that may reduce the profitability of drug products. Among other things, 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 outpatient 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; and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. In June 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. The current U.S. presidential administration has made several changes to how the ACA is implemented. For example, in January 2025, President Trump issued Executive Order 14148, which revoked Executive Order 14009 issued by President Biden in January 2021, that had initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. It is possible that the ACA will be subject to further judicial or Congressional challenges in the future. It is unclear what healthcare reform measures will be implemented by the current presidential administration going forward, but further changes are anticipated.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In July 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act" (OBBBA), was signed into law which is expected to reduce Medicaid spending and enrollment by shortening the open enrollment period, disqualifying Deferred Action for Childhood Arrivals (DACA) recipients, implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declined to extend the ACA's enhanced advanced premium tax credits, which expired in 2025, and these changes, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. Additionally, under the sequestration required by the Budget Control Act of 2011, beginning April 1, 2013, Medicare payments to providers were reduced, which will remain in effect through 2032 unless additional Congressional action is taken. Enacted in January 2013, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, enacted in March 2021, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation and regulations designed to, among other things, reduce the cost of prescription drugs under Medicare, 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, in August 2022, the Inflation Reduction Act of 2022 (IRA) was enacted. 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 to establish a "maximum fair price" for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). CMS published the negotiated maximum prices for the initial ten drugs that were subject to the IRA's negotiation process, which are effective in 2026, and published the negotiated maximum prices for the subsequent 15 drugs to be effective in 2027. 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. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. In December 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, which, under the Bayh-Dole Act, gives the federal government authority to "march in" and grant compulsory patent licenses to third parties in some circumstances. Under the draft guidance, march-in rights include the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Further, there is uncertainty surrounding this program with the current U.S. presidential administration, especially in light of the administration's budget cuts which impact an agency's ability to regulate through guidance. Further, it is unclear how the new leadership of HHS, CMS, etc. will approach the issue of drug pricing. 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, drug price reporting, and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across-the-board price caps for pharmaceuticals, or are seeking to regulate drug distribution. 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.

The future course of federal or state healthcare legislation and regulation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, is subject to considerable uncertainty. The current presidential administration is pursuing policies to reduce regulations and expenditures across the federal government, including at HHS, the FDA, the CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for the pharmaceutical industry and our business. These actions and proposals include, for example, (a) reducing agency workforce and cutting programs; (b) rescinding a prior presidential administration's executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending; (c) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing most-favored-nation pricing for pharmaceutical products; (d) imposing tariffs of imported pharmaceutical products; and (e) directing certain federal agencies to enforce existing law regarding hospital and price plan price transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, or Loper Bright, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. The U.S. Congress may introduce and ultimately pass healthcare related legislation that could, among others, impact the drug approval process and make changes to modify the Medicare Drug Price Negotiation Program created under the IRA.

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. In addition, we expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. 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 or withdrawals, and 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 $10.0 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, as amended by HITECH. 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), requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. 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.

In addition to the state comprehensive data privacy laws, recent years have brought substantial changes to the federal and state treatment of non-HIPAA consumer health information. The Federal Trade Commission (FTC) and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination, and security practices that appear to be unfair or deceptive. The FTC brought three enforcement actions in 2023 against a range of companies that handle electronic health information relating to collection and disclosure of non-HIPAA covered consumer health information under Section 5 of the FTC Act, two of which included allegations made under the FTC's Health Breach Notification Rule (HBNR). The FTC's focus on health information continued in 2024 with changes to the HBNR that clarified its scope and emphasized applicability to non-HIPAA health care providers as well as three additional enforcement actions against companies for their use of health information for advertising purposes. At the state level, Washington and Nevada have adopted significant new legislation addressing businesses treatment of consumer health information, and Connecticut added more stringent protections for health information to its existing comprehensive state privacy law. In both Washington's and Nevada's laws, there are restrictive provisions limiting collection and disclosure of consumer health information, and Washington's law provides a separate private right of action for violations.

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 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 or perceived 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.

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any (subject to limitations), until such unused losses expire (if at all). As of December 31, 2025, we had net operating loss (NOL) carryforwards of approximately $161.4 million for federal income tax purposes and $231.3 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 2038. 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.

Inflation could adversely affect our business and results of operation.

While inflation in the United States has been relatively low in recent years, the economy in the United States encountered a material level of inflation since 2021. Although inflation eased somewhat in 2024, it has raised our costs for commodities, labor, materials, and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with public health concerns, geopolitical developments, and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty, and uncertainty about the interest rate environment, which may make it more difficult, costly, or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition and results of operations.

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, 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 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 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. If we are unable to adequately fund our patent prosecution and maintenance, or if the costs of defending our patents against third-party challenges become prohibitive, our competitive position could be weakened. Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents. 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 geopolitical conflicts in and around Ukraine and the Middle East; retaliatory measures by foreign countries in response to actions by the U.S., in particular, tariffs) 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. Many foreign countries could threaten to impose retaliatory measures that may adversely impact our intellectual property rights in those countries. For example, government actions may prevent filing, prosecution, and maintenance of issued patents in various jurisdictions experiencing geopolitical conflict. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in such jurisdictions. In addition, jurisdictions outside of the U.S. could also permit our patents to be exploited without consent or compensation. For example, on March 14, 2025, Brazil enacted Law No. 15.122/2025 (known as the Economic Reciprocity Law), which provides a framework that allows for the suspension of obligations related to foreign entity's intellectual property rights. In such circumstances we would not be able to prevent third parties from practicing our inventions or from selling or importing products made using our inventions in and into such jurisdictions. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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 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. Additionally, administrative changes at the USPTO or other applicable patent authorities, such as reduced hiring and/or funding, may result in delays in issuance of a patent or in accrual of patent term extension, thereby reducing the amount of patent term extension that could otherwise be received. Administrative changes (e.g., at the FDA or USPTO) may also lead to delays in review and analysis of requests for patent term extension, which could result in a patent term extension not being timely granted (e.g., before the expiration of the patent). Moreover, the applicable time period or the scope of patent protection afforded could be less than we project or 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 project or 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 our ecDTx that is 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 our ecDTx or the use of our ecDTx. We are aware of an issued patent in the United States and certain patent applications elsewhere that contain claims that may cover one of our CHK1 related ecDTx. While we believe we 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. Additionally, we may be subject to claims of patent infringement during those proceedings, and delays caused by the federal agencies may increase the time period that we are subject to such claims. For example, administrative changes, including reduced staff and budgets experienced by the Patent and Trial Appeal Board, could further delay our ability to timely challenge any such patents. 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. For example, recent shifts in USPTO policy and increased discretionary denials may restrict our ability to challenge third-party patents, increasing our litigation risk and costs. Our ability to use *inter partes* review (IPR) and other post-grant proceedings to challenge the validity of third-party patents is subject to evolving procedural rules and increased administrative discretion. If we are unable to use the Patent Trial and Appeal Board to invalidate questionable patents, we may face increased litigation expenses in slower and more costly district court venues. These policy shifts could result in infringement liability, licensing fees, or injunctions that could adversely affect our product development timelines, market share, and overall financial condition. If we do not prevail in the patent proceedings, 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 names, 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 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

An active, liquid, and orderly market for our common stock may not 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 began trading on The Nasdaq Global Select Market (Nasdaq) in late March 2024, and we can provide no assurance that an active trading market for our common stock will be sustained. If an active market for our common stock is not sustained, it may impair your ability 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 shares of our common stock at or above the price they paid to purchase them. 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;
- 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, have the ability to significantly influence all matters submitted to stockholders for approval.

As of December 31, 2025, our executive officers, directors, greater than 5% stockholders, and their respective affiliates, in the aggregate, owned approximately 41.4% of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. 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 combinations involving us, or discouraging a potential acquiror 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.

As of December 31, 2025, 4,578,055 shares of our outstanding common stock, or 20.4%, were held by our directors, executive officers, and other affiliates. Such shares may be sold under Rule 144 under the Securities Act, subject to volume limitations. 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 securities.

The holders of 4,193,340 shares of our outstanding common stock, or approximately 18.7% of our total outstanding common stock as of December 31, 2025, may have registration rights that entitle such holders to require us to register their shares for resale under the Securities Act. 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, or the registration of such shares, could also significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. For example, in April 2025, we entered into an Open Market Sale Agreement[SM] with Jefferies LLC under which we may sell shares of our common stock in "at the market" (ATM) offerings through or to Jefferies, as sales agent or principal, and pursuant to the prospectus for the ATM offering, we may sell shares from time to time having an aggregate offering price of up to $14.5 million. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

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 Jumpstart Our Business Startups Act of 2012 (JOBS Act), and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of our IPO, or December 31, 2029. 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 December 31, 2029. 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 Act);
- 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 stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this report. In particular, in this report, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Investors may find our common stock less attractive because we rely on these exemptions. 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 elected to avail ourselves of this exemption and, therefore, we may not be subject to new or revised accounting standards at the same time that they become applicable to 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 the Sarbanes-Oxley Act.

We are also a smaller reporting company as defined in Rule 12b-2 under 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 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;
- that the total number of directors on our board of directors is established by our board of directors, which may delay the ability of stockholders to change the composition 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 to fill any vacancy on our board of directors however occurring, which prevents stockholders from being able to fill vacancies on our board of directors, subject to any special rights of the holders of any series of preferred stock;
- no director may be removed from office except for cause and, in addition to any other vote required by law, upon the approval of at least 66-2/3% of the voting power of all of our then outstanding shares of our voting stock entitled to vote at an election of directors, subject to any special rights of the holders of any then outstanding series of preferred stock;
- 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 amend or repeal our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the then outstanding 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;
- that a special meeting of stockholders may be called only by or at the direction of our board of directors, the chair of our board of directors, our chief executive officer, or our president, 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 which a corporation may not 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 is the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts are 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.

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. Our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States are 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 require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, 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, and the application of existing laws, regulations, and standards may evolve over time as they are subject to varying interpretations and new guidance is provided by regulatory and governing bodies. This may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies substantially increase our legal and financial compliance costs and make some activities more time consuming and costly. The increased costs decrease our net income or increase our net loss, and may require us to reduce expenditures in other areas of our business. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we incur substantial costs to maintain the same or similar coverage. 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 nor 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 including changes related to the U.S. and foreign governments in tariffs and trade policies affecting trade between the United States and other countries. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including geopolitical conflict in and around Ukraine and 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, changes in tariffs and trade policies 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.

International trade policies, including tariffs, sanctions, and trade barriers may adversely affect our business, financial condition, results of operations, and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition, and prospects.

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 and to package, label, ship, store, and distribute our ecDTx for clinical and preclinical development, and we intend to rely on third parties for such services for our commercial products if our ecDTx receives regulatory approval. Currently, we work with some suppliers located outside of the United States, including a manufacturer of drug substance for BBI-940 that is located in China. We also rely on specialized laboratory equipment, supplies and materials, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs could result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment, and other research materials and components. In addition, such tariffs could increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating entirely domestically or in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our suppliers or future customers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers, and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, results of operations and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition, and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

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. For example, the U.S. government recently enacted the OBBBA, which (along with other recent U.S. federal tax reform) has resulted in significant changes to the taxation of business entities including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, and the deductibility of expenses, or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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 the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting, and when we lose our status as an "emerging growth company" and do not qualify as a non-accelerated filer, 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. 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 legal proceedings or 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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management Strategy

We have developed our cybersecurity risk management program, including a cybersecurity incident response plan, based on the National Institute of Standards and Technology Cybersecurity Framework's (NIST CSF) principles: Identify, Protect, Detect, Respond, and Recover. This does not, however, imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program, which is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas, is intended to address current vulnerabilities and anticipate future cybersecurity threats and risks to our cyber ecosystem. Our cybersecurity risk management program includes: (a) assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment; (b) a security team principally responsible for managing our cybersecurity risk assessment processes, our security controls, and our response to cybersecurity incidents; (c) the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls; (d) cybersecurity awareness training of our employees, including our senior management, and incident response personnel; (e) a cybersecurity incident response process that includes procedures for responding to cybersecurity incidents; and (f) a risk evaluation of the service providers, suppliers, and vendors of critical systems during contracting.

As of the filing date of this report, we have not identified incidents from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. There can be no assurance, however, that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with or effective in protecting our systems and information. For more information, see the section titled "Risk Factors—Risks Related to Our Business Operations and Industry— 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."

Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function and has delegated to our audit committee oversight of cybersecurity and other information technology risks. Our audit committee oversees our management team's implementation of our cybersecurity risk management program, receives periodic reports from our management team on our cybersecurity risks, and receives reports from our management team, as necessary, regarding material cybersecurity incidents, as well as any incidents with lesser impact potential.

Our audit committee reports to our board of directors regarding its activities, including those related to cybersecurity. Our board of directors also receives briefings from our management team on our cyber risk management program.

Our management team is responsible for assessing and managing our material risks from cybersecurity threats, and has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team oversees efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public, or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties.

Our corporate headquarters are currently located in San Diego, California, where we lease approximately 80,168 square feet of laboratory and office space pursuant to a lease that expires in October 2034. We believe our existing facilities are adequate to meet our current business requirements for the near term, and that additional space will be available on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

There currently is no material pending legal proceeding to which we are a party or to which any of our property is subject. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock began trading under the symbol "BOLD" on the Nasdaq Global Select Market on March 28, 2024.

Holders of Our Common Stock

As of March 8, 2026, there were approximately 66 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers, and other fiduciaries.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects, and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Unregistered Sales of Equity Securities

None.

Use of Proceeds from our IPO

On March 27, 2024, our registration statement on Form S-1 (File No. 333-277696), as amended, 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 and other offering expenses.

Pending the uses described below, the net proceeds from our IPO have been held in cash, cash equivalents, and short-term investments. Our planned use of the net proceeds from our IPO has changed from that described in the prospectus for our IPO due to our portfolio prioritization decisions, which have focused our activity on the BBI-940 program in lieu of other research programs and other ecDTx development programs, including the POTENTIATE and STARMAP trials, as discussed above. Net proceeds that may have been used to fund other research and development programs, and that are not used to wind down the POTENTIATE trial, are now expected to be directed to support the development of BBI-940, including through initial proof-of-concept clinical data, and to be used for working capital and other general corporate purposes. We may also use a portion of the net proceeds and our existing cash, cash equivalents, and short-term investments to in-license, acquire, or invest in complementary businesses, technologies, products, or assets. However, we have no current commitments or obligations to do so. We cannot predict with certainty all of the particular uses for the net proceeds from our IPO. Our expected use of the net proceeds from our IPO represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress and costs of our development activities, the status of and results from clinical trials and preclinical studies, as well as any collaborations that we may enter into with third parties for our ecDTx, and the amount of cash used in our operations and any unforeseen cash needs, as well as other factors described in Item 1A, "Risk Factors," in Part I of this Annual Report on Form 10-K. Our management has broad discretion in the application of the net proceeds from our IPO, and investors will be relying on their judgment regarding the application of the net proceeds.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward Looking Statements." As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results and the timing of events could differ materially from the results and timing described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 interrogating extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in 14 to 17% of cancer patients. Our mission is to be the foremost biopharma company interrogating ecDNA biology to deliver transformative therapies that improve and extend the lives of patients with previously intractable oncogene amplified cancers.

ecDNA are large circular units of nuclear DNA that are a primary mechanism of gene amplification and are detected only in cancer cells, not in healthy cells. Despite tremendous advancements in treating cancer broadly, patients with oncogene amplified cancers generally derive little benefit from existing therapies, such as molecular targeted therapies or immunotherapies, and have worse survival rates than patients without oncogene amplification. Using our proprietary Spyglass platform, we identify targets essential for ecDNA functionality in oncogene amplified cancer cells, then design and develop small molecule drugs called ecDNA-directed therapeutic candidates (ecDTx) to inhibit those targets, with the aim to prevent cancer cells from using chromosomal instability and ecDNA amplification biology to grow, adapt, and become resistant to existing therapies. Instead of directly targeting the proteins produced by amplified oncogenes, which is the approach of traditional targeted therapies, our ecDTx are intended to be synthetic lethal in tumor cells reliant on ecDNA amplification biology. In the context of drug development, synthetic lethality is a therapeutic approach wherein using a drug to inhibit one target is lethal to cancer cells harboring a specific genetic alteration to a second target, but not lethal to healthy cells that lack the genetic alteration to the second target. Accordingly, our ecDTx are designed to preferentially kill ecDNA-enabled cancer cells, but not healthy cells. They are engineered to disrupt the underlying cellular machinery that enables ecDNA or functional amplification.

Our lead ecDTx, BBI-940, is a novel, oral, selective degrader that targets a previously undrugged kinesin involved in DNA segregation, including ecDNA segregation during mitosis. BBI-940 has demonstrated potent anti-tumor activity across a range of cancer cell lines as well as in mouse xenograft models, including single-agent tumor regressions. In February 2026, we initiated a Phase 1, open-label, multicenter, first-in-human clinical trial of BBI-940 in patients with estrogen receptor positive and human epidermal growth factor receptor 2 negative, or ER+/HER2-, breast cancer who have progressed following treatment with a cyclin-dependent kinase 4 and/or 6 inhibitor, or CDK4/6 inhibitor, plus endocrine therapy, as well as patients with triple-negative breast cancer luminal androgen receptor subtype, or TNBC-LAR. We refer to this trial as KOMODO-1 for Kinesin Oral Molecular Degrader for Oncology-1(clinicaltrials.gov identifier NCT07408089). In the KOMODO-1 trial, we contemplate two distinct biomarkers for patient selection, and we will retrospectively assess ecDNA status using multiple techniques for inferring ecDNA in tumor samples. For additional information, see "Our Lead ecDTx: BBI-940 Kinesin Degrader" in Part I, Item 1., "Business," of this Annual Report on Form 10-K. We expect to have initial proof-of-concept safety and efficacy clinical data from the KOMODO-1 trial of BBI-940 within our existing cash runway timeline discussed below.

We have been investigating BBI-355, a novel, oral, selective inhibitor of checkpoint kinase 1 designed to target replication stress in oncogene amplified cancers, and BBI-825, a novel oral, selective inhibitor of ribonucleotide reductase, in the clinic in the POTENTIATE trial and the STARMAP trial. We made decisions to cease enrollment in these previously initiated trials, and, accordingly, we also do not plan to invest further in the development of ECHO, which is an ecDNA diagnostic clinical trial assay used in the POTENTIATE trial. We completed winding down the STARMAP trial of BBI-825 in 2025. For additional information, see "Other Programs" in Part I, Item 1., "Business," of this Annual Report on Form 10-K.

Spyglass is our internal proprietary platform used to identify new targets. We utilized Spyglass to identify targets that exploit cellular vulnerabilities of oncogene amplified cancers. Our target identification efforts revealed multiple distinct nodes of vulnerability within the lifecycle of ecDNA. In addition to the program described above, we have preclinically validated multiple additional targets and have historically initiated ecDTx drug discovery efforts to identify potential candidates against such targets. We continue to deploy Spyglass to inform development of BBI-940 and potential complementary targets or assets that we may wish to acquire or internally develop in the future.

Business Overview

Since we commenced operations in 2018, we have devoted substantially all of our efforts and resources to organizing and staffing our company, business planning, raising capital, building our proprietary Spyglass platform, discovering our ecDTx, developing our 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. During this time, we have incurred significant operating losses and, as of December 31, 2025, we had an accumulated deficit of $259.7 million. We expect to continue to incur losses for the foreseeable future, and, in general, we anticipate these losses will increase substantially in the future as we continue our development of, seek regulatory approval for, and potentially commercialize our ecDTx, conduct our ongoing and planned clinical trials and preclinical studies, utilize third parties to manufacture our ecDTx and related raw materials, leverage Spyglass to potentially identify additional development opportunities for our ecDTx and expand our therapeutic pipeline, seek to expand and protect our intellectual property, as well as incur additional costs associated with being a public company. If we obtain regulatory approval for 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 December 31, 2025, we have raised a total of $353.8 million to fund our operations primarily from the gross proceeds from the sale and issuance of our convertible preferred and common stock. In April 2024, we completed our IPO, in which we sold and issued 6,250,000 shares of our common stock for gross proceeds of $100.0 million. In April 2025, we commenced an “at the market” (ATM) offering as defined in Rule 415(a)(4) under the Securities Act, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $14.5 million from time to time through or to our sales agent, as described further under “Liquidity and Capital Resources” below. As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $117.6 million.

In response to clinical data and other market considerations, we have made a series of portfolio prioritization decisions and taken steps to streamline operations in connection with those decisions. As of January 2026, we are focusing our research and development activities on BBI-940. Based on our current operating plans, we believe that our existing cash, cash equivalents, and short-term investments will be sufficient to fund our operations into the second half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. See “Liquidity and Capital Resources” below for more information. 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 several years and may never occur. We will need substantial additional funding 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 such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter 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 our ecDTx obtains 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, ship, 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.

Macroeconomic, Political, and Regulatory Environment Considerations

Uncertainty in the United States and global macroeconomic, political, and regulatory environments present significant risks to our business. Our operating costs, ability to raise additional capital, and stock price could be materially and adversely affected by macroeconomic and geopolitical events and conditions outside of our control, including market volatility, high interest rates, inflation, tariffs and other trade barriers, retaliatory measures taken by foreign countries, slowed economic growth or recession, uncertainty with respect to the federal budget and debt ceiling, potential or prolonged government shutdowns related thereto, liquidity concerns at financial institutions, supply chain disruptions, military conflicts, and other geopolitical events and instability. Further, one or more of our current service providers or vendors, manufacturers, clinical investigative sites, financial institutions, 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.

In addition, FDA-regulated industries, such as ours, face uncertainty with regard to the regulatory environment we will face as we proceed with research and development and possibly in the future commercialization. The FDA has recently experienced significant leadership changes, voluntary and involuntary staff departures, shifts in scientific and regulatory priorities, and political pressure to increase scrutiny of certain products. These and other factors increased uncertainties associated with interpreting the FDA's guidance and predicting its areas of focus and responses to various issues. Changes and disruptions at the FDA, including due to federal government shutdowns, could impact the FDA's ability to retain key personnel and hire additional personnel and may result in delays or limitations on our ability to obtain guidance from agency staff and slow review times for applications we submit to obtain the requisite regulatory approvals in the future. Moreover, actions that the federal government recently has taken and may take in the future to freeze or reduce federal funding for medical research, has and could further decrease the ability of facilities that rely on such funding to conduct clinical trials or increase the costs to us of conducting clinical trials at those facilities. There remains general uncertainty regarding future activities. New executive orders, regulations, policies, or guidance could be issued or promulgated that adversely affect us or create a more challenging or costly environment to pursue the development and commercialization of our ecDTx, including in areas relating to regulatory framework and oversight, research and development funding, drug pricing reform, intellectual property rights, global trade policy, and tariffs.

Although, to date, our business has not been materially impacted, the ultimate impact of global economic and market conditions and changes in government agencies, regulations and policies remains highly uncertain and will depend on future developments and factors that continue to evolve. We closely monitor these ongoing developments and the potential impact of these factors on our business, operating expenses, and cash position and, if circumstances warrant, we may make adjustments to our operating plan. For more information regarding these risks and uncertainties, see Item 1A, "Risk Factors," in Part I of this Annual Report on Form 10-K.

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 our 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 building our Spyglass platform, our ecDTx discovery efforts, our preclinical and clinical development activities, and the development of a diagnostic test. 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. Certain shared costs are allocated ratably between BBI-355 and BBI-825. Indirect costs are not included in program costs, as these costs are general in nature and benefit all our discovery efforts and development programs.

Our direct, or development program specific, R&D costs consist of:

- 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 a diagnostic test; and
- expenses related to manufacturing our ecDTx for clinical trials and preclinical studies, including fees paid to third-party manufacturers.

Our indirect R&D costs include:

- personnel-related costs, including salaries, severance, bonuses, benefits, travel, and stock-based compensation expenses for employees engaged in R&D 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.

The successful development of our ecDTx is highly uncertain. There are numerous factors associated with the successful development of our 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 ultimately expect that our R&D expenses will increase substantially in the long-term to support advanced clinical development of our ecDTx, hiring of additional personnel, and maintaining, expanding, protecting, and enforcing our intellectual property portfolio; however, in the short term, we intend to manage our R&D expenses to help enable delivery of initial proof-of-concept clinical data for BBI-940.

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 clinical trials and preclinical activities;
- 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 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;
- a decision not to advance the clinical development of an ecDTx;
- the necessity and cost of developing a diagnostic for our ecDTx;
- the costs of laboratory supplies and equipment and pharmacology supplies for our preclinical activities and clinical trials;
- the extent of changes in government regulation and regulatory guidance;
- disruptions at the FDA that hinder its ability to perform routine activities or function in the normal course;
- 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 our ecDTx could significantly change the costs and timing associated with the development of our 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 ecDTx or any future ecDTx may be affected by a variety of factors. We may never succeed in achieving regulatory approval for our ecDTx. Preclinical and clinical development timelines, the probability of success, and total development costs can differ materially from expectations. As we have done in recent months, we anticipate that we will continue to make determinations as to how much funding to direct to our ecDTx on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, and our ongoing assessment of our ecDTx's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast whether our 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, severance, 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 in the future as we grow our business and, if our ecDTx receives marketing approval, when we commence commercialization activities. We expect to continue to incur increased facilities-related costs related to our current headquarters facilities. We also expect to continue to incur expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with securities exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Other Income, Net

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

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 44,845	$ 55,267	$ (10,422)
General and administrative	18,707	18,000	707
Total operating expenses	63,552	73,267	(9,715)
Loss from operations	(63,552)	(73,267)	9,715
Other income, net:			
Interest income	5,357	7,892	(2,535)
Other income (expense), net	(2)	12	(14)
Total other income, net	5,355	7,904	(2,549)
Net loss	$ (58,197)	$ (65,363)	$ 7,166

Research and Development Expenses

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

	Year Ended December 31,		
	2025	2024	Change
Direct program costs:			
BBI-355	$ 9,687	$ 10,024	$ (337)
BBI-825	2,887	11,644	(8,757)
Other development programs	7,659	5,178	2,481
Total direct program costs	20,233	26,846	(6,613)
Indirect program costs:			
Personnel-related (including stock compensation)	12,740	16,820	(4,080)
Outside services and consulting	1,670	4,079	(2,409)
Lab and pharmacology supplies	580	1,899	(1,319)
Facilities-related (including depreciation)	7,797	3,818	3,979
Other indirect program costs	1,825	1,805	20
Total indirect program costs	24,612	28,421	(3,809)
Total R&D expenses	$ 44,845	$ 55,267	$ (10,422)

R&D expenses were $44.8 million and $55.3 million for the years ended December 31, 2025 and 2024, respectively. The $10.4 million decrease was primarily attributable to (i) a $6.6 million decrease in direct program costs, driven by reduced spending on the STARMAP and POTENTIATE trials, partially offset by increased investment in other development programs, primarily BBI-940, (ii) a $4.1 million decrease in personnel-related costs, primarily due to workforce reductions implemented in 2024 and 2025, (iii) a $2.4 million decrease in outside services and consulting costs, and (iv) a $1.3 million decrease in laboratory and pharmacology supply costs due to lower material needs in certain development programs. These decreases were partially offset by a $4.0 million increase in facilities-related expenses, primarily due to the commencement of the lease related to our corporate headquarters in the fourth quarter of 2024, which resulted in a full-year impact on facilities-related costs in 2025 compared to a partial-year impact in 2024.

General and Administrative Expenses

G&A expenses were $18.7 million and $18.0 million for the years ended December 31, 2025 and 2024, respectively. The $0.7 million increase in G&A expenses was primarily attributable to a $1.9 million increase in facilities-related costs, primarily due to the relocation of our corporate headquarters in the fourth quarter of 2024, partially offset by a $1.2 million decrease in personnel-related costs, primarily due to workforce reductions implemented in 2024 and 2025.

Other Income, Net

Other income, net was $5.4 million and $7.9 million for the years ended December 31, 2025 and 2024, respectively. The $2.5 million decrease resulted primarily from a reduction in interest income generated by our available-for-sale investment securities portfolio, due to both a decrease in the amount of cash equivalents available for investing purposes and a decline in the market yields available for such investment securities compared to the prior year.

Liquidity and Capital Resources

Sources of Liquidity

Through December 31, 2025, we have raised a total of $353.8 million to fund our operations primarily from the gross proceeds from the sale and issuance of shares of our convertible preferred stock prior to our IPO and the sale and issuance of 6,250,000 shares of our common stock in our IPO, which closed in April 2024. Our IPO generated gross proceeds of $100.0 million, which resulted in net proceeds to us of approximately $87.7 million, after deducting underwriting discounts and commissions and other offering expenses.

In April 2025, we entered into an Open Market Sale Agreement℠ (the Sales Agreement) with Jefferies LLC (the Agent), pursuant to which we may, from time to time, sell shares of our common stock in "at-the-market" offerings through or to the Agent, acting as

sales agent or principal. See Note 1 to our financial statements included elsewhere in this Annual Report on Form 10-K under the section entitled "ATM Offering" for further information. We are not obligated to sell any shares under the Sales Agreement, and the Agent is not obligated to buy or sell any shares of our common stock. We cannot provide any assurance that we will sell any shares under the Sales Agreement, or, if we do, as to the prices, amounts, or timing of any such sales. As of December 31, 2025, no shares had been sold under the Sales Agreement.

Future Funding Requirements

As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $107.6 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents, and short-term investments will be sufficient to fund our operations into the second half of 2028. 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, 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 December 31, 2025, we had an accumulated deficit of $259.7 million. We expect to continue to incur losses for the foreseeable future, and, in general, we anticipate these losses will increase substantially in the future as we continue our development of, seek regulatory approval for, and potentially commercialize our ecDTx, conduct our ongoing and planned clinical trials and preclinical studies, utilize third parties to manufacture our ecDTx and related raw materials, leverage Spyglass to potentially identify additional development opportunities for our ecDTx and expand our therapeutic pipeline, seek to expand and protect our intellectual property, as well as incur additional costs associated with being a public company. We also have substantial payment obligations under a long-term non-cancellable facility lease, as discussed below. If we obtain regulatory approval for 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.

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;
- the costs and timing of manufacturing for our ecDTx, including commercial manufacture at sufficient scale, if our ecDTx is approved;
- the costs and timing of obtaining raw materials for manufacturing sufficient quantities of our ecDTx or obtaining sufficient quantities of any combination agents or other materials needed for use in our clinical trials and preclinical studies;
- the costs and timing of developing diagnostics, if required, and the outcome of their regulatory review;
- the costs, timing, and outcome of regulatory meetings and reviews of our ecDTx;
- changes in regulatory policies or approval pathways;
- disruptions at the FDA that hinder its ability to perform routine activities or function in the normal course;
- the costs, timing, and outcome of seeking to obtain, maintain, expand, enforce, defend, and protect our patents and other intellectual property and proprietary rights or, if necessary, challenging third-party patents and other intellectual property and proprietary rights;
- the costs and timing of purchasing laboratory supplies and equipment and pharmacology supplies for our preclinical activities and clinical trials;
- the amount of our variable lease payment obligations under our facility lease;
- potential costs not currently contemplated due to events that may occur as a result of, or that are associated with, streamlining our operations as discussed above;
- the costs associated with hiring additional personnel and consultants, as needed, to support our clinical and preclinical development efforts;
- the costs and timing of establishing or securing sales and marketing capabilities if our 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 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 (including through the Sales Agreement), 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 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. 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, inflation, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. 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 ecDTx development 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 (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Net cash used in operating activities	$ (46,661)	$ (60,841)	$ 14,180
Net cash provided by (used in) investing activities	37,801	(26,101)	63,902
Net cash provided by financing activities	141	89,823	(89,682)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (8,719)	$ 2,881	$ (11,600)

Operating Activities

Net cash used in operating activities was $46.7 million and $60.8 million for the years ended December 31, 2025 and 2024, respectively. The net cash used in operating activities during the year ended December 31, 2025 was primarily due to our reported net loss of $58.2 million, net of noncash charges (including stock-based compensation expense, depreciation, and right-of-use (ROU) asset amortization) totaling $8.1 million and a $3.5 million decrease of our net operating assets. The net cash used in operating activities during the year ended December 31, 2024 was primarily due to our reported net loss of $65.4 million, net of noncash charges (including stock-based compensation expense, depreciation, and ROU asset amortization) totaling $6.2 million and a $1.7 million increase of our net operating assets. The decrease in cash used in operations during the year ended December 31, 2025 in comparison to the year ended December 31, 2024 was primarily attributable to a decrease in third-party spending associated with our discovery, development, and

clinical activities and a decrease in personnel-related costs, each resulting from a reduction in scope of our programs and our headcount following our portfolio prioritization.

Investing Activities

Investing activities consist primarily of purchases and maturities of investment securities and, to a lesser extent, capital expenditures for property and equipment. Investing activities resulted in a net cash inflow of approximately $37.8 million during the year ended December 31, 2025, compared to a net cash outflow of approximately $26.1 million during the year ended December 31, 2024. The net inflow during 2025 was primarily driven by higher maturities of investment securities relative to purchases as we managed our available-for-sale securities portfolio to maintain liquidity. In contrast, the net outflow during 2024 was primarily attributable to greater purchases of investment securities as we invested proceeds from financing activities, primarily the issuance of shares of our common stock in our IPO. Purchases of property and equipment were $0.5 million in 2025, compared to $2.5 million in 2024, reflecting lower capital investment requirements following the Company's relocation to its new headquarters in 2024.

Financing Activities

Our financing activities relate to the offering and sale of shares of our common stock in our IPO and under our 2024 Employee Stock Purchase Plan (ESPP), and the exercise of common stock options by our employees and consultants. Net cash provided by financing activities was $0.1 million during the year ended December 31, 2025, representing net proceeds from the sale of shares of our common stock under our ESPP. Net cash provided by financing activities was $89.8 million during the year ended December 31, 2024, primarily due to the net proceeds from our IPO.

Contractual Obligations and Other Commitments

We lease office and lab space under a non-cancellable lease agreement that commenced in November 2024 and expires in October 2034. As of December 31, 2025, future undiscounted lease payment obligations under this lease agreement totaled $69.8 million, which is exclusive of future variable lease payments for our allocated share of variable costs associated with the operation and management of the property, which include utilities, property taxes, common area maintenance, and amenities costs. Due to an abatement period, base rent payments under this lease did not commence until July 2025. Accordingly, our total minimum lease payments for future years under the lease agreement will be substantially greater than our total lease payments for the year ended December 31, 2025. See Note 7 to our financial statements included elsewhere in this Annual Report on Form 10-K for further information.

We enter into contracts in the normal course of our business with various third parties for clinical trial and preclinical research services, contract manufacturing services, and professional and other services and products related to our business. These contracts generally provide for termination after a notice period, and, therefore, are cancellable 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 (GAAP). The preparation of these financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, and expenses, as well as the disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, assumptions, and judgments, including those related to accrued research and development expenses, and stock-based compensation expense. 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 value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to the financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the accounting policies described below are critical to understanding and evaluating our financial condition and results of operations because they involve a significant degree of estimation uncertainty and have had, or are reasonably likely to have, a material impact on our financial condition or results of operations.

Accrued R&D Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued R&D expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued R&D expenses as of each balance sheet date based on facts and circumstances known to us at that time. The significant estimates in our accrued R&D expenses include the costs incurred for services performed by our vendors in connection with services for which we have not yet been invoiced.

We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct R&D on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows.

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the R&D expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation Expense

Stock-based compensation expense represents the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period of the award) on a straight-line basis. We estimate the grant date fair value of stock-based awards, which for the years ended December 31, 2025 and 2024, consisted of stock option awards and, subsequent to completion of our IPO, rights to purchase shares under our 2024 Employee Stock Purchase Plan (ESPP), using the Black-Scholes option pricing model and recognize forfeitures as they occur. The Black-Scholes option pricing model requires the use of subjective assumptions, including the risk-free interest rate, the expected stock price volatility, the expected term of the award, the expected dividend yield, and, prior to the completion of our IPO, the estimated fair value of our common stock. Changes in these assumptions can materially affect the grant date fair value of our stock-based awards, and ultimately, how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant judgment to develop. See Note 2 under “Stock-Based Compensation” and Note 10 to our financial statements included elsewhere in this Annual Report on Form 10-K for information concerning the subjectivity and judgment involved in developing these assumptions and certain of the specific inputs we used in applying the Black-Scholes option pricing model to determine the estimated fair value of stock options granted and rights to purchase ESPP shares in the years ended December 31, 2025 and 2024.

Prior to our IPO, since there was no public market for our common stock, we were required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. The fair value of the common stock underlying our equity awards was determined on each grant date by our board of directors, taking into account input from management and independent third-party valuation analyses. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we developed an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock were made using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: Valuation of Privately Held Company Equity Securities Issued as Compensation (the Practice Aid).

Following our IPO, the fair value of our common stock is based on the closing price per share on the Nasdaq Global Select Market on the date of grant. We will continue to use judgment in evaluating the interest rates, expected stock price volatility, expected terms of the stock-based awards, and expected dividend yield utilized for our stock-based compensation expense calculations on a prospective basis.

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 standards as of public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including, without limitation, the exemption from the auditor attestation requirement of Section 404(b) of the Sarbanes-Oxley Act, for so long as we remain eligible.

We will remain an emerging growth company until the earliest of (i) December 31, 2029, which is 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 Rule 12b-2 under 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.

Recently Adopted and Issued Accounting Pronouncements

See Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted.

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

Interest Rate Risk

As of December 31, 2025, our cash, cash equivalents, and short-term investments consisted of cash held in readily available checking and money market accounts, as well as short-term debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. However, because of the short-term nature of the instruments in our portfolio, we believe that our exposure to interest rate risk is not significant, and a hypothetical sudden 10% change in market interest rates would not be expected to have a material impact on our financial condition or results of operations during the periods presented.

Foreign Currency

We contract with vendors in foreign countries, including countries in Europe and the Asia Pacific. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements, however we believe our exposure to foreign currency exchange rate risk is not significant and we do not hedge our foreign currency exchange rate risk.

Net realized and unrealized gains and losses from foreign currency transactions are reported in other income (expense), net, in the statements of operations and comprehensive loss. The impact of foreign currency costs on our operations have been negligible for all periods presented.

Inflation Risk

Inflation generally affects us by increasing labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data.

Our financial statements required to be filed pursuant to this Item 8, together with the report of our independent registered public accounting firm, appear beginning on page F-1 of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on this evaluation, our principal executive officer and our principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (ICFR), as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. ICFR cannot provide absolute assurance due to its inherent limitations; it is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. ICFR also can be circumvented by collusion or improper management override. Because of such inherent limitations, ICFR may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with applicable policies or procedures may deteriorate. Our ICFR is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Management, with the participation of our principal executive officer and our principal financial officer, conducted an assessment of the effectiveness of our ICFR as of the end of the period covered by this Annual Report on Form 10-K using the criteria set forth in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our ICFR was effective as of December 31, 2025 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

As an "emerging growth company" and a "non-accelerated filer," we are not required to provide an auditor attestation report on our ICFR, and we did not engage our independent registered public accounting firm to perform an audit of our ICFR.

Changes in Internal Control over Financial Reporting

Management, with the participation of our principal executive officer and our principal financial officer, evaluated any changes in our ICFR that occurred during the quarter ended December 31, 2025, as required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act. Management concluded that there was no change in our ICFR that occurred during the quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our ICFR.

Item 9B. 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 trading arrangements 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 December 31, 2025, none of our officers or directors adopted, modified, or terminated such a trading arrangement.

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

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement for our 2026 Annual Meeting of Stockholders, which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2025 (Definitive Proxy Statement), under the headings "Board of Directors," "Corporate Governance," "Executive Officers," and, if applicable, "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our Code of Business Conduct and Ethics is available on our website at www.boundlessbio.com under the "Investors — Governance Overview" section. We intend to disclose on our website any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics that would otherwise be required to be disclosed under applicable SEC rules or the listing standards of Nasdaq.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Definitive Proxy Statement under the heading "Executive Compensation and Other Information," and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our Definitive Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans," is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Definitive Proxy Statement under the headings "Certain Relationships and Related Person Transactions" and "Corporate Governance" and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in our Definitive Proxy Statement under the heading "Proposal 2 Ratification of Appointment of Independent Registered Public Accounting Firm," and is incorporated herein by reference.

Our independent public accounting firm is KPMG LLP, San Diego, CA, PCAOB Auditor ID: 185.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

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

(3) Exhibits:

Exhibit Index

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	4/2/2024	3.1	
3.2	Amended and Restated Bylaws	8-K	4/2/2024	3.2	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	3/21/2024	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	3/6/2024	4.2	
4.3	Description of the Registrant's securities	10-K	3/27/2025	4.3	
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	3/6/2024	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	3/21/2024	10.2	
10.3#	Boundless Bio, Inc. 2024 Employee Stock Purchase Plan	S-1/A	3/21/2024	10.3	
10.4#	Non-Employee Director Compensation Program (as amended and restated effective March 27, 2025)	10-Q	5/9/2025	10.1	
10.5#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Zachary D. Hornby and the Registrant	S-1	3/6/2024	10.6	
10.6#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Christian Hassig, Ph.D. and the Registrant	S-1	3/6/2024	10.12	
10.7#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Jessica Oien and the Registrant	S-1	3/6/2024	10.16	
10.8#	Amended and Restated Employment Offer Letter Agreement, dated April 2, 2024, between David Hinkle and the Registrant	10-K	3/27/2025	10.8	
10.9#	Employment Offer Letter Agreement, dated January 27, 2025, between Robert Doebele, M.D. Ph.D. and the Registrant	10-K	3/27/2025	10.9	
10.11#	Severance and Change in Control Severance Plan	S-1	3/6/2024	10.17	
10.12#	Corporate Bonus Plan	S-1	3/6/2024	10.18	
10.13#	Form of Indemnification Agreement for Directors and Officers	S-1/A	3/21/2024	10.19	
10.14	Lease Agreement, dated December 20, 2021, between ARE-10933 NORTH TORREY PINES, LLC, and the Registrant	10-Q	5/9/2025	10.3(a)	
10.15	First Amendment to the Lease Agreement, dated November 1, 2024, between ARE-10933 NORTH TORREY PINES, LLC, and the Registrant	10-Q	5/9/2025	10.3(b)	
19.1	Boundless Bio, Inc. Insider Trading Compliance Policy and Procedures	10-K	3/27/2025	19.1	
23.1	Consent of KPMG LLP, independent registered public accounting firm				X

24.1	Power of attorney (included on signature page)				X
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*	Certifications 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
97.1#	Policy for Recovery of Erroneously Awarded Compensation	S-1	3/6/2024	10.20	
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.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Boundless Bio, Inc.

Date: March 9, 2026

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

Date: March 9, 2026

By: /s/ David Hinkle
David Hinkle
Senior Vice President, Finance, Controller and Treasurer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY AND SIGNATURES

Each person whose individual signature appears below hereby authorizes and appoints Zachary D. Hornby and David Hinkle, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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

Name	Title	Date
/s/ Zachary D. Hornby **Zachary D. Hornby**	President and Chief Executive Officer (Principal Executive Officer)	March 9, 2026
/s/ David Hinkle **David Hinkle**	Senior Vice President, Finance, Controller and Treasurer (Principal Financial and Accounting Officer)	March 9, 2026
/s/ Jonathan E. Lim **Jonathan E. Lim, M.D.**	Chairman	March 9, 2026
/s/ Kristina Burow **Kristina Burow**	Director	March 9, 2026
/s/ James Christensen **James Christensen, Ph.D.**	Director	March 9, 2026
/s/ Jennifer Lew **Jennifer Lew**	Director	March 9, 2026
/s/ Nancy Whiting **Nancy Whiting, Pharm.D**	Director	March 9, 2026

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets as of December 31, 2025 and 2024	F-3
Statements of Operations and Comprehensive Loss for the Years ended December 31, 2025 and 2024	F-4
Statements of Convertible Preferred Stock and Stockholders' Equity for the Years ended December 31, 2025 and 2024	F-5
Statements of Cash Flows for the Years ended December 31, 2025 and 2024	F-6
Notes to Financial Statements	F-7

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Boundless Bio, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Boundless Bio, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

San Diego, California
March 9, 2026

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

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 17,868	$ 26,587
Short-term investments	89,713	125,527
Prepaid expenses and other current assets	2,030	2,276
Total current assets	109,611	154,390
Property and equipment, net	3,216	4,321
Right-of-use asset, net	43,659	47,039
Restricted cash	560	560
Other assets	13	99
Total assets	$ 157,059	$ 206,409
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 6,727	$ 5,354
Accrued compensation	2,643	2,781
Lease liabilities, current portion	3,167	—
Total current liabilities	12,537	8,135
Lease liabilities, non-current	45,868	47,632
Total liabilities	58,405	55,767
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 70,000 shares authorized and no shares issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 700,000 shares authorized, 22,407 shares issued and outstanding as of December 31, 2025; 700,000 shares authorized, 22,300 shares issued and outstanding as of December 31, 2024	2	2
Additional paid-in-capital	358,257	351,991
Accumulated other comprehensive income	64	121
Accumulated deficit	(259,669)	(201,472)
Total stockholders' equity	98,654	150,642
Total liabilities and stockholders' equity	$ 157,059	$ 206,409

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

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

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 44,845	$ 55,267
General and administrative	18,707	18,000
Total operating expenses	63,552	73,267
Loss from operations	(63,552)	(73,267)
Other income, net:		
Interest income	5,357	7,892
Other income (expense), net	(2)	12
Total other income, net	5,355	7,904
Net loss	$ (58,197)	$ (65,363)
Comprehensive loss:		
Net loss	$ (58,197)	$ (65,363)
Unrealized gain (loss) on short-term investments	(57)	81
Comprehensive loss	$ (58,254)	$ (65,282)
Net loss per share, basic and diluted	$ (2.60)	$ (3.85)
Shares used in calculation	22,360	16,984

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

Boundless Bio, Inc.
Statements of Convertible Preferred Stock and Stockholders' Equity
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional paid-in capital	Accumulated other comprehensive income/ (loss)	Accumulated deficit	Total stockholders' equity/ (deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	287,447	$ 247,617	1,247	$ —	$ 8,987	$ 40	$ (136,109)	$ (127,082)
Issuance of common stock in initial public offering, net of $12,305 in discounts and offering costs	—	$ —	6,250	1	87,694	—	$ -	87,695
Conversion of convertible preferred stock into common stock upon initial public offering	(287,447)	(247,617)	14,741	1	247,616	—	—	247,617
Vesting of early exercised stock options	—	—	1	—	6	—	—	6
Exercise of stock options	—	—	16	—	62	—	—	62
Issuance of common stock under the Employee Stock Purchase Plan	—	—	45	—	110	—	—	110
Stock-based compensation	—	—	—	—	7,516	—	—	7,516
Unrealized gain on short-term investments	—	—	—	—	—	81	—	81
Net loss	—	—	—	—	—	—	(65,363)	(65,363)
Balance at December 31, 2024	—	$ —	22,300	$ 2	$ 351,991	$ 121	$ (201,472)	$ 150,642
Stock-based compensation	—	—	—	—	6,125	—	—	6,125
Issuance of common stock under the Employee Stock Purchase Plan	—	—	107	—	141	—	—	141
Unrealized loss on short-term investments	—	—	—	—	—	(57)	—	(57)
Net loss	—	—	—	—	—	—	(58,197)	(58,197)
Balance at December 31, 2025	—	$ —	22,407	$ 2	$ 358,257	$ 64	$ (259,669)	$ 98,654

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

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

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (58,197)	$ (65,363)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	6,125	7,516
Depreciation and amortization	1,251	1,086
Accretion of investments, net	(2,590)	(5,055)
Non-cash lease expense	3,288	2,551
Other	—	102
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	332	(302)
Accounts payable and accrued liabilities	1,634	775
Operating lease liabilities	1,496	(2,151)
Net cash used in operating activities	(46,661)	(60,841)
Cash flows from investing activities		
Purchases of investments	(174,897)	(208,465)
Maturities of investments	213,244	184,900
Purchases of property and equipment	(546)	(2,536)
Net cash provided by (used in) investing activities	37,801	(26,101)
Cash flows from financing activities		
Proceeds from the issuance of common stock from initial public offering, net of discounts	—	93,000
Payments of common stock offering costs	—	(3,349)
Proceeds from the exercise of stock options	—	62
Proceeds from issuance of common stock under the Employee Stock Purchase Plan	141	110
Net cash provided by financing activities	141	89,823
Net increase (decrease) in cash, cash equivalents, and restricted cash	(8,719)	2,881
Cash, cash equivalents, and restricted cash at beginning of year	27,147	24,266
Cash, cash equivalents, and restricted cash at end of year	$ 18,428	$ 27,147
Components of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 17,868	$ 26,587
Restricted cash	560	560
Cash, cash equivalents, and restricted cash at end of year	$ 18,428	$ 27,147
Non-cash investing and financing activities		
Change in unpaid common stock issuance costs	$ —	$ (197)
Addition to right-of-use assets obtained in exchange for lease obligation	$ —	$ 47,588
Decrease to right-of-use assets due to remeasurement of lease obligation	$ (92)	$ —
Vesting of early exercised stock options	$ —	$ 6
Unpaid property and equipment purchases	$ —	$ 400

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

Boundless Bio, Inc.

Notes to Financial Statements

1. Organization and Basis of Presentation

Description of Business

Boundless Bio, Inc. (the Company) is 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 interrogating extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in 14 to 17% of cancer patients. The Company has been focused on identifying targets essential for ecDNA functionality in oncogene amplified cancer cells, then designing and developing small molecule drugs called ecDNA-directed therapeutic candidates (ecDTx) to inhibit those targets, with the aim to prevent cancer cells from using chromosomal instability and ecDNA amplification biology to grow, adapt, and become resistant to existing therapies. The Company's mission is to be the foremost biopharma company interrogating ecDNA biology to deliver transformative therapies that improve and extend the lives of patients with previously intractable oncogene amplified cancers. The Company's lead ecDTx, BBI-940, is in early clinical development in patients with estrogen receptor positive and human epidermal growth factor receptor 2 negative, or ER+/HER2-, breast cancer who have progressed following treatment with a cyclin-dependent kinase 4 and/or 6 inhibitor, or CDK4/6 inhibitor, plus endocrine therapy, as well as patients with triple-negative breast cancer luminal androgen receptor subtype, or TNBC-LAR. The Company was incorporated in the state of Delaware on April 10, 2018 and is headquartered in San Diego, California.

Initial Public Offering

On April 2, 2024, the Company completed its initial public offering (IPO), issuing 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, all outstanding shares of convertible preferred stock of the Company automatically converted into 14,740,840 shares of its common stock, and no shares of convertible preferred stock remained outstanding thereafter. In connection with the closing of the IPO, on April 2, 2024, the Company amended and restated its certificate of incorporation to authorize 700,000,000 shares of common stock and 70,000,000 shares of undesignated preferred stock, each with a par value of $0.0001 per share.

ATM Offering

On April 1, 2025, the Company entered into an Open Market Sale Agreement℠ (the Sales Agreement) with Jefferies LLC (the Agent), under which the Company may, from time to time, sell shares of the Company's common stock in "at the market" (ATM) offerings through or to the Agent, as sales agent or principal. The shares of common stock will be offered and issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-286302), including the Sales Agreement prospectus contained therein, filed with the Securities and Exchange Commission (SEC) on April 1, 2025 and declared effective by the SEC on April 10, 2025. Pursuant to the Sales Agreement prospectus, the Company may sell shares of its common stock having an aggregate offering price of up to $14.5 million. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the Sale Agreement. The Company is not obligated to sell, and the Agent is not obligated to buy or sell, any shares of common stock under the Sales Agreement. No assurance can be given that the Company will sell any shares of common stock under the Sales Agreement, or, if it does, as to the price or amount of shares of common stock that it sells or the dates when such sales will take place. The Company did not sell any shares under the Sales Agreement during the year ended December 31, 2025.

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, 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. The Company does not have any products for sale and has not generated any revenue to date. The Company has funded its operations primarily from the sale and issuance of shares of its convertible preferred stock (prior to the IPO) and common stock.

As of December 31, 2025, the Company had cash, cash equivalents, and short-term investments of $107.6 million. The Company believes that its existing cash, cash equivalents, and short-term investments will be sufficient to fund its operations for at least twelve months from the issuance date of the accompanying financial statements.

Boundless Bio, Inc.
Notes to Financial Statements

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 its ecDTx, utilizes third parties to manufacture its ecDTx and related raw materials, potentially identifies additional development opportunities for its ecDTx, seeks to expand its therapeutic pipeline, and expands and protects its intellectual property. The Company also has substantial payment obligations under a long-term non-cancellable facility lease. 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. The Company does not expect to generate any revenue from product sales until it successfully completes development of and obtains regulatory approval for one or more of its ecDTx, which the Company expects will take several years and may never occur. As of December 31, 2025, the Company had an accumulated deficit of $259.7 million, and, during the year ended December 31, 2025, the Company incurred a net loss of $58.2 million and had negative cash flows from operations of $46.7 million. As the Company continues to pursue its business plan, it will need to acquire a substantial amount of additional funding until such time as it is able to generate significant revenues to fund its research and development activities and operations. Accordingly, the Company expects to finance its cash requirements through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. There can be no assurance that the Company will be successful in acquiring additional funding or that any additional funding would be sufficient to continue operations in future periods.

Basis of Presentation

The accompanying financial statements are presented in U.S. dollars and have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP). 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

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, accrued research and development costs and, prior to the closing of its IPO, its common stock. 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 stock-based compensation expense 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 under the Company's headquarters facility lease. The Company has classified the restricted cash as a noncurrent asset on its balance sheets as of December 31, 2025 and 2024.

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 $1.4 million as of December 31, 2025. 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 Financial Statements

Short-Term Investments

Short-term investments consist of money market funds, U.S. government obligations, corporate debt securities, government agency securities, asset-backed securities, and commercial paper. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bid and/or offers. The Company classifies its investment securities as available-for-sale, as the sale of such securities may be required prior to maturity. Management determines the appropriate classification of its investments in debt securities at the time of purchase. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than 12 months from, the balance sheet date are classified as short-term investments. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

At each balance sheet date, the Company reviews its available-for-sale debt securities that are in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in the statements of operations. For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the above criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income, net through an allowance account. There have been no impairment or credit losses recognized during any of the periods presented.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under US 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 and Common Stock Issuance Costs

The Company capitalizes certain legal, professional, accounting, and other third-party costs that are directly attributable to equity financings as deferred offering costs until such financings are consummated. Upon consummation of an equity financing, these costs are recorded as a reduction to additional paid-in capital within stockholders' equity. In connection with the closing of the Company's IPO in April 2024, all amounts previously recorded as deferred offering costs were reclassified to additional paid-in capital.

Property and Equipment, Net

Property and equipment, including leasehold improvements, are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the related assets, which range from three to seven years. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful

lives of the assets or the remaining lease term. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operating expenses as incurred.

Impairment of Long-Lived Assets

An impairment loss is recorded if and when events and circumstances indicate that any of the Company's long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company has not recognized any impairment losses in any of the periods presented in these financial statements.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease and whether such a lease should be classified as a financing lease or operating lease based on the unique facts and circumstances present, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. In 2025 and 2024, the Company leased real estate facilities under non-cancellable operating leases with various expiration dates through fiscal year 2034. As of December 31, 2025, the Company had one operating lease, which expires in 2034. As of December 31, 2025 and 2024, the Company had no financing leases.

Operating leases with a term greater than one year are recognized as right-of-use (ROU) assets and lease liabilities in the accompanying balance sheets. Operating lease ROU assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company considers the lease term to be the non-cancellable period that it has the right to use the underlying asset, together with any periods where it is reasonably certain it will exercise an option to extend (or not terminate) the lease. The Company does not assume renewals or early terminations unless it is reasonably certain to exercise these options.

Operating lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term discounted based on (i) the interest rate implicit in the lease if that rate is readily determinable, or if not, (ii) the Company's incremental borrowing rate (which is the estimated interest rate the Company would be required to pay for a collateralized borrowing equal to the total lease payments over a similar term as the lease term and in a similar economic environment). Because the Company's operating leases do not provide an implicit rate, the Company estimates its incremental borrowing rate based on the information available at the lease commencement date for borrowings with a similar term. The Company's operating lease ROU assets are measured based on the corresponding operating lease liability adjusted for (i) payments made to the lessor at or before the commencement date, (ii) initial direct costs incurred and (iii) tenant incentives under the lease.

Operating lease costs are recognized on a straight-line basis over the lease term. The Company elected not to allocate consideration between lease and non-lease components. Variable lease payments are recognized in the period in which the obligations for those payments are incurred. In addition, the Company elected not to recognize lease assets or lease liabilities for leases with a term of 12 months or less for all asset classes.

Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company operates and manages its business as one reporting and one operating segment, which is the business of designing and developing ecDTx, for which no revenue has been recorded. All of the Company's long-lived assets are located in the United States. The Company's CODM is its Chief Executive Officer. For purposes of assessing the Company's financial performance and making resource allocation decisions, the CODM reviews total expenses, as well as expenses by nature.

Convertible Preferred Stock

The Company's convertible preferred stock was classified as temporary equity in the accompanying balance sheet as of December 31, 2023 and excluded from stockholders' equity/ (deficit) as the potential redemption of such stock was outside the Company's control and would have required the redemption of the then-outstanding convertible preferred stock. The convertible preferred stock was 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 were recorded as a reduction of gross proceeds from issuance. The

Boundless Bio, Inc.
Notes to Financial Statements

Company did not accrete the carrying values of the convertible preferred stock to the redemption values since the occurrence of these events was not considered probable as of December 31, 2023. Immediately prior to the closing of the IPO on April 2, 2024, 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.

Research and Development Expenses

Research and development (R&D) expenses are costs incurred by the Company in connection with its discovery and research efforts and the preclinical and clinical development of ecDTx. The Company's R&D expenses include direct program costs, consisting of expenses incurred under arrangements with third parties, such as contract research organizations, contract manufacturers, consultants and its scientific advisors; and indirect costs, consisting of personnel-related expenses, including salaries, severance, bonuses, benefits, travel, and stock-based compensation expenses, for those individuals involved in R&D efforts, the costs of lab and pharmacology supplies and acquiring, developing, and manufacturing preclinical and clinical study materials, and facilities and depreciation, which include direct and allocated expenses for rent of facilities and depreciation of equipment. R&D costs are expensed as incurred.

The Company records accruals for estimated R&D costs, comprising payments for work performed by third party contractors, labs, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Non-refundable advance payments for goods or services that will be used or rendered for future R&D activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

General and Administrative Expenses

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

Costs related to filing and pursuing patent applications are recorded as G&A expense and are expensed as incurred since the recoverability of such expenditures is uncertain.

Stock-Based Compensation

The Company measures employee and nonemployee stock-based awards based on the estimated fair value of the awards on the date of grant and records compensation expense on a straight-line basis over the requisite service period of the award. All stock-based compensation costs are recorded in the statements of operations and comprehensive loss based upon the underlying employees' or nonemployees' roles within the Company. Forfeitures are accounted for as they occur.

The fair value of stock option grants and shares purchasable under the Company's 2024 Employee Stock Purchase Plan (ESPP) is estimated on the date of grant using the Black-Scholes options-pricing model, which requires inputs based on certain subjective assumptions, including the:

- Fair value of common stock. Subsequent to the closing of the IPO, the fair value of the Company's common stock is the closing price per share on the Nasdaq Global Select Market on the date of grant of the award. For periods prior to the closing of the IPO on April 2, 2024, the Company utilized methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately Held Company Equity Securities Issued as Compensation* (The Practice Aid) to estimate the fair value of its common stock. The fair value of the common stock was determined based upon a variety of factors, including the Company's stage of development and material risks related to the business; the progress of the Company's R&D programs; business conditions and projections; financial position and historical and forecasted performance and operating results; the lack of an active public market for the Company's common stock and preferred stock; the prices of the Company's preferred stock sold to or exchanged between outside investors in arm's length transactions and the rights, preferences, and privileges of the preferred stock as compared to those of the Company's common stock, including liquidation preferences of the Company's preferred stock; the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company in light of prevailing market conditions; the hiring of key personnel and the experience of management; trends and developments in the

Company's industry; and external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry.

- Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to the expected term of the award being valued.
- Expected volatility. Given that there was no active trading market for the Company's common stock prior to the completion of the IPO and there is not yet sufficient trading history for the Company's common stock, the Company derived the expected volatility from the average historical volatilities of the common stock of a group of comparable publicly-traded companies in the biotechnology industry over a period approximately equal to the expected term of the award being valued. The Company will continue to apply this process until enough historical information regarding the volatility of its own stock price becomes available.
- Expected term. The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term of stock options issued is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term. For rights to purchase shares of common stock under the ESPP, the expected term represents the period from the first day of the offering period to the purchase date.
- Expected dividend yield. The Company has never paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. Therefore, the Company uses an expected dividend yield of zero.

The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date.

The assumptions used in determining the estimated fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of significant judgment.

The Company reviews all stock-based award modifications, including situations in which an original award is exchanged for a new award. Stock award modifications are accounted for as modifications under ASC 718. In such cases, the Company measures incremental compensation cost as the excess of the fair value of the modified award over the fair value of the original award immediately prior to the modification, based on the relevant factors at the modification date.

For vested awards, the Company recognizes any incremental compensation cost in the period in which the modification occurs. For unvested awards, if the modified award is probable of vesting both before and after the modification, the Company recognizes, on a prospective basis over the remaining requisite service period, the sum of (i) the incremental compensation cost and (ii) any remaining unrecognized compensation cost associated with the original award as of the modification date. If the fair value of the modified award is lower than the fair value of the original award immediately before the modification, the Company continues to recognize compensation cost at least equal to the cost of the original award.

During 2025, the Company entered into consulting arrangements with several former employees that provided for the continued vesting of outstanding stock options. The Company accounted for these arrangements as award modifications under ASC 718. Results of operations for the year ended December 31, 2025 include an immaterial amount of additional stock-based compensation expense associated with these modifications.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements and related disclosures. Deferred tax assets and liabilities are determined on the basis of the differences between the Company's financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including projected future taxable income, future reversals of existing taxable temporary differences, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their

net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. Interest and penalties are included as a component of income tax expense.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. Any resulting unrecognized tax benefits are included within the related tax liability.

In July 2025, legislation commonly referred to as the One Big Beautiful Bill Act (OBBBA) was enacted, which includes changes to U.S. tax law, including provisions affecting the deductibility of domestic research expenditures, limitations on interest expense deductions, and bonus depreciation. The Company evaluated the impact of the enacted legislation under ASC 740. Any remeasurement of deferred tax assets resulting from the legislation was fully offset by the Company's existing valuation allowance. Accordingly, the enactment of the OBBBA did not have a material impact on the Company's financial statements.

Comprehensive income (loss)

The Company reports all components of comprehensive income (loss), including net loss, in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments. Other comprehensive income (loss) includes unrealized gains and losses on short-term investments, which was the only difference between net loss and comprehensive loss for the applicable periods.

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 calculated by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding during the period. The Company's potentially dilutive securities, which include its options to purchase common stock, common stock subject to repurchase related to unvested restricted stock and options early exercised, and, for periods prior to April 2, 2024, convertible preferred stock, have been excluded from the calculation 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.

Emerging Growth Company Status

The Company is still an emerging growth company (EGC) as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has elected to use the extended transition period for complying with new or revised accounting standards, which means that when an accounting standard is issued or revised and it has different effective dates for public and private companies, the Company can comply with the effective dates applicable to private companies. As a result, the Company's financial statements may not be comparable to companies that comply with new or revised accounting standards as of public company effective dates.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*. The update enhances income tax disclosure requirements, including expanded information related to the effective tax rate reconciliation and income taxes paid, and does not affect the recognition or measurement of income taxes. The Company adopted this guidance effective January 1, 2025 and applied the new disclosure requirements prospectively for the year ended December 31, 2025. The adoption did not materially affect the Company's financial statements, and the additional required disclosures are included in Note 11.

Recently Issued Accounting Pronouncements Pending Adoption

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU 2024-03)*. The new guidance requires more detailed information about specified types of expenses (including purchases of inventory, employee compensation,

Boundless Bio, Inc.
Notes to Financial Statements

depreciation, amortization, and depletion) in commonly presented expense captions (such as R&D and G&A) presented on the face of the statement of operations on an annual and interim basis. This guidance will be effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027. The new standard permits early adoption and can be applied prospectively or retrospectively. The Company is evaluating the effect that this guidance will have on its financial statements and related disclosures.

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 described in Note 2 above (in thousands):

		Fair Value Measurements Using		
As of December 31, 2025	**Amount**	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds (1)	$ 16,100	$ 16,100	$ —	$ —
U.S. government obligations (2)	89,713	—	89,713	—
Total fair value of assets	$ 105,813	$ 16,100	$ 89,713	$ —

(1) Included in cash and cash equivalents on the balance sheets.
(2) Included in short-term investments on the balance sheets.

		Fair Value Measurements Using		
As of December 31, 2024	**Amount**	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds (1)	$ 24,889	$ 24,889	$ —	$ —
U.S. government obligations (2)	118,289	—	118,289	—
Corporate debt securities (2)	7,238	—	7,238	—
Total fair value of assets	$ 150,416	$ 24,889	$ 125,527	$ —

(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 in active markets for identical assets. 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 any period presented.

4. Investments

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

	As of December 31, 2025			
	Acquisition Cost	**Unrealized Gain**	**Unrealized Loss**	**Estimated Fair Value**
Money market funds	$ 16,100	$ —	$ —	$ 16,100
U.S. government obligations	89,649	64	—	89,713
Total cash equivalents and investments	$ 105,749	$ 64	$ —	$ 105,813
Classified as:				
Cash equivalents				$ 16,100
Short-term investments				89,713
Total cash equivalents and investments				$ 105,813

Boundless Bio, Inc.
Notes to Financial Statements

	As of December 31, 2024			
	Acquisition Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 24,889	$ —	$ —	$ 24,889
U.S. government obligations	118,170	121	(2)	118,289
Corporate debt securities	7,236	2	—	7,238
Total cash equivalents and investments	$ 150,295	$ 123	$ (2)	$ 150,416
Classified as:				
Cash equivalents				$ 24,889
Short-term investments				125,527
Total cash equivalents and investments				$ 150,416

On December 31, 2025 and 2024, the remaining contractual maturities of all the Company's available-for-sale investments were less than twelve months. As of December 31, 2025 and 2024, the Company has not established an allowance for credit losses for any of its available-for-sale securities.

As of December 31, 2025, there were no available-for-sale securities in a gross unrealized loss position. As of December 31, 2024, there was one available-for-sale security, with an estimated fair value of $8.0 million, in a gross unrealized loss position. Based on its review of these investments as of December 31, 2025 and 2024, the Company believed that the unrealized loss as of December 31, 2024 was not other-than-temporary in nature.

5. Property and Equipment

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

	As of December 31,	
	2025	2024
Lab equipment	$ 4,373	$ 4,338
Computers and software	896	895
Leasehold improvements	1,054	981
Furniture and fixtures	1,853	1,816
Total property and equipment	8,176	8,030
Less accumulated depreciation and amortization	4,960	3,709
Property and equipment, net	$ 3,216	$ 4,321

Depreciation and amortization expense related to property and equipment was $1.3 million and $1.1 million for the years ended December 31, 2025 and 2024, respectively.

6. Accounts Payable and Accrued Liabilities

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

	As of December 31,	
	2025	2024
Accounts payable	$ 1,491	$ 1,274
Accrued research and development costs	4,719	2,584
Other accrued liabilities	517	1,496
Total accounts payable and accrued liabilities	$ 6,727	$ 5,354

7. Lease Agreements

2024 Lease

The Company is a party to a non-cancellable facility lease for approximately 80,168 square feet of lab and office space in San Diego, California (the 2024 Lease). The 2024 Lease has an initial lease term of 120 months, which commenced in November 2024; the

lease also provides the Company with the right to extend the lease term for an additional 60 months at expiry, which has not been included in the lease term used for measurement. The 2024 Lease includes obligations to make base rent payments and additional variable lease payments for the Company's allocated share of variable costs associated with the operation and management of the property, which include utilities, property taxes, common area maintenance, and amenities costs. The lease provided for a rent abatement period through July 2025.

The Company is required to maintain a security deposit under the 2024 Lease in the form of a standby letter-of-credit. This letter of credit is collateralized by a restricted cash deposit at the Company's bank of approximately $0.6 million, which is included in long-term other assets in the balance sheet. The 2024 Lease does not contain any material residual value guarantees or material restrictive financial covenants. See the table below for information about the Company's future undiscounted operating lease payment obligations under the 2024 Lease as of December 31, 2025, exclusive of future variable lease costs.

The Company recorded an operating lease liability for this obligation based on the present value of the lease payments using an estimated incremental borrowing rate of approximately 8.3%, as the 2024 Lease does not have a stated rate and the implicit rate was not readily determinable, and a right-of-use (ROU) asset based on the corresponding operating lease liability. Management exercised judgment in estimating the incremental borrowing rate and in determining the lease term. The renewal option was evaluated at lease commencement and excluded from the lease term, as the Company is not reasonably certain to exercise the option. The net ROU asset and associated lease liability are reflected in the Company's balance sheet as of December 31, 2025 and 2024.

Operating leases

As of December 31, 2025, the 2024 Lease, which expires in October 2034, was the Company's only lease. The Company previously was a party to a non-cancellable operating lease for the rental of other lab and office space in San Diego, California, which served as its prior corporate headquarters and for which the lease term ended in November 2024. Lease expense related to the 2024 Lease and the lease agreement for the Company's prior corporate headquarters totaled approximately $9.6 million and $4.0 million for the years ended December 31, 2025 and 2024, respectively, and included operating lease costs of $7.3 million and $3.6 million, and variable lease costs of $2.3 million and $0.4 million, respectively.

The Company paid $2.6 million in cash for amounts included in operating lease liabilities, which was included in the operating activities section of the statements of cash flows, for each of the years ended December 31, 2025 and 2024. The remaining lease term and discount rate for the 2024 Lease were 8.8 years and 8.3%, respectively, as of December 31, 2025, and 9.8 years and 8.3%, respectively, as of December 31, 2024 (the calculations of remaining lease term excludes the renewal option). Future undiscounted operating lease payments under the 2024 Lease as of December 31, 2025, exclusive of future variable lease payments, are as follows (in thousands):

Year ending December 31,		
2026	$	7,052
2027		7,255
2028		7,465
2029		7,680
2030		7,902
Thereafter		32,465
Total undiscounted operating lease payments	$	69,819
Less: Amount representing interest		(20,784)
Operating lease liabilities	$	49,035

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, other than payment for any products or services provided by the counterparty through the notice date or effective time of termination and any non-cancellable and non-refundable obligations incurred by the counterparty prior to the notice date or effective time of the termination, and do not contain any minimum purchase commitments.

Boundless Bio, Inc.
Notes to Financial Statements

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 agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into 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 because of their status or service as officers or directors. The maximum potential future payments the Company could be required to make under these indemnification arrangements is, in many cases, unlimited. To date, the Company has not incurred any material costs because of these indemnifications. The Company has not accrued any liabilities related to such indemnification arrangements in its financial statements as of December 31, 2025 or 2024 because it determined the likelihood of incurring a payment obligation pursuant to such arrangements was not probable.

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 years ended December 31, 2025 and 2024.

9. 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 any class of the Company's capital stock having any preference or priority over the common stock then outstanding, if any. The common stock has no preemptive rights, conversion rights, redemption rights, preference rights, or exchange 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.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Shares reserved for exercise of stock options issued and outstanding	4,234	3,818
Shares reserved for future issuance under the equity incentive plan	3,348	2,648
Shares reserved for future issuance under the ESPP	303	187
Total	7,885	6,653

10. Stock-Based Compensation

Equity Incentive Plan

In March 2024, the Company's board of directors adopted, and the Company's stockholders approved, the 2024 Incentive Award Plan (the Plan), which became effective in connection with the IPO and has a term of ten years. The Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, dividend equivalents, restricted stock units, stock appreciation rights, and other stock or cash-based awards to the Company's 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 granted under the Plan shall not be less than 100% of the fair market value of the Company's common stock on the date of grant. In addition, the Plan includes an "evergreen" provision whereby the number of shares of common stock available for issuance under the Plan will be increased annually on the first day of each calendar year during the term of the Plan, beginning in 2025, by an amount equal to the lesser of (i) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year or (ii) such number of shares as determined by the Company's board of directors or an authorized committee of the board of directors. As of December 31, 2025, a total of 3,947,716 shares of common

stock were authorized for issuance under the Plan. On December 31, 2025, 3,347,667 of these shares were available for grant under the Plan. On January 1, 2026, pursuant to the evergreen provision of the Plan, the aggregate number of shares that may be issued under the Plan was automatically increased by 1,120,362 shares to 5,068,078.

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, the shares subject to awards issued under the Predecessor Plan that were outstanding as of March 27, 2024, the effective date of the Plan, and that are subsequently cancelled or forfeited, will become available for issuance under, and will increase the number of shares that may be issued under, the Plan.

Repricing of Outstanding Options

In August 2024, the compensation committee of the Company's board of directors, as administrator of the Plan and the Predecessor Plan, approved an option repricing (2024 Repricing), which was effective on August 19, 2024 (the Repricing Effective Date). The repricing applied to options to purchase up to an aggregate of 3,484,346 shares of the Company's common stock with an exercise price per share in excess of the closing price per share of the Company's common stock on the Repricing Effective Date, held by eligible employees of the Company that were granted under the Plan or the Predecessor Plan and were outstanding as of the Repricing Effective Date (the Repriced Options). As of the Repricing Effective Date, the exercise price of each of the Repriced Options was reduced to $3.56 per share, which was the closing price of the Company's common stock on the Repricing Effective Date; provided, however, that if prior to the Premium End Date (as defined below), a Repriced Option is exercised or an employee's employment or service with the Company terminates for any reason other than due to a Qualifying Termination (as defined below), the exercise price per share that applied to the Repriced Option immediately prior to the Repricing Effective Date will apply in lieu of the reduced exercise price. The "Premium End Date" means the earliest of: (1) August 19, 2026, (2) the date immediately prior to the closing of a Change in Control (as defined in the Plan), or (3) the date of the employee's Qualifying Termination. A "Qualifying Termination" means (a) the involuntary termination of the employee's employment by the Company due to a reduction in force (and other than for Cause (as defined in the Plan)), subject to the employee's execution of an effective general release of claims in favor of the Company, (b) the employee's death, or (c) termination of the employee's employment by the Company following the employee's Disability (as defined in the Plan). Except for the reduction in the exercise prices of the Repriced Options as described above, the Repriced Options retain their existing terms, including their respective original vesting schedules.

The repricing resulted in a total incremental non-cash stock-based compensation expense of $0.9 million, which was calculated using the Black-Scholes option-pricing model, of which $0.2 million is associated with vested Repriced Options and will be recognized on a straight-line basis through the Premium End Date. The remaining $0.7 million of the incremental non-cash stock-based compensation expense is associated with unvested Repriced Options and will be recognized as follows: (i) if the Premium End Date occurs later than the end of the remaining vesting period of the Repriced Option, the incremental cost will be amortized on a straight-line basis through the Premium End Date, or (ii) if the Premium End Date occurs earlier than the end of the remaining vesting period of the Repriced Option, the incremental cost will be amortized on a straight-line basis over the remaining vesting period. The Company recognized incremental stock-based compensation expense totaling $0.2 million and $0.1 million associated with the 2024 Repricing for the years ended December 31, 2025 and 2024, respectively.

Stock Options

Stock option activity under the Plan and the Predecessor Plan and certain other related information is as follows (in thousands except weighted-average exercise price and remaining term):

	Number	Weighted-Average Exercise Price	Weighted-Average Remaining Term (years)	Aggregate-Intrinsic Value
Balance as of December 31, 2024	3,818	$ 6.37	7.2	$ —
Granted	1,513	$ 2.28		
Forfeited and expired	(1,097)	$ 4.74		
Balance as of December 31, 2025	4,234	$ 5.22	7.4	$ 28
Vested and expected to vest at December 31, 2025	4,234	$ 5.22	7.4	$ 28
Exercisable as of December 31, 2025	2,315	$ 5.38	6.6	$ 9

Aggregate intrinsic value in the above table is the difference between the estimated fair value of the Company's common stock as of either December 31, 2025 or 2024, and the exercise price of stock options that had exercise prices below that value.

Boundless Bio, Inc.
Notes to Financial Statements

For the Repriced Options, the calculation of the weighted-average prices and intrinsic value information in the table above is based on the exercise price per share that applied immediately prior to the Repricing Effective Date pending satisfaction of the requisite service requirement.

There were no options exercised during the year ended December 31, 2025; the options exercised during the year ended December 31, 2024 had an insignificant intrinsic value at exercise.

Employee Stock Purchase Plan

In March 2024, the Company's board of directors adopted, and the Company's stockholders approved, the Company's 2024 Employee Stock Purchase Plan, which became effective in connection with the IPO. The ESPP permits participants to contribute up to a specified percentage of their eligible compensation during a series of offering periods of 24 months, each comprised of four six-month purchase periods, to purchase shares of the Company's common stock. The purchase price of the shares will be 85% of the fair market value of the Company's common stock on the first day of trading of the applicable offering period or on the applicable purchase date, whichever is lower. In addition, the ESPP includes an "evergreen" provision whereby the number of shares of common stock available for issuance under the ESPP will be increased annually on the first day of each calendar year during the term of the ESPP by an amount equal to the lesser of (i) 1% of the shares of common stock outstanding on the final day of the immediately preceding calendar year or (ii) such number of shares as determined by the Company's board of directors or an authorized committee of the board of directors. On January 1, 2026, pursuant to the evergreen provision of the ESPP, the aggregate number of shares authorized for issuance under the ESPP automatically increased by 224,072 shares to 678,991.

The Company recognized stock-based compensation expense related to the ESPP of $0.4 million and $0.5 million for the years ended December 31, 2025 and 2024, respectively.

The Company issued and sold 107,208 and 44,532 shares under the ESPP during the years ended December 31, 2025 and 2024, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense, including the expense related to the ESPP, as recorded in the accompanying statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 2,136	$ 3,050
General and administrative	3,989	4,466
Total stock-based compensation	$ 6,125	$ 7,516

As of December 31, 2025, unrecognized compensation cost related to outstanding stock options (all of which have time-based vesting) was $9.2 million, which is expected to be recognized over a weighted-average period of 2.2 years.

As of December 31, 2025, unrecognized compensation cost related to the ESPP was $0.6 million, which is expected to be recognized as expense over approximately 1.3 years.

Excluding any effect of the Repriced Options, except for Repriced Options held by employees who experienced a Qualifying Termination, the weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock options granted during the periods indicated in the table were as follows:

	Year Ended December 31,	
	2025	2024
Expected option life (in years)	5.9	6.0
Assumed volatility	105.2%	90.8%
Assumed risk-free interest rate	4.4%	3.9%
Expected dividend yield	—	—

Boundless Bio, Inc.
Notes to Financial Statements

Excluding any effect due to the Repriced Options, except for Repriced Options held by employees who experienced a Qualifying Termination, the weighted-average grant date per share fair value of options granted during the years ended December 31, 2025 and 2024 were $1.88 and $7.19, respectively.

11. Income Taxes

Income Tax Expense

For the years ended December 31, 2025 and 2024, the Company's pre-tax loss was entirely domestic. The Company adopted ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, effective January 1, 2025. See Note 1 for additional information regarding the adoption of this standard.

The reconciliation of income taxes computed at the federal statutory rate to the Company's effective income tax rate for the year ended December 31, 2025, prepared in accordance with ASC 740 as amended by ASU 2023-09, is as follows (in thousands, except percentages):

	Year Ended December 31, 2025	
	Amount	%
Income tax computed at the federal statutory tax rate	$ (12,221)	21.0%
Tax credits	(1,220)	2.1
Change in valuation allowance	11,966	(20.6)
Nontaxable or nondeductible items		
Other non-deductible permanent items	(93)	0.2
Limitation on officer compensation	425	(0.7)
Stock compensation	1,142	(2.0)
Other	1	—
Income tax expense (benefit)	$ —	—%

The reconciliation of income taxes computed at the federal statutory rate to the Company's effective income tax rate for the year ended December 31, 2024 (prior to adoption of ASU 2023-09) was as follows (in thousands, except percentages):

	Year Ended December 31, 2024	
	Amount	%
Income tax computed at the federal statutory tax rate	$ (13,726)	21.0%
State and local income taxes, net of federal benefit	(4,126)	6.3
Tax credits	(4,347)	6.7
Change in valuation allowance	20,544	(31.5)
Other permanent differences	(31)	—
Stock compensation	607	(0.9)
Uncertain tax position	1,065	(1.6)
Other	14	—
Income tax expense (benefit)	$ —	—%

The majority of our domestic operations are located in the state of California. The Company paid no federal, state, or foreign income taxes, net of refunds received, during the years ended December 31, 2025 and 2024.

As of December 31, 2025, the Company has not recorded any current or deferred federal, state, or foreign income tax expense or benefit due to its full valuation allowance against deferred tax assets.

Boundless Bio, Inc.
Notes to Financial Statements

Deferred Tax Assets and Liabilities

Significant components of deferred tax assets and liabilities as of December 31, 2025 and 2024 were as follows (in thousands):

	As of December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 45,574	$ 27,618
Research tax credits	10,124	8,313
Lease liability	13,769	13,335
Capitalized R&D	15,726	20,155
Intangible assets	39	44
Other, net	2,268	2,637
Total deferred tax assets	87,500	72,102
Less valuation allowance	(75,150)	(58,844)
Net deferred tax assets	12,350	13,258
Deferred tax liabilities:		
ROU asset	(12,259)	(13,169)
Property and equipment	(91)	(89)
Total deferred tax liabilities	(12,350)	(13,258)
Net deferred tax assets	$ —	$ —

Valuation Allowance

Activity in the valuation allowance for the years ended December 31, 2025 and 2024 was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Balance, beginning of period	58,844	38,323
Charged to federal income tax expense	11,966	14,047
Charged to state income tax expense	4,324	6,497
Charged (credited) to other comprehensive loss	16	(23)
Balance, end of period	75,150	58,844

Net Operating Loss and Credit Carryforwards

The Company has established a full valuation allowance against its net deferred tax assets due to uncertainty regarding realization. In assessing the need for a valuation allowance, management considered the Company's history of cumulative pre-tax losses, the lack of sufficient taxable income in prior carryback periods, the limited existence of taxable temporary differences, and the uncertainty surrounding future taxable income.

During 2025 and 2024, total deferred tax assets, net of deferred tax liabilities, increased by approximately $16.3 million and $20.5 million, respectively. Due to the full valuation allowance position, the Company's valuation allowance increased by a corresponding amount in each period.

As of December 31, 2025 and 2024, federal net operating loss ("NOL") carryforwards, state NOL carryforwards, and research and development tax credit carryforwards consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Federal NOL carryforwards	$ 161,402	$ 91,864
State NOL carryforwards	$ 231,270	$ 183,313
Federal research and development tax credit carryforwards	$ 9,294	$ 7,667
State research tax credit carryforwards	$ 5,850	$ 4,853

Boundless Bio, Inc.
Notes to Financial Statements

Federal net operating loss carryforwards are subject to potential limitations under Section 382 of the Internal Revenue Code of 1986, as amended ("IRC"). Certain state NOL carryforwards begin to expire in 2038. Federal research tax credits begin to expire in 2040, while unused state credits carry forward indefinitely.

Section 382 Limitations

Pursuant to IRC Sections 382 and 383, the Company's ability to use its NOL and research tax credit carryforwards to offset future taxable income may be limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of NOL and research tax carryforwards available to offset future taxable income and income tax liabilities in future years may be significantly reduced, restricted, or eliminated. The Company has also not performed a formal research and development credit study with respect to these credits. As such, the amount of such credits may be reduced in the future should the Company complete such a study. Moreover, deferred tax assets associated with such NOLs and research tax credits could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382.

Recent Tax Legislation

On July 4, 2025, the reconciliation bill commonly referred to as the One Big Beautiful Bill Act ("OBBBA") was signed into law in the United States. The OBBBA includes a broad range of tax reform provisions affecting U.S. corporate income taxation. Certain provisions became effective beginning in 2025, including an elective deduction for domestic research and development expenditures, reinstatement of 100% first-year bonus depreciation, and repeal of the fiscal year-end requirement for certain non-U.S. corporations. Other provisions of the OBBBA will become effective in 2026 and subsequent years, including a more favorable tax rate applicable to Foreign-Derived Deduction Eligible Income and income from non-U.S. subsidiaries (Net CFC Tested Income).

Due to the Company's full valuation allowance on deferred tax assets, the enactment of the OBBBA did not have a material impact on the Company's financial statements for the year ended December 31, 2025, other than the reclassification of certain deferred tax assets and liabilities.

There are no accruals for interest or tax penalties in the accompanying balance sheets, and the Company has not recognized any such interest or tax penalties in the accompanying statements of operations and comprehensive loss. Although it is not currently under a tax examination, all of the Company's tax years remain open to audit in all of the tax jurisdictions in which it operates due to the Company's net operating losses carryforwards.

Uncertain Tax Benefits

Activity related to the Company's gross unrecognized tax benefits for the years ended December 31, 2025 and 2024 was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Balance at beginning of period	$ 9,212	$ 8,048
Increase related to current year positions	656	1,164
Balance at the end of the year	$ 9,868	$ 9,212

The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties.

The Company is not currently under examination by any taxing authority. Due to the existence of net operating loss carryforwards, all tax years remain open to examination in the jurisdictions in which the Company operates.

Boundless Bio, Inc.
Notes to Financial Statements

12. Net Loss Per Common Share

The following table summarizes the calculation of basic and diluted net loss per common share attributable to common stockholders (in thousands, except per share data):

	Year Ended December 31,	
	2025	2024
Net loss	$ (58,197)	$ (65,363)
Weighted-average shares of common stock used in computing net loss per share, basic and diluted	22,360	16,984
Net loss per share, basic and diluted	$ (2.60)	$ (3.85)

The Company excluded approximately 4,234,000 and 3,818,000 shares of common stock underlying outstanding stock options from the calculation of diluted net loss per share for the years ended December 31, 2025 and 2024, respectively, because their inclusion would have been anti-dilutive.

13. Segment Information

The CODM reviews the budget versus actual expense by nature of expense. The following table sets forth our segment loss disclosure for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
R&D – Compensation and benefits (excludes stock-based compensation)	$ 10,601	$ 13,758
R&D – Clinical trial costs	9,850	11,507
R&D – Outsourced services & Consulting	11,826	19,022
R&D – Lab and pharmacology supplies	754	2,295
R&D – Other costs (1)	1,879	1,818
G&A – Compensation and benefits (excludes stock-based compensation)	5,744	6,438
G&A – Professional service fees	2,669	2,866
G&A – Insurance	821	678
G&A – Other costs (2)	2,413	2,333
Facilities related	9,619	3,951
Stock-based compensation and depreciation	7,376	8,601
Total operating expense	63,552	73,267
Loss from operations	(63,552)	(73,267)
Interest and other income, net	5,355	7,904
Segment net loss	$ (58,197)	$ (65,363)

(1) Includes expenses such as software licenses, database subscriptions, lab service contracts, travel, and other costs.

(2) Includes expenses such as travel, investor relations services, software licenses, employee training and development, and other costs.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-278354) on Form S-8 and (No. 333-286302) on Form S-3 of our report dated March 9, 2026, with respect to the financial statements of Boundless Bio, Inc.

/s/ KPMG LLP

San Diego, California
March 9, 2026

Exhibit 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

I, Zachary D. Hornby, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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: March 9, 2026

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

Exhibit 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

I, David Hinkle, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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: March 9, 2026

/s/ David Hinkle
David Hinkle
Senior Vice President, Finance, Controller and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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 Annual Report on Form 10-K of Boundless Bio, Inc. (the Company) for the year ended December 31, 2025 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 David Hinkle, Senior Vice President, Finance, Controller, and Treasurer 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 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: March 9, 2026

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

Date: March 9, 2026

By: /s/ David Hinkle
David Hinkle
Senior Vice President, Finance, Controller and Treasurer
(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.