Filed Pursuant to Rule 424(b)(4)
Registration No. 333-277696

6,250,000 Shares

Common Stock

This is the initial public offering of shares of common stock by Boundless Bio, Inc. We are offering 6,250,000 shares of our common stock.

Prior to this offering, there has been no public market for our common stock. The initial public offering price is $16.00 per share. Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "BOLD."

We are an "emerging growth company" and a "smaller reporting company" as defined under U.S. federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements in this prospectus and future filings.

See section titled "Risk Factors" beginning on page 14 to read about factors you should consider before deciding to invest in shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities nor passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$16.00	$100,000,000
Underwriting discounts and commissions(1)	$1.12	$7,000,000
Proceeds, before expenses, to Boundless Bio, Inc.	$14.88	$93,000,000

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 937,500 shares of our common stock at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on April 2, 2024.

Goldman Sachs & Co. LLC **Leerink Partners** **Piper Sandler** **Guggenheim Securities**

Prospectus dated March 27, 2024

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Through and including April 21, 2024 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to, the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Special Note Regarding Forward-Looking Statements," and our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "Boundless," the "Company," "we," "us," and "our" refer to Boundless Bio, Inc. In addition, in this prospectus we refer to our ecDNA-directed therapeutic candidates as "ecDTx," which are under clinical or preclinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

Overview

We are a clinical-stage oncology company dedicated to unlocking a new paradigm in cancer therapeutics that addresses the significant unmet need in patients with oncogene amplified tumors by targeting extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in more than 14% 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, like oncogene amplifications, 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 with other types of cancer. 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 ecDNA to express amplified oncogenes and 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. In the context of drug development, synthetic lethality is a therapeutic approach wherein using a drug to pharmacologically 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-bearing cancer cells, but not healthy cells without ecDNA. They are engineered to disrupt the underlying cellular machinery that enables ecDNA to function properly, such as proteins essential for ecDNA replication, transcription, assembly, repair, and segregation.

Our lead ecDTx, BBI-355, is a novel, oral, selective inhibitor of checkpoint kinase 1 (CHK1), which manages ecDNA replication and transcription in cancer cells. BBI-355 demonstrated CHK1 inhibition and tumor regressions in ecDNA-enabled preclinical cancer models and is currently being studied in a first-in-human, Phase 1/2 clinical trial in patients with oncogene amplified cancers. We refer to this trial as POTENTIATE (Precision Oncology Trial Evaluating Novel Therapeutic Interrupting Amplifications Tied to ecDNA). We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies from the POTENTIATE trial in the second half of 2024 from approximately 50 to 90 total enrolled patients (single

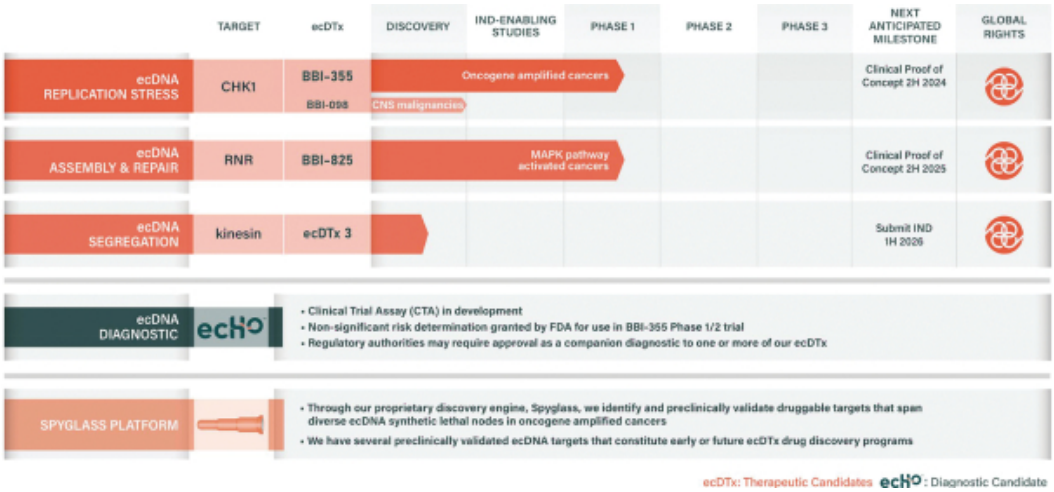
agent cohorts N=~30 to 40, combination cohorts N=~20 to 50). Our second ecDTx, BBI-825, is a novel, oral, selective inhibitor of ribonucleotide reductase (RNR), which is essential for ecDNA assembly and repair in cancer cells. BBI-825 demonstrated RNR inhibition and tumor regressions in amplification-enabled preclinical cancer models. In February 2024, we initiated a first-in-human, Phase 1/2 clinical trial of BBI-825 in patients with resistance gene amplifications. We refer to this trial as STARMAP (Study Treating Acquired Resistance: MAPK Amplifications). We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-825 in combination with targeted therapies from the STARMAP trial in the second half of 2025. Our third ecDTx program is directed at a previously undrugged kinesin target essential for ecDNA segregation and inheritance during cell division. We are advancing our third ecDTx program through drug discovery to candidate identification and expect to submit an investigational new drug application (IND) in the first half of 2026.

To assist in identifying patients that may benefit from our ecDTx, we have developed an ecDNA diagnostic, which we internally call ECHO (ecDNA Harboring Oncogenes), to detect ecDNA in patient tumor samples. This test analyzes the genomic data output from routine next-generation sequencing (NGS) assays that are commonly used by commercial reference and academic laboratories to profile patient tumor samples. We are working with an *in vitro* diagnostic company to develop this diagnostic test into a clinical trial assay, which we intend to use in our ongoing Phase 1/2 POTENTIATE clinical trial. The FDA has determined that the ecDNA diagnostic is a non-significant risk device when used in patient selection for the POTENTIATE trial, meaning that we will not be required to obtain FDA approval of an Investigational Device Exemption (IDE) for the use of the ecDNA diagnostic in this trial.

Our current pipeline consists of three ecDTx programs directed against three different ecDNA targets, as well as our ecDNA diagnostic. We also continue to identify new ecDNA targets, both novel and previously clinically validated, through our proprietary Spyglass platform. We have built our Spyglass platform to identify specific, druggable targets essential to ecDNA formation and function in cancer cells. To our knowledge, Spyglass is the only platform in the biopharma industry focused on identifying ecDNA-enabled vulnerabilities in cancer. All of our ecDTx have been discovered internally, and we retain global rights for all of our programs.

As we are, to our knowledge, the first company formed to develop new cancer medicines directed at ecDNA and the only company to date to bring an ecDTx into the clinic to treat cancer patients, we consider ourselves to be the world's leading ecDNA company. 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 20 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. We leverage this unique expertise to identify new cancer targets that are synthetic lethal in ecDNA-bearing cancer cells and to develop new medicines for patients with oncogene amplified cancers.

Our Pipeline and Platform



Our lead ecDTx, BBI-355, is a novel, oral, selective small molecule CHK1 inhibitor being studied in the ongoing first-in-human, Phase 1/2 POTENTIATE clinical trial in patients with oncogene amplified cancers. CHK1 is a master regulator of cells' response to replication stress (RS). RS is elevated in ecDNA-enabled oncogene amplified cancer cells and, because of this, represents a key vulnerability of those cells. BBI-355 is designed to exploit the elevated RS in ecDNA-enabled oncogene amplified cancer cells by disrupting proper CHK1 function in regulating RS, and thereby facilitating catastrophic RS to preferentially kill cancer cells relative to healthy cells. We believe that using CHK1 inhibition as a therapeutic strategy to target ecDNA-induced RS coupled with our approach to specifically identify patients whose tumors harbor ecDNA differentiates us from other biopharma industry efforts to therapeutically target CHK1 or other components of the cellular RS response. In addition, BBI-355 is orally administered, which, unlike intravenous (IV) dosing of a CHK1 inhibitor, allows for continuous or chronic intermittent dosing, which we believe is critical for targeting ecDNA biology. BBI-355 showed inhibition of CHK1 in a host of tumor cell lines and demonstrated *in vitro* and *in vivo* single agent tumor growth inhibition or tumor regressions across a range of tumor models representing different oncogene amplifications and tumor types. BBI-355 also demonstrated synergistic tumor growth inhibition or tumor regressions when combined with targeted therapies, both *in vitro* and *in vivo,* across multiple oncogene amplification tumor settings. We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies from our ongoing POTENTIATE clinical trial in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=~30 to 40, combination cohorts N=~20 to 50).

Our second ecDTx, BBI-825, is a novel, oral, selective small molecule RNR inhibitor. In February 2024, we initiated the first-in-human, Phase 1/2 STARMAP clinical trial in patients with resistance gene amplifications. RNR is a rate-limiting enzyme responsible for cellular *de novo* synthesis of deoxyribonucleotide triphosphates (dNTPs), the building blocks of DNA, and essential to the assembly and repair of ecDNA. The premise for this ecDTx program is based on the observation that RNR inhibition starved ecDNA-reliant cancer cells of dNTPs, depleted ecDNA, and was synthetic lethal in certain oncogene amplified cancer models. BBI-825 has demonstrated preclinical proof of concept in multiple tumor types and across different oncogene amplifications, including both driver oncogene and resistance settings. BBI-825 demonstrated RNR inhibition in a host of tumor cell lines and showed *in*

vitro and *in vivo* single agent tumor growth inhibition and synergistic activity, including tumor regressions, when combined with specific targeted therapies in amplification-enabled tumor models, in particular, cancer models that develop resistance amplifications in response to mitogen activated protein kinase (MAPK) pathway targeting therapies, such as $BRAF^{V600}$ and $KRAS^{G12C}$ inhibitors. We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-825 in combination with targeted therapies from the STARMAP clinical trial in the second half of 2025.

Our third ecDTx program is directed to ecDNA segregation, which we identified as a unique node of ecDNA vulnerability via our Spyglass platform. Specifically, we are targeting a kinesin involved with the cellular mechanism for segregation of ecDNA, and its resulting inheritance, into dividing cells. We are advancing our third ecDTx program through drug discovery to candidate identification and expect to submit an IND in the first half of 2026.

We continue to leverage Spyglass to identify and preclinically validate additional ecDNA-essential targets. These candidate targets span multiple, diverse ecDNA synthetic lethal nodes in oncogene amplified cancers. In addition to our three ecDTx programs described above, we have preclinically validated multiple additional ecDNA targets and have initiated ecDTx drug discovery efforts to identify candidates against such targets. We expect to continue to identify and preclinically validate additional ecDNA targets using our Spyglass platform in the future.

We believe our unique approach to developing ecDTx has many potential benefits for patients, including:

- addressing oncogene amplified cancers, a type of cancer without effective treatment options;
- identifying patients whose tumors have ecDNA and are likely to benefit from our ecDTx by using our proprietary ecDNA diagnostic; and
- employing a tumor-agnostic development strategy, focusing on oncogene amplified cancers across a broad range of tumor types and amplified oncogene drivers.

Since our inception, we have raised $252.1 million from leading life science investors, including our 5% or greater stockholders, ARCH Venture Partners, Fidelity Management & Research Company LLC, RA Capital Management, Leaps by Bayer, Nextech Invest, and Vertex Ventures HC, as well as other investors. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and strategies and have purchased their shares in prior offerings at prices lower than the price offered to the public in this offering. In addition, some of these investors may not be subject to reporting requirements under Section 16 of the Securities Exchange Act of 1934, as amended (the Exchange Act), and, thus, prospective investors may not necessarily know the total amount of investment by each of the prior investors and if and when some of the prior investors decide to sell any of their shares. See the sections titled “Certain Relationships and Related Person Transactions” and “Principal Stockholders” for more information on prior purchases by and current holdings of these stockholders.

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., 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; Howard Hughes Medical Investigator; member of the National Academy of Sciences; current member of our Scientific Advisory Board.
- Ben Cravatt, Ph.D., Professor and Gilula Chair of Chemical Biology 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., Professor in the Department of Neurosurgery at Yale University School of Medicine.

In 2022, a team led by Dr. Mischel and multiple Boundless Bio scientific co-founders was declared as one of the winners of the Cancer Grand Challenges, a global initiative funded by Cancer Research UK (CRUK) and the National Cancer Institute (NCI), to further investigate the pathogenesis of ecDNA in cancer.

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, Loxo Oncology, Sierra Oncology, Halozyme Therapeutics, and Inhibrx, leading pharmaceutical companies such as Bristol-Myers Squibb, Genentech/Roche, Eli Lilly, Merck, and Novartis, and leading investment banks such as Morgan Stanley & Co. LLC and Goldman Sachs & Co. LLC.

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, Klaus Wagner, M.D., Ph.D., is a practicing oncologist who most recently served as Chief Medical Officer and Executive Vice President at Inhibrx (acquisition by Sanofi pending), where he led an integrated clinical development organization that was responsible for advancing three

oncology programs from pre-IND into clinical development. Our Chief Financial Officer, Jami Rubin, most recently served as Chief Financial Officer at EQRx (acquired by Revolution Medicines) where she led the go public and capital raising process.

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-355, a CHK1 inhibitor, through clinical development and regulatory approval in patients with oncogene amplified cancers enabled by ecDNA.***
- ***Advance our second ecDTx, BBI-825, an RNR inhibitor, through clinical development and regulatory approval in patients whose cancers harbor resistance amplifications.***
- ***Advance our ecDTx 3 program to identify a development candidate and progress it into IND-enabling studies.***
- ***Deploy our proprietary ecDNA diagnostic, ECHO, to identify patients most likely to benefit from our ecDTx.***
- ***Leverage Spyglass to continue to identify and preclinically validate additional ecDNA targets to expand our pipeline of novel ecDTx.***
- ***Opportunistically pursue strategic collaborations to accelerate development timelines and maximize the commercial potential of our ecDTx.***

Summary of Risks Associated with Our Business

Our ability to execute our business strategy is subject to numerous risks and uncertainties that you should consider before investing in us, as more fully described in the section titled “Risk Factors” immediately following this Prospectus Summary. These risks include, among others:

- 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.
- Even if this offering is successful, 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 development programs, commercialization efforts or other operations.
- We are early in our development efforts and have only two ecDTx, BBI-355 and BBI-825, in clinical development. All of our other ecDTx programs are still in the preclinical or discovery stage. If we are unable to successfully develop, obtain regulatory approval, and ultimately commercialize any of our current or future ecDTx, or experience significant delays in doing so, our business will be materially harmed.

- Our approach to treating cancer with oncogene amplifications by developing ecDTx directed against ecDNA is unproven, and we do not know whether we will be able to develop any ecDTx 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 results of prior preclinical studies and early clinical trials are not necessarily predictive of future results. Our ecDTx may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.
- Use of our ecDTx could be associated with adverse side effects, adverse events, or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon a ecDTx, limit the commercial profile of an approved label, or result in other significant negative consequences that could severely harm our business, financial condition, results of operations, and prospects.
- If we are unable to successfully develop an ecDNA diagnostic to enable patient selection for our ecDTx, or if we experience significant delays in doing so, or if we do not obtain, or face delays in obtaining, FDA approval of such a diagnostic, if required, we may not realize the full commercial potential of, or may be unable to commercialize, our ecDTx.
- We face significant competition, and if our competitors develop and commercialize technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than our ecDTx, our business and our ability to develop and successfully commercialize ecDTx will be adversely affected.
- We rely on third parties to conduct our clinical trials and preclinical studies, to develop an ecDNA diagnostic, and to manufacture our ecDTx, and these third parties may not perform satisfactorily, which could delay, prevent, or impair our development or commercialization efforts.
- If we are unable to obtain, maintain, and enforce patent or other intellectual property protection for our ecDTx, diagnostic test 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.

Corporate and Other 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. Our principal executive offices are located at 9880 Campus Point Drive, Suite 120, San Diego, CA 92121, and our telephone number is (858) 766-9912. Our website address is www.boundlessbio.com. The information contained in, or accessible through, our website does not constitute part of this prospectus. We have included our website address as an inactive textual reference only.

We use our trademarks in this prospectus 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 prospectus 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.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). An emerging growth company may take advantage of certain reduced disclosure and other requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- 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 of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the 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 in our periodic reports, proxy statements and registration statements; 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 may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the Securities Act), which such fifth anniversary will occur in 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 in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed $1.235 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information in this prospectus and that we provide to our stockholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

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. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. 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 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.

The Offering	
Common stock offered by us	6,250,000 shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to 937,500 additional shares of common stock from us at any time within 30 days from the date of this prospectus.
Common stock to be outstanding immediately after this offering	22,239,333 shares (or 23,176,833 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $88.4 million (or approximately $102.3 million if the underwriters exercise their option to purchase additional shares in full) from the sale of the shares of common stock offered by us in this offering, based on the initial public offering price of $16.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, to fund the research and development of our ecDTx, ecDNA diagnostic test, and Spyglass platform, and for working capital and general corporate purposes. See the section titled “Use of Proceeds.”
Risk factors	See the section titled “Risk Factors” for a discussion of risks you should consider carefully before deciding to invest in our common stock.
Nasdaq Global Select Market symbol	“BOLD”

The number of shares of our common stock to be outstanding after this offering set forth above is based on 15,989,333 shares of our common stock outstanding as of December 31, 2023, including 1,481 shares subject to a right of repurchase after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock immediately prior to the closing of this offering, and excludes:

- 2,813,937 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2023, with a weighted-average exercise price of $4.13 per share;
- 840,292 shares of common stock issuable upon exercise of stock options granted subsequent to December 31, 2023, with a weighted-average exercise price of $8.19 per share;

- a number of shares of our common stock issuable upon the exercise of stock options (the IPO Grants) equal to 2.2% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' option to purchase additional shares), granted in connection with this offering under our 2024 Incentive Award Plan (the 2024 Plan), which became effective in connection with this offering, to certain of our executive officers, directors, employees and consultants, at an exercise price equal to the initial public offering price in this offering;
- a number of shares of our common stock reserved for future issuance under our 2024 Plan (which number includes the IPO Grants), which will equal the sum of (1) a number of shares equal to 12.0% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares), plus (2) 24,841 shares of our common stock remaining available for future issuance under our 2018 Equity Incentive Plan (the 2018 Plan) as of the effectiveness of the 2024 Plan, which shares will be added to the share reserve under the 2024 Plan upon its effectiveness, plus (3) any potential evergreen increases pursuant to the terms of the 2024 Plan; and
- a number of shares of our common stock reserved for future issuance under our 2024 Employee Stock Purchase Plan (the ESPP), which became effective in connection with this offering, which will equal the sum of (1) a number of shares equal to 1% of the number of our shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares), plus (2) any potential evergreen increases pursuant to the terms of the ESPP.

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to the following:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the closing of this offering;
- the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock immediately prior to the closing of this offering;
- a one-for-19.5 reverse stock split of our common stock, which we effected on March 19, 2024;
- no exercise of the outstanding stock options described above; and
- no exercise by the underwriters of their option to purchase up to 937,500 additional shares of our common stock.

Summary Financial Data

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the summary statements of operations data for the years ended December 31, 2022 and 2023 and the summary balance sheet data as of December 31, 2023 from our audited financial statements included elsewhere in this prospectus. You should read these data together with our financial statements and related notes included elsewhere in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of our future results.

	Year Ended December 31,	
	2022	2023
(in thousands, except per share data)		
Statements of Operations Data:		
Operating expenses:		
Research and development	$ 37,159	$ 42,637
General and administrative	9,310	12,159
Total operating expenses	46,469	54,796
Loss from operations	(46,469)	(54,796)
Other income (expense), net:		
Interest income	668	5,282
Other income (expense)	(100)	80
Total other income (expense), net	568	5,362
Net loss	$(45,901)	$(49,434)
Net loss per common share, basic and diluted[1]	$ (41.80)	$ (40.65)
Weighted-average shares used in net loss per common share calculation, basic and diluted[1]	1,098	1,216
Pro forma net loss per common share, basic and diluted (unaudited)[2]		$ 3.53
Pro forma weighted-average shares used in pro forma net loss per common share calculation, basic and diluted (unaudited)[2]		13,990

(1) See Notes 2 and 13 to our audited financial statements included elsewhere in this prospectus for an explanation of the methods used to calculate historical net loss per share, basic and diluted, and the weighted-average number of shares of common stock used in the computation of the per share amounts.

(2) Unaudited pro forma net loss per share, basic and diluted, attributable to common stockholders, is calculated giving effect to the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock. Unaudited pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received in this offering. Unaudited pro forma net loss per share attributable to common stockholders for the years ended December 31, 2022 and 2023 were calculated using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates, if later, and an adjustment to the net loss in the pro forma basic and diluted net loss per share calculation to remove gains from the remeasurement of the preferred stock purchase right liability.

	December 31, 2023		
(in thousands)	Actual	Pro Forma[1] (unaudited)	Pro Forma As Adjusted[2] (unaudited)
Balance Sheet Data:			
Cash, cash equivalents, and short-term investments	$120,752	$120,752	$209,102
Working capital[3]	114,845	114,845	203,195
Total assets	129,894	129,894	218,244
Total liabilities	9,359	9,359	9,359
Convertible preferred stock	247,617	—	—
Accumulated deficit	(136,109)	(136,109)	(136,109)
Total stockholders' (deficit) equity	(127,082)	120,535	208,885

(1) Gives effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering.

(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above, and (ii) the issuance and sale of 6,250,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes included elsewhere in this prospectus and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before making an investment decision. If any of the following risks are realized, our business, financial condition, results of operations, and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business, results of operations, financial condition, and prospects.

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

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

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

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We do not have any products approved for sale and have not generated any revenue since our inception. If we are unable to successfully develop, obtain requisite approval for and commercialize our ecDTx, we may never generate revenue. Our net losses were $45.9 million and $49.4 million for the years ended December 31, 2022 and 2023, respectively. As of December 31, 2023, we had an accumulated deficit of $136.1 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our ecDTx will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize any of our ecDTx and seek to discover and develop additional ecDTx, as well as operate as a public company.

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

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

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

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, will be sufficient to fund our operations into the second half of 2026. In particular, we expect that the net proceeds from this offering and our existing cash, cash equivalents and short-term investments will allow us to fund development of BBI-355 through preliminary clinical proof of concept safety and antitumor activity data from the POTENTIATE trial and BBI-825 through preliminary proof of concept safety and antitumor activity data from the STARMAP trial, as well as submit an IND for our third ecDTx program. We have based these estimates on assumptions that may prove to be wrong, and we could use 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. The net proceeds of this offering, together with our existing capital, may not be sufficient to complete development of our ecDTx, or any future ecDTx, and after this offering, we will require substantial capital in order to advance our ecDTx and any future ecDTx through clinical trials, regulatory approval, and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds may be adversely impacted by global economic conditions, disruptions to, and volatility in, the credit and

financial markets in the United States and worldwide, and diminished liquidity and credit availability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts, or even cease operations. We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our ecDTx.

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

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

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

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

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or ecDTx.

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

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

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

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

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

- successful initiation and enrollment of clinical trials, and timely completion of clinical trials and preclinical studies with favorable results;

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

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

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

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

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

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

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

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

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

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

Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered

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

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

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

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

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

- inability to obtain animals or materials to initiate and generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining allowance from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;

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

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations, or guidelines, and are subject to oversight by these governmental agencies and ECs or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with GCP and other regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to

demonstrate a benefit from using a drug, changes in governmental regulations, or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial.

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

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

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

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

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

In particular, because our ecDTx are focused on patients with tumors harboring oncogene amplifications on ecDNA, our ability to enroll eligible patients may be limited or take more time than we anticipate, due to the frequency of the biomarker we are seeking to target, or our ability to effectively identify such biomarker. We also may encounter difficulties in identifying and enrolling patients with the proper tumor characteristics or stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. Additionally, other pharmaceutical companies targeting these same types of cancer are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials, and obtaining regulatory approval of our ecDTx may be delayed. Additionally, because our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our ecDTx, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

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

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

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

Moreover, if our ecDTx are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the ecDTx if approved. Unacceptable enhancement of certain toxicities may be seen when our ecDTx are combined with standard of care therapies, or when

they are used as single agents. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compounds.

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

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

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

- regulatory authorities may withdraw, suspend, or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials, or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

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

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

We are early in our development efforts for our ecDTx, have never completed any clinical trials, and we will need to successfully complete our ongoing and later-stage and pivotal clinical trials in order

to obtain FDA or comparable foreign regulatory approval to market our ecDTx. Carrying out later-stage clinical trials and the submission of a successful NDA is a complicated process. We are currently conducting our first Phase 1/2 clinical trial for BBI-355 and recently initiated our first Phase 1/2 clinical trial for BBI-825. We have not yet conducted any clinical trials for our other ecDTx or development programs. We have limited experience as a company in preparing and submitting marketing applications and have not previously submitted an NDA or other comparable foreign regulatory submission for any ecDTx. In addition, as a company, we have had limited interactions with the FDA and no interaction with other comparable foreign regulatory authorities and cannot be certain how many additional clinical trials of our ecDTx will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission and regulatory approval of any of our ecDTx. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of ecDTx that we develop. Failure to commence or complete, or delays in, our planned clinical trials could prevent us from or delay us in submitting marketing applications, including NDAs, for and commercializing our ecDTx.

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

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

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

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

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

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

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

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

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

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

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

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

- additional foreign regulatory requirements;

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

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

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

In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular ecDTx or product and our company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, ecDTx or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our ecDTx may be harmed, which could harm our business, operating results, prospects, or financial condition.

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

As our ecDTx progress through clinical trials to regulatory approval and commercialization, it is common that various aspects of the ecDTx development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield, and manufacturing batch size, minimize costs, and achieve consistent quality and results. For example, in

the future we may consider developing a higher dosage strength tablet for use in our ongoing Phase 1/2 POTENTIATE clinical trial of BBI-355. There can be no assurance that this or any other future manufacturing or formulation changes will achieve their intended objectives. These changes and any future changes we may make to our ecDTx may also cause such candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or related unfavorable clinical trial results could delay initiation or completion of additional clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential regulatory approval, and jeopardize our ability to commercialize our ecDTx, if approved, and generate revenue.

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

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

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. As such, we expect we may need to obtain approval for any ecDNA diagnostic we may develop for use with our ecDTx. The approval or clearance of a companion diagnostic as part of the therapeutic product's 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 any of our ecDTx, whether before, simultaneously with, or after the candidate 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 product. We or our third-party developers may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our ecDTx, if approved, on a timely or profitable basis, if at all.

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

- an inability to initiate or continue clinical trials of our ecDTx;

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

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

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

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

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

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

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

Because we currently rely on third parties for the development of a diagnostic and to manufacture our ecDTx and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary

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

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

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

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

Risks Related to Commercialization of Our ecDTx

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Specifically, for BBI-355, Acrivon Therapeutics, Esperas Pharma, and PharmaEngine have CHK1 inhibitors in clinical development. BenevolentAI, Fosun Pharma, and Impact Therapeutics have publicly disclosed preclinical stage CHK1 inhibitors. For BBI-825, there are several generic approved agents that inhibit RNR as part of their broader mechanism of action, including gemcitabine and hydroxyurea. For our pipeline of ecDTx programs, potential competition includes established companies as well as emerging biotechnology companies that may launch programs against similar targets; however, we are not aware of any companies with ecDNA-directed therapeutic programs in clinical development or a patient selection strategy for ecDNA-enabled oncogene amplification. We are aware of one early-stage private company that is focused on research in ecDNA, 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 the scientific literature, publicly available clinical molecular reports, patient foundations, or market research, and may prove to be incorrect. Further, new trials or information may change the estimated incidence or prevalence of these cancers. Further, specific to our biomarker-driven strategy, data analytics and information from databases that we rely on for identifying or validating some of our biomarker-target relationships may not accurately reflect potential patient populations or may be based on incorrect methodology. As ecDNA in oncogene amplified cancers is a new and novel approach, this heightens the risk that our estimates of the eligible patient population may not be accurate. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our ecDTx, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

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

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

ecDTx that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our ecDTx effectively. If we are not successful in commercializing our ecDTx, either on our own or through arrangements with one or more third parties, we may not be able to generate any future ecDTx revenue and we would incur significant additional losses.

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

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

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

Risks Related to Our Business Operations and Industry

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

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

- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our ecDTx, which may change from

time to time, including the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;

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

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

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

Our success depends in part on our continued ability to attract, recruit, retain, manage, and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our clinical trials and preclinical studies, regulatory approvals, or the commercialization of our ecDTx. Although we have executed employment agreements 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. 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 because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

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

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

As of March 1, 2024, we had 72 full-time employees. As we continue development and pursue the potential commercialization of our ecDTx, as well as transition to functioning as a public company, we will need to expand our financial, development, regulatory, manufacturing, information technology, marketing, and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, and other third parties, and we may not be successful in doing so. Our future financial performance and our ability to develop and commercialize our ecDTx and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly

presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations,

contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs.

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

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

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

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus the ACA will remain in effect in its current form.

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

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

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

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

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

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

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

- decreased demand for our ecDTx;
- injury to our reputation and significant negative media attention;

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

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

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

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

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

We and our service providers maintain a large quantity of sensitive information, including confidential business and patient health information, in connection with our clinical trials, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers may be affected by or subject to existing, amended, or new laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, thus creating potentially complex compliance issues for us and our service providers, strategic partners, and future customers. The cost of compliance with these laws, regulations, and standards is high and is likely to increase in the future. Any failure or perceived failure

by us to comply with federal, state, or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties, and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

In the ordinary course of business, we collect, store, and transmit confidential information including but not limited to intellectual property, clinical trial data, proprietary and confidential business information, and personal information of our employees and contractors (collectively, Confidential Information). Our information technology systems and those of our third-party service providers, strategic partners, and other contractors or consultants are vulnerable to attack, damage, and interruption from computer viruses and malware (e.g. ransomware), malicious code, misconfigurations,

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

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

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

insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

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

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

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

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

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

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants, and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless, and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar

regulatory requirements, including those laws that require the reporting of true, complete, and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud, and abuse and other healthcare laws and regulations in the United States and abroad (iv) laws that require the true, complete, and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and may never achieve profitability. As of December 31, 2023, we had net operating loss (NOL) carryforwards of approximately $66.4 million for federal income tax purposes and $127.0 million

for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOL carryforwards will not expire but may generally be used to offset only 80% of taxable income, which may require us to pay federal income taxes in future years despite having additional federal NOL carryforwards to utilize. Our state NOL carryforwards begin to expire in various amounts in 2040. Our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an "ownership change." For these purposes, an "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not determined the amount of the cumulative change in our ownership resulting from this offering 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 this offering. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to Our Intellectual Property

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

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

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

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

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

Any issued patents may not afford sufficient protection of our ecDTx or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies or products. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. In the event we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we own or may license in the future covering our ecDTx could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U.S. Patent and Trademark Office (USPTO). Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on our ecDTx for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, or enforceability of our patents and/or other intellectual property. Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our ecDTx. Further, if we encounter delays in our development and testing of our ecDTx, clinical trials, or regulatory review and approval of our ecDTx, the period of time during which we could market our ecDTx under patent protection may be reduced (i.e., patents protecting the ecDTx might expire before or shortly after such ecDTx are commercialized). Thus, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if patent applications issue as patents, they may not issue in a

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

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

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

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

Filing, prosecuting, maintaining, enforcing, and defending patents on our ecDTx in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, limiting patent protection to specifically disclosed embodiments. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and obtained patent protection to develop their own products

and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or patents we may license in the future or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

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

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

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

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some circumstances, we may be dependent on any future licensors to take the necessary action to comply with these requirements with respect to any licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. In certain circumstances, we may rely on licensing partners to pay these fees due to the U.S. and non-U.S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in

accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to

attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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

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

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

Our patent rights may be subject to priority, validity, inventorship, ownership, and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources

from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any future licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated, or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

Depending upon the timing, duration, and specifics of any FDA regulatory approval of any of our ecDTx, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved

drug, a method for using it, or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we may license from a third party in the future, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed).

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

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

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

In addition to seeking patent protection for our ecDTx and proprietary technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other

third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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

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

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

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

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future ecDTx in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after

the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our ecDTx could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent, and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or ecDTx are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our ecDTx. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our ecDTx that are held to be infringing. We might, if possible, also be forced to redesign ecDTx or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

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

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

Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our therapeutic and diagnostic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our ecDTx and diagnostic programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure that our ecDTx and diagnostic programs and other proprietary technologies we develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our ecDTx and diagnostic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed

by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our ecDTx. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover ecDTx or the use of our ecDTx. We are aware of certain patent applications in the United States and elsewhere that contain claims that, if issued in their present form, may cover one of our ecDTx. While we believe we would have valid defenses to claims of patent infringement, we cannot be certain that we would prevail in any dispute, and we cannot be certain how an adverse determination would affect our business.

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

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

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public

announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our ecDTx.

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

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

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

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented, or declared generic or determined to be infringing, misappropriating, or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In the event that our trademarks are successfully challenged or determined to be infringing, misappropriating, or violating other marks, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, in the USPTO and in comparable agencies in

many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we may propose to use with our ecDTx in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate, or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our ecDTx or utilize similar technology but that are not covered by the claims of the patents that we own or may license in the future;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our licensors or collaborators might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending and future patent applications that we own or may license will not lead to issued patents;
- any issued patent that we own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;

- our competitors or other third parties might conduct research and development activities in countries where we or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;
- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secret.

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

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

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

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

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our ecDTx. More established companies may have a

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

Risks Related to This Offering and Ownership of Our Common Stock

There has been no public market for our common stock. An active, liquid, and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and you may not be able to resell your common stock at or above the initial public offering price or at all.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for listing on the Nasdaq Global Select Market (Nasdaq), an active trading market for our common stock may never develop or may not be sustained following this offering. We and the representatives of the underwriters determined the initial public offering price of our common stock through negotiation. This price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. The lack of an active market 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, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with the listing requirements of Nasdaq.

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

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. 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 its use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire, or license additional ecDTx;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators, or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by us, our insiders, or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- general economic, industry, geopolitical, and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors, or key personnel;
- intellectual property, product liability, or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations, or principles.

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

We may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of

the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit, or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering.

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the closing of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately $6.61 per share, based on the initial public offering price of $16.00 per share. In the past, we issued options to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding options are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

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

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will own approximately 38.7% of our outstanding common stock (assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options and without giving effect to any potential purchases by such persons in this offering). As a result, such persons, acting together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential 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.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common

stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

Based on shares of common stock outstanding as of December 31, 2023, upon the closing of this offering, we will have a total of 22,239,333 shares of common stock outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of these shares, only the 6,250,000 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

Our directors and executive officers and substantially all of our securityholders have entered into lock-up agreements with the representatives pursuant to which they may not, with limited exceptions and among other things, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Goldman Sachs & Co. LLC, Leerink Partners LLC, Piper Sandler & Co., and Guggenheim Securities, LLC. The underwriters may permit our officers, directors, and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. See the section titled "Underwriting." Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, up to an additional 15,989,333 shares of common stock will be eligible for sale in the public market, of which 8,604,336 shares will be held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, in each without giving effect to any potential purchases by such persons in this offering.

In addition, 2,813,937 shares of common stock that were subject to outstanding options under our employee benefit plans as of December 31, 2023 became eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 14,740,840 shares of our outstanding common stock, or approximately 66.3% of our total outstanding common stock based on shares outstanding as of December 31, 2023, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. See the section titled "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer", as defined under the Exchange Act, our annual gross revenue exceeds $1.235 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain

disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, 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. We cannot predict whether investors will find our common stock less attractive if 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 irrevocably elected to avail ourselves of this exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect immediately prior to the consummation of this offering will contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in

control or changes in our management without the consent of our board of directors. The provisions in our charter documents will include the following:

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

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

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

Our current amended and restated certificate of incorporation provides, and our amended and restated certificate of incorporation that will be in effect immediately prior to the consummation of this offering will provide, that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the 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.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors, and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

General Risk Factors

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

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will 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, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of

effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

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

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

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may

impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

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

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

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

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

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

near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

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

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market, or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases

to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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

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

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

We could be subject to securities class action litigation.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design, and conduct of our ongoing and planned clinical trials and preclinical studies for our ecDTx, ecDNA diagnostic candidate, and other development programs, the timing and likelihood of regulatory filings and approvals for our ecDTx, our ability to commercialize our ecDTx, if approved, the pricing and reimbursement of our ecDTx, if approved, the potential to develop future ecDTx, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans, and objectives of management for future operations, and future results of anticipated ecDTx development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential,” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial and other trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties, and assumptions described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. 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 rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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. Except as required by applicable law, we undertake no obligation 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. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See the section titled “Where You Can Find More Information.”

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 prospectus, 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.

MARKET AND INDUSTRY DATA

We obtained the industry, market, and competitive position data used throughout this prospectus 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 prospectus, does not constitute a portion of this prospectus 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 based on 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 prospectus and we believe the industry, market, and competitive position data included in this prospectus 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 in the sections titled “Risk Factors” and “Special Note Regarding Forward-Looking Statements.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $88.4 million (or approximately $102.3 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $16.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock, and to facilitate our future access to the public equity markets. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, as follows:

- approximately $22.0 million to fund the development of BBI-355, including through preliminary clinical proof of concept safety and antitumor activity data of BBI-355 from the POTENTIATE trial;
- approximately $29.0 million to fund the development of BBI-825, including through preliminary clinical proof of concept safety and antitumor activity data of BBI-825 from the STARMAP trial;
- approximately $24.0 million to fund research and development of our other ecDTx development programs, ecDNA diagnostic, and Spyglass platform, including through submission of an IND for our third ecDTx program; and
- the remainder, if any, for working capital and other general corporate purposes.

We may also use a portion of the remaining 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.

Based on our current operating plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, will be sufficient to fund our operations into the second half of 2026. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Additionally, our expected use of existing cash, cash equivalents, and short-term investments and our net proceeds from this offering represent 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 the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Special Note Regarding Forward-Looking Statements.” The net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, will not be sufficient to complete development of our ecDTx or ecDNA diagnostic test, and after this offering, we will require substantial capital in order to advance our current and any future ecDTx and ecDNA diagnostic tests through clinical trials, regulatory approval, and commercialization. Until such time, if ever, as we can generate substantial ecDTx revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of

those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including the anticipated growth of our business.

Pending the uses described above, we plan to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit, and direct or guaranteed obligations of the United States.

DIVIDEND POLICY

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

CAPITALIZATION

The following table sets forth our cash, cash equivalents, and short-term investments and capitalization as of December 31, 2023:

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 6,250,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and related notes included in this prospectus and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other financial information contained in this prospectus.

	December 31, 2023		
(in thousands, except par value and share data)	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted (unaudited)
Cash, cash equivalents, and short-term investments	$ 120,752	$ 120,752	$ 209,102
Convertible preferred stock, $0.0001 par value; 287,446,844 shares authorized, issued, and outstanding, actual; no shares authorized, issued, and outstanding, pro forma, and pro forma as adjusted	$ 247,617	$ —	$ —
Stockholders’ (deficit) equity:			
Preferred stock, $0.0001 par value; no shares authorized, issued, and outstanding, actual; 70,000,000 shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, $0.0001 par value; 402,600,000 shares authorized, 1,248,493 shares issued and 1,247,012 shares outstanding, excluding 1,481 shares subject to a right of repurchase, actual; 700,000,000 shares authorized, 15,989,333 shares issued, and 15,987,852 outstanding, excluding 1,481 shares subject to a right of repurchase, pro forma; 700,000,000 shares authorized, 22,239,333 shares issued, and 22,237,852 shares outstanding, excluding 1,481 shares subject to a right of repurchase, pro forma as adjusted	—	2	2
Additional paid-in capital	8,987	256,602	344,952
Accumulated other comprehensive loss	40	40	40
Accumulated deficit	(136,109)	(136,109)	(136,109)
Total stockholders’ (deficit) equity	(127,082)	120,535	208,885
Total capitalization	$ 120,535	$ 120,535	$ 208,885

If the underwriters’ option to purchase additional shares is exercised in full, our pro forma as adjusted cash, cash equivalents, and short-term investments, additional paid-in capital, total stockholders’ equity, and total capitalization as of December 31, 2023, would be $223.1 million, $358.9 million, $222.8 million, and $222.8 million, respectively.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted in the table above, above is based on 15,989,333 shares of our common stock outstanding as December 31, 2023, including 1,481 shares subject to our right of repurchase, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock immediately prior to the closing of this offering, and excludes:

- 2,813,937 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2023, with a weighted-average exercise price of $4.13 per share;
- 840,292 shares of common stock issuable upon exercise of stock options granted subsequent to December 31, 2023, with a weighted-average exercise price of $8.19 per share;
- a number of the IPO grants equal to 2.2% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' option to purchase additional shares), granted in connection with this offering under our 2024 Plan, which became effective in connection with this offering, to certain of our executive officers, directors, employees and consultants, at an exercise price equal to the initial public offering price in this offering;
- a number of shares of our common stock reserved for future issuance under our 2024 Plan (which number includes the IPO Grants), which will equal the sum of (1) a number of shares equal to 12.0% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares), plus (2) 24,841 shares of our common stock remaining available for future issuance under our 2018 Plan as of the effectiveness of the 2024 Plan, which shares will be added to the share reserve under the 2024 Plan upon its effectiveness, plus (3) any potential evergreen increases pursuant to the terms of the 2024 Plan; and
- a number of shares of our common stock reserved for future issuance under our ESPP, which became effective in connection with this offering, which will equal the sum of (1) a number of shares equal to 1% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares), plus (2) any potential evergreen increases pursuant to the terms of the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately and substantially diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of December 31, 2023, our historical net tangible book value (deficit) was $(127.1) million, or $(101.79) per share of our common stock, based on 1,248,493 shares of common stock issued and outstanding as of such date, including 1,481 shares subject to our right of repurchase as of such date. Our historical net tangible book value (deficit) per share represents total tangible assets less total liabilities and convertible preferred stock, which is not included within permanent equity, divided by the number of shares of common stock outstanding at December 31, 2023.

On a pro forma basis, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering, our pro forma net tangible book value (deficit) as of December 31, 2023 would have been approximately $120.5 million, or approximately $7.54 per share of our common stock.

After giving further effect to the sale and issuance of 6,250,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2023 would have been approximately $208.9 million, or approximately $9.39 per share. This amount represents an immediate increase in pro forma net tangible book value of approximately $1.85 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $6.61 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Initial public offering price per share			$ 16.00
Historical net tangible book value (deficit) per share as of December 31, 2023	$	(101.79)	
Pro forma increase in historical net tangible book value per share as of December 31, 2023 attributable to the pro forma adjustments described above	$	109.33	
Pro forma net tangible book value per share as of December 31, 2023	$	7.54	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering		1.85	
Pro forma as adjusted net tangible book value per share after this offering			9.39
Dilution per share to new investors participating in this offering			$ 6.61

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be approximately $9.61 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be approximately $2.08 per share, and the dilution per share to investors in this offering would be $6.39 per share, in each case based on the initial public offering price of $16.00 per share.

The following table summarizes on the pro forma as adjusted basis described above, as of December 31, 2023, the differences between the number of shares purchased from us, the total consideration paid to us in cash, and the weighted-average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid by new investors in this offering. The calculations below are based on the initial public offering price of $16.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	15,989,333	71.9%	$253,492,717	71.7%	$ 15.85
New investors participating in this offering	6,250,000	28.1%	100,000,000	28.3%	$ 16.00
Total	22,239,333	100.0%	$353,492,717	100.0%	

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 69.0% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors participating in this offering will increase to 7,187,500, or approximately 31.0% of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations above (other than the historical net tangible book value calculations) are based on 15,989,333 shares of our common stock outstanding as of December 31, 2023, including 1,481 shares subject to our right of repurchase, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock immediately prior to the closing of this offering, and exclude:

- 2,813,937 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2023, with a weighted-average exercise price of $4.13 per share;
- 840,292 shares of common stock issuable upon exercise of stock options granted subsequent to December 31, 2023, with a weighted-average exercise price of $8.19 per share;
- a number of the IPO grants equal to 2.2% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' option to purchase additional shares), granted in connection with this offering under our 2024 Plan, which became effective in connection with this offering, to certain of our executive officers, directors, employees and consultants, at an exercise price equal to the initial public offering price in this offering;
- a number of shares of our common stock reserved for future issuance under our 2024 Plan (which number includes the IPO Grants), which will equal the sum of (1) a number of

shares equal to 12.0% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares), plus (2) 24,841 shares of our common stock remaining available for future issuance under our 2018 Plan as of the effectiveness of the 2024 Plan, which shares will be added to the share reserve under the 2024 Plan upon its effectiveness, plus (3) any potential evergreen increases pursuant to the terms of the 2024 Plan; and

- a number of shares of our common stock reserved for future issuance under our 2024 ESPP, which became effective in connection with this offering, which will equal the sum of (1) a number of shares equal to 1% of the number of shares of our common stock to be outstanding upon the closing of this offering (calculated on an as-converted basis and after giving effect to the number of shares of our common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares), plus (2) any potential evergreen increases pursuant to the terms of the ESPP.

To the extent any outstanding options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional equity or convertible securities in the future, there will be further dilution to new investors participating in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis are set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, and includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

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

Our lead ecDTx, BBI-355, is a novel, oral, selective small molecule CHK1 inhibitor being studied in the ongoing first-in-human, Phase 1/2 POTENTIATE clinical trial in patients with oncogene amplified cancers. We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=~30 to 40, combination cohorts N=~20 to 50). Our second ecDTx, BBI-825, is a novel, oral, selective small molecule RNR inhibitor. In February 2024, we initiated the first-in-human, Phase 1/2 STARMAP clinical trial in patients with resistance gene amplifications. Our third ecDTx program, in the drug discovery stage, is directed at a previously undrugged kinesin target essential for ecDNA segregation and inheritance during cell division, and we are advancing this program through drug discovery to candidate identification and expect to submit an IND in the first half of 2026. We continue to leverage Spyglass to identify and preclinically validate additional ecDNA-essential targets. In addition to our three ecDTx programs described above, we have preclinically validated multiple additional ecDNA targets and have initiated ecDTx drug discovery efforts to identify candidates against such targets. We expect to continue to identify and preclinically validate additional ecDNA targets using our Spyglass platform in the future. To date, all of our ecDTx have been discovered internally, and we retain global rights for all of our programs. To assist in identifying patients that may benefit from our ecDTx, we have developed an ecDNA diagnostic test, internally called ECHO, to detect ecDNA in patient tumor samples via routine NGS assays. We are working with an *in vitro* diagnostic company to develop the ecDNA diagnostic into a clinical trial assay, which we intend to use in our ongoing Phase 1/2 POTENTIATE clinical trial. The FDA has determined that the ecDNA diagnostic is a non-significant risk device when used in patient selection for the POTENTIATE trial, meaning that we will not be required to obtain FDA approval of an IDE for the use of the ecDNA diagnostic in this trial.

Since we commenced operations in 2018, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, building our proprietary

Spyglass platform, discovering our ecDTx, developing our ecDNA diagnostic, establishing our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of our ecDTx and related raw materials, and providing general and administrative support for these operations.

We have incurred significant operating losses since our inception and, as of December 31, 2023, we had an accumulated deficit of $136.1 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize any of our ecDTx and seek to discover and develop additional ecDTx, develop our ecDNA diagnostic, conduct our ongoing and planned clinical trials and preclinical studies, continue our research and development activities, utilize third parties to manufacture our ecDTx and related raw materials, hire additional personnel, expand and protect our intellectual property, as well as incur additional costs associated with being a public company. If we obtain regulatory approval for any of our ecDTx, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and preclinical studies and our other research and development activities and capital expenditures.

Through December 31, 2023, we have raised a total of $253.5 million to fund our operations primarily from the gross proceeds from the sale and issuance of our convertible preferred stock. As of December 31, 2023, we had cash, cash equivalents, and short-term investments of $120.8 million. Based upon our current operating plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, will be sufficient to fund our operations into the second half of 2026.

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

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

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from the sale of products. We do not expect to generate any such revenue unless and until such time that our ecDTx have advanced through clinical development and regulatory approval, if ever. If we fail to complete preclinical and clinical development of ecDTx or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Operating Expenses

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

Research and Development

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

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

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

Although R&D activities are central to our business model, the successful development of our ecDTx is highly uncertain. There are numerous factors associated with the successful development of any ecDTx, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory

factors beyond our control may impact our clinical development programs. Product candidates in later stages of development generally have higher development costs than those in earlier stages of development. As a result, we expect that our R&D expenses will increase substantially for the foreseeable future as we continue to conduct our ongoing R&D activities, advance preclinical research programs toward clinical development, conduct clinical trials, hire additional personnel, and maintain, expand, protect, and enforce our intellectual property portfolio.

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

- the number and scope, rate of progress, expense and results of our discovery and preclinical activities and clinical trials;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the cost of developing an ecDNA diagnostic test;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our ecDTx;
- the phase of development of our ecDTx;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of our ecDTx;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish collaboration, license, or other arrangements.

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

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

General and Administrative

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

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

Other Income (Expense), Net

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

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2023

The following table summarizes our results of operations for each of the periods indicated:

(in thousands)	Year Ended December 31, 2022	2023	Change
Operating expenses:			
Research and development	$ 37,159	$ 42,637	$ 5,478
General and administrative	9,310	12,159	2,849
Total operating expenses	46,469	54,796	8,327
Loss from operations	(46,469)	(54,796)	(8,327)
Other income (expense), net	568	5,362	4,794
Net loss	$ (45,901)	$ (49,434)	$ (3,533)

Research and Development Expenses

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

(in thousands)	Year Ended December 31, 2022	2023	Change
Direct program costs:			
BBI-355	$ 8,675	$ 7,252	$(1,423)
BBI-825	5,553	5,912	359
Other development programs	2,971	4,456	1,485
Total direct program costs:	17,199	17,620	421
Indirect R&D costs			
Personnel-related (including stock compensation)	11,538	13,688	2,150
Outside services and consulting	2,182	4,326	2,144
Lab and pharmacology supplies	2,638	2,897	259
Facilities-related (including depreciation)	2,388	2,776	388
Other development programs	1,214	1,330	116
Total indirect program costs:	19,960	25,017	5,057
Total R&D expenses	$37,159	$42,637	$ 5,478

R&D expenses were $37.2 million and $42.6 million for the years ended December 31, 2022 and 2023, respectively. The $5.5 million increase in R&D expenses resulted from a $2.7 million increase in outside services costs primarily due to the initiation of our Phase 1/2 POTENTIATE clinical trial for BBI-355, an additional $2.1 million of personnel-related costs due to an increase in headcount and additional stock-based compensation expense, and a $0.7 million increase in rent expense and other R&D costs.

General and Administrative Expenses

G&A expenses were $9.3 million and $12.2 million for the years ended December 31, 2022 and 2023, respectively. The $2.8 million increase primarily resulted from a $1.3 million increase in personnel-related costs due primarily to an increase in employee headcount, salary increases, and additional stock-based compensation expense, $0.8 million of additional legal and other professional costs, and a $0.7 million increase in rent expense and other operating costs and expenses.

Other Income (Expense), Net

Other income (expense), net was $0.6 million and $5.4 million for the years ended December 31, 2022 and 2023, respectively. The $4.8 million increase resulted from the additional interest income generated by our available-for-sale investment securities portfolio due to the net proceeds of $99.7 million arising from the sale of shares of our Series C convertible preferred stock in April and May 2023, as well as the increase in market yields available for such investment securities in comparison to the prior year period.

Liquidity and Capital Resources

Sources of Liquidity

Through December 31, 2023, we have raised a total of $253.5 million to fund our operations primarily from the gross proceeds from the sale and issuance of our convertible preferred stock.

Future Funding Requirements

As of December 31, 2023, we had cash, cash equivalents, and short-term investments of $120.8 million. Based upon our current operating plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents, and short-term investments, will be sufficient to fund our operations into the second half of 2026. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies, manufacturing ecDTx, developing our ecDNA diagnostic, and testing ecDTx in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain.

We have incurred significant operating losses since our inception and, as of December 31, 2023, we had an accumulated deficit of $136.1 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize any of our ecDTx and seek to discover, and develop additional ecDTx, conduct our ongoing and planned clinical trials and preclinical studies, continue our research and development activities, utilize third parties to manufacture our ecDTx and related raw materials, hire additional personnel, expand and protect our intellectual property, as well as incur additional costs associated with being a public company. If we obtain regulatory approval for any of our ecDTx, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and preclinical studies and our other research and development activities and capital expenditures.

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

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our ecDTx that we are pursuing or may choose to pursue in the future, including the costs of any third-party products used as combination agents in our combination clinical trials;
- the costs and timing of manufacturing for our ecDTx, including commercial manufacture at sufficient scale, if any ecDTx is approved;
- the costs and timing of developing ecDNA diagnostics, if required, and the outcome of their regulatory review;
- the costs, timing, and outcome of regulatory meetings and reviews of our ecDTx;
- the costs of obtaining, maintaining, enforcing, and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;

- the costs associated with hiring additional personnel and consultants as our clinical and preclinical activities increase and as we operate as a public company;
- the costs and timing of establishing or securing sales and marketing capabilities if any ecDTx is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire; and
- the effects of competing technological and market developments as well as disruptions to and volatility in the credit and financial markets.

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

Cash Flows

Comparison of the Years Ended December 31, 2022 and 2023

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

	Year Ended December 31,		
(in thousands)	2022	2023	Change
Net cash used in operating activities	$ (39,596)	$ (46,855)	$ (7,259)
Net cash provided by investing activities	16,132	(38,260)	(54,392)
Net cash provided by financing activities	126	97,897	97,770
Increase (decrease) in cash, cash equivalents, and restricted cash	$ (23,338)	$ 12,782	$ 36,119

Operating Activities

Net cash used in operating activities was $39.6 million and $46.9 million for the years ended December 31, 2022 and 2023, respectively. The net cash used in operating activities during the year ended December 31, 2022 was primarily due to our reported net loss of $45.9 million, net of noncash charges (including stock-based compensation expense, depreciation, and right-of-use asset amortization) totaling $5.4 million and a $0.9 million decrease of our net operating assets. The net cash used in operating activities during the year ended December 31, 2023 was primarily due to our reported net loss of $49.4 million and a $0.8 million increase in our net operating assets, adjusted for noncash charges (including stock-based compensation expense, depreciation, and right-of-use amortization) totaling $3.4 million. The increase in cash used in operations during the year ended December 31, 2022 in comparison to the year ended December 31, 2023 was primarily attributable to higher personnel-related costs and an increase in third-party spending associated with our discovery, development, and clinical activities.

Investing Activities

Investing activities consist primarily of the cash flows of purchases and maturities of investment securities and the cash outflow associated with purchases of property and equipment. Such activities resulted in a net outflow of funds of approximately $16.1 million during the year ended December 31, 2022, primarily from the net maturities of our available-for-sale securities portfolio, and a net outflow of funds of $38.3 million during the year ended December 31, 2023, primarily from net purchases of available-for-sale securities portfolio.

Financing Activities

Our financing activities generally consist of the proceeds from the sale of our convertible preferred stock and common stock. Net cash provided by financing activities was $0.1 million during the year ended December 31, 2022 as a result of the exercise of common stock options by our employees and consultants. Net cash provided by financing activities was $97.9 million during the year ended December 31, 2023 primarily due to the net proceeds generated from the sale and issuance of our Series C convertible preferred stock in April and May 2023.

Contractual Obligations and Other Commitments

We lease office and lab space under lease agreements with varying expiration dates through 2035. As of December 31, 2023, total future aggregate operating lease commitments was $74.2 million. During the normal course of our business, we enter into contracts for research and professional services, and for the purchase of lab supplies used in our research activities. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not separately presented.

Off-Balance Sheet Arrangements

Since our inception, we did not have, 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 and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this prospectus, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

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 cost of the estimated grant date fair value of stock option awards amortized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of all stock option grants using the Black-Scholes option pricing model and recognize forfeitures as they occur.

Estimating the fair value of equity awards at the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of complex variables, including:

- *Fair Value of Common Stock*. See the subsection titled “Determination of Fair Value of Our Common Stock” below.
- *Expected Volatility*. Given that our common stock has been privately held prior to this offering, there has no active trading market for our common stock. The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.
- *Risk-Free Interest Rate*. We base the risk-free interest rate assumption on the U.S. Treasury’s rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.
- *Expected Term.* The expected term represents the period of time that options are expected to be outstanding. Because we do not have significant historical exercise behavior, we determine the expected life assumption using the “simplified” method, which is an average of the contractual term of the option and its vesting period.
- *Expected Dividend Yield*. We use an expected dividend yield of zero, as we have never paid dividends on our common stock and have no present intention of doing so in the foreseeable future.

These inputs are subjective and generally require significant analysis and judgment to develop. Changes in these assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized.

The intrinsic value of all outstanding options as of December 31, 2023 was $33.4 million based on the initial public offering price of $16.00 per share of which approximately $11.2 million was related to vested options and approximately $22.2 million was related to unvested options.

In February 2024, we granted stock options to purchase approximately 0.8 million shares of our common stock at an exercise price of $8.19 per share, which generally vest over a requisite service period of four years. The exercise prices for the stock options we granted in February 2024 were equal to the fair value of a share of our common stock on the grant date as determined by our board of directors on the date of grant. In light of progress made towards completion of an IPO and information received in estimation of our initial public offering price range, we preliminarily established the fair value of the February 2024 grants for financial reporting purposes based on a straight-line interpolation from a third-party valuation of our common stock on September 15, 2023 to the midpoint of the initial price range for this offering in order to determine the appropriate stock-based compensation expense. We elected to use the September 15, 2023 third-party valuation as that was the first point in time when our development progress gave better visibility into the potential for an IPO (coupled with the initial filing of a draft Registration Statement), and since that time the continued progress on our research and development programs and an increased likelihood of an IPO resulted in a ratable increase in value throughout the applicable quarter. Therefore, while we have not yet prepared financial statements for the first quarter of 2024, we expect, solely for financial reporting purposes, to recognize stock-based compensation expense for the February 2024 grants of approximately $9.5 million, to be amortized over a weighted average term of 3.9 years. The amount of stock-based compensation expense related to these options is based upon our estimates, and could change as events and circumstances change. Upon completion of this offering, our common stock will be publicly traded and we will rely on the closing price of our common stock as reported on the date of grant to determine the fair value of our common stock.

Determination of Fair Value of Our Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering contemporaneous independent third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant, including: the prices at which we sold shares of our convertible preferred stock to outside investors in arms-length transactions, and the superior rights, preferences, and privileges of the convertible preferred stock relative to the common stock at the time of each grant; the progress of our company's R&D programs, including their stages of development, and our company's business strategy; external market and other conditions affecting the biotechnology industry, and trends within the biotechnology industry; our company's financial position, including cash on hand, and our historical and forecasted performance and operating results; the lack of an active public market for our company's common stock; the likelihood of achieving a liquidity event for our company's securityholders, such as an initial public offering or a sale of the company, taking into consideration prevailing market conditions; the hiring of key personnel and the experience of management; and the analysis of initial public offerings and the market performance of peer companies in the biopharmaceutical industry, as well as completed mergers and acquisitions of peer companies.

These independent third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (Practice Aid). The methodology to determine the fair value of our common stock included estimating the fair value of the enterprise using a market approach, which estimates the fair value of a company by including an estimation of the value of the business based on guideline public companies under a number of different scenarios. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

In accordance with the Practice Aid, we considered the following methods:

- *Option Pricing Method (OPM)*. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the convertible preferred stock and common stock are inferred by analyzing these options. This method is appropriate to use when the range of possible future outcomes is so difficult to predict that estimates would be highly speculative, and dissolution or liquidation is not imminent.
- *Probability-Weighted Expected Return Method (PWERM)*. The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.
- *Hybrid Method*. The Hybrid Method is a hybrid between PWERM and OPM, where the equity value probability-weighted value across multiple scenarios but using the OPM to estimate the allocation of value within one or more of those scenarios.

Based on our early stage of development, the difficulty in predicting the range of specific outcomes (and their likelihood), and other relevant factors, a Hybrid Method computing the probability-weighted value across two scenarios (the Current Value Method (CVM) scenario and the OPM scenario or, as applicable a market-adjusted OPM scenario) was considered most appropriate for valuations through April 2023. For options granted after April 2023, a Hybrid Method computing the probability-weighted value across an OPM scenario and an IPO scenario was determined to be the most appropriate valuation methodology given our development progress and the potential for an

eventual IPO. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an initial public offering or other liquidity event, and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss, and net loss per share of common stock could have been significantly different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options or for any other such awards we may grant, as the fair value of our common stock will be determined based on the closing price of our common stock as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Recently Adopted Accounting Pronouncements

See Note 2 to our audited financial statements and unaudited condensed financial statements included elsewhere in this prospectus for recently adopted accounting pronouncements.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash, cash equivalents, and short-term investments consist of cash held in readily available checking and money market accounts, as well as short-term debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. 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, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations.

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. 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 our cost of 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.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This period allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

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

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

BUSINESS

Overview

We are a clinical-stage oncology company dedicated to unlocking a new paradigm in cancer therapeutics that addresses the significant unmet need in patients with oncogene amplified tumors by targeting extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in more than 14% 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, like oncogene amplifications, 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 with other types of cancer. 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 ecDNA to express amplified oncogenes and 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. In the context of drug development, synthetic lethality is a therapeutic approach wherein using a drug to pharmacologically 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-bearing cancer cells, but not healthy cells without ecDNA. They are engineered to disrupt the underlying cellular machinery that enables ecDNA to function properly, such as proteins essential for ecDNA replication, transcription, assembly, repair, and segregation.

Our lead ecDTx, BBI-355, is a novel, oral, selective inhibitor of checkpoint kinase 1 (CHK1), which manages ecDNA replication and transcription in cancer cells. BBI-355 demonstrated CHK1 inhibition and tumor regressions in ecDNA-enabled preclinical cancer models and is currently being studied in a first-in-human, Phase 1/2 clinical trial in patients with oncogene amplified cancers. We refer to this trial as POTENTIATE (Precision Oncology Trial Evaluating Novel Therapeutic Interrupting Amplifications Tied to ecDNA). We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies from the POTENTIATE trial in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=~30 to 40, combination cohorts N=~20 to 50). Our second ecDTx, BBI-825, is a novel, oral, selective inhibitor of ribonucleotide reductase (RNR), which is essential for ecDNA assembly and repair in cancer cells. BBI-825 demonstrated RNR inhibition and tumor regressions in amplification-enabled preclinical cancer models. In February 2024, we initiated a first-in-human, Phase 1/2 clinical trial of BBI-825 in patients with resistance gene amplifications. We refer to this trial as STARMAP (Study Treating Acquired Resistance: MAPK Amplifications). We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-825 in combination with targeted therapies from the STARMAP trial in the second half of 2025. Our third ecDTx program is directed at a previously undrugged kinesin target essential for ecDNA segregation and inheritance during cell division. We are advancing our third ecDTx program through drug discovery to candidate identification and expect to submit an investigational new drug application (IND) in the first half of 2026.

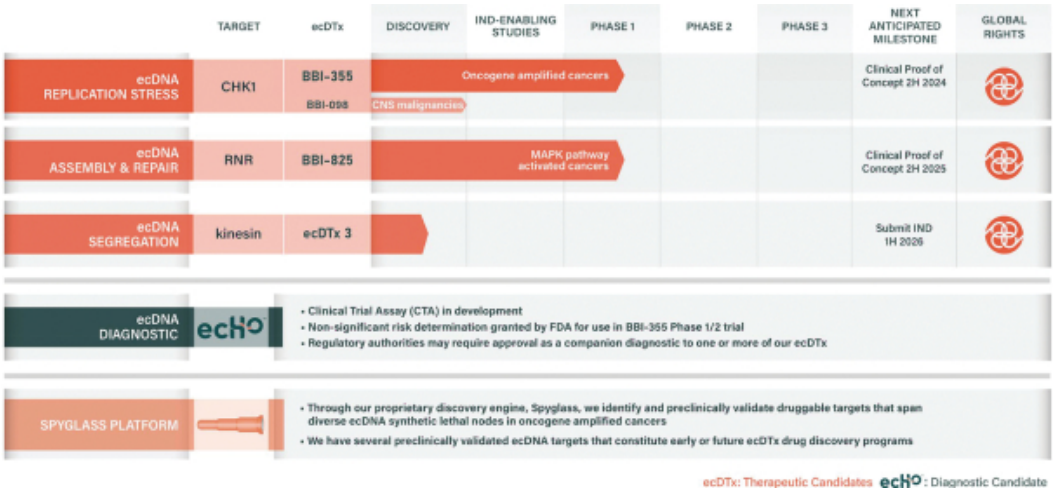
To assist in identifying patients that may benefit from our ecDTx, we have developed an ecDNA diagnostic, which we internally call ECHO (ecDNA Harboring Oncogenes), to detect ecDNA in patient tumor samples. This test analyzes the genomic data output from routine next-generation sequencing

(NGS) assays that are commonly used by commercial reference and academic laboratories to profile patient tumor samples. We are working with an *in vitro* diagnostic company to develop this diagnostic test into a clinical trial assay, which we intend to use in our ongoing Phase 1/2 POTENTIATE clinical trial. The FDA has determined that the ecDNA diagnostic is a non-significant risk device when used in patient selection for the POTENTIATE trial, meaning that we will not be required to obtain FDA approval of an Investigational Device Exemption (IDE) for the use of the ecDNA diagnostic in this trial.

Our current pipeline consists of three ecDTx programs directed against three different ecDNA targets, as well as our ecDNA diagnostic. We also continue to identify new ecDNA targets, both novel and previously clinically validated, through our proprietary Spyglass platform. We have built our Spyglass platform to identify specific, druggable targets essential to ecDNA formation and function in cancer cells. To our knowledge, Spyglass is the only platform in the biopharma industry focused on identifying ecDNA-enabled vulnerabilities in cancer. All of our ecDTx have been discovered internally, and we retain global rights for all of our programs.

As we are, to our knowledge, the first company formed to develop new cancer medicines directed at ecDNA and the only company to date to bring an ecDTx into the clinic to treat cancer patients, we consider ourselves to be the world's leading ecDNA company. 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 20 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. We leverage this unique expertise to identify new cancer targets that are synthetic lethal in ecDNA-bearing cancer cells and to develop new medicines for patients with oncogene amplified cancers.

Our Pipeline and Platform



Our lead ecDTx, BBI-355, is a novel, oral, selective small molecule CHK1 inhibitor being studied in the ongoing first-in-human, Phase 1/2 POTENTIATE clinical trial in patients with oncogene amplified cancers. CHK1 is a master regulator of cells' response to replication stress (RS). RS is elevated in ecDNA-enabled oncogene amplified cancer cells and, because of this, represents a key vulnerability of those cells. BBI-355 is designed to exploit the elevated RS in ecDNA-enabled oncogene amplified

cancer cells by disrupting proper CHK1 function in regulating RS, and thereby facilitating catastrophic RS to preferentially kill cancer cells relative to healthy cells. We believe that using CHK1 inhibition as a therapeutic strategy to target ecDNA-induced RS coupled with our approach to specifically identify patients whose tumors harbor ecDNA differentiates us from other biopharma industry efforts to therapeutically target CHK1 or other components of the cellular RS response. In addition, BBI-355 is orally administered, which, unlike intravenous (IV) dosing of a CHK1 inhibitor, allows for continuous or chronic intermittent dosing, which we believe is critical for targeting ecDNA biology. BBI-355 showed inhibition of CHK1 in a host of tumor cell lines and demonstrated *in vitro* and *in vivo* single agent tumor growth inhibition or tumor regressions across a range of tumor models representing different oncogene amplifications and tumor types. BBI-355 also demonstrated synergistic tumor growth inhibition or tumor regressions when combined with targeted therapies, both *in vitro* and *in vivo,* across multiple oncogene amplification tumor settings. We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies from our ongoing POTENTIATE clinical trial in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=~30 to 40, combination cohorts N=~20 to 50).

Our second ecDTx, BBI-825, is a novel, oral, selective small molecule RNR inhibitor. In February 2024, we initiated the first-in-human, Phase 1/2 STARMAP clinical trial in patients with resistance gene amplifications. RNR is a rate-limiting enzyme responsible for cellular production of deoxyribonucleotide triphosphates (dNTPs), the building blocks of DNA, and essential to the assembly and repair of ecDNA. The premise for this ecDTx program is based on the observation that RNR inhibition starved ecDNA-reliant cancer cells of dNTPs, depleted ecDNA, and was synthetic lethal in certain oncogene amplified cancer models. BBI-825 has demonstrated preclinical proof of concept in multiple tumor types and across different oncogene amplifications, including both driver oncogene and resistance settings. BBI-825 demonstrated RNR inhibition in a host of tumor cell lines and showed *in vitro* and *in vivo* single agent tumor growth inhibition and synergistic activity, including tumor regressions, when combined with specific targeted therapies in amplification-enabled tumor models, in particular, cancer models that develop resistance amplifications in response to mitogen activated protein kinase (MAPK) pathway targeting therapies, such as $BRAF^{V600}$ and $KRAS^{G12C}$ inhibitors. We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-825 in combination with targeted therapies from the STARMAP clinical trial in the second half of 2025.

Our third ecDTx program is directed to ecDNA segregation, which we identified as a unique node of ecDNA vulnerability via our Spyglass platform. Specifically, we are targeting a kinesin involved with the cellular mechanism for segregation of ecDNA, and its resulting inheritance, into dividing cells. We are advancing our third ecDTx program through drug discovery to candidate identification and expect to submit an IND in the first half of 2026.

We continue to leverage Spyglass to identify and preclinically validate additional ecDNA-essential targets. These candidate targets span multiple, diverse ecDNA synthetic lethal nodes in oncogene amplified cancers. In addition to our three ecDTx programs described above, we have preclinically validated multiple additional ecDNA targets and have initiated ecDTx drug discovery efforts to identify candidates against such targets. We expect to continue to identify and preclinically validate additional ecDNA targets using our Spyglass platform in the future.

We believe our unique approach to developing ecDTx has many potential benefits for patients, including:

- addressing oncogene amplified cancers, a type of cancer without effective treatment options;
- identifying patients whose tumors have ecDNA and are likely to benefit from our ecDTx by using our proprietary ecDNA diagnostic; and

- employing a tumor-agnostic development strategy, focusing on oncogene amplified cancers across a broad range of tumor types and amplified oncogene drivers.

Since our inception, we have raised $252.1 million from leading life science investors, including our 5% or greater stockholders, ARCH Venture Partners, Fidelity Management & Research Company LLC, RA Capital Management, Leaps by Bayer, Nextech Invest, and Vertex Ventures HC, as well as other investors. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and strategies and have purchased their shares in prior offerings at prices lower than the price offered to the public in this offering. In addition, some of these investors may not be subject to reporting requirements under Section 16 of the Exchange Act, and, thus, prospective investors may not necessarily know the total amount of investment by each of the prior investors and if and when some of the prior investors decide to sell any of their shares. See the sections titled “Certain Relationships and Related Person Transactions” and “Principal Stockholders” for more information on prior purchases by and current holdings of these stockholders.

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-355, a CHK1 inhibitor, through clinical development and regulatory approval in patients with oncogene amplified cancers enabled by ecDNA***. We believe that with the optimized biochemical profile of BBI-355, including its oral route of administration, along with our differentiated precision oncology development strategy and approach to identify patients with oncogene amplifications on ecDNA using our ecDNA diagnostic, we can overcome the historical challenges encountered with prior CHK1 inhibitors. As of February 21, 2024, we have enrolled 22 patients in our Phase 1/2 POTENTIATE clinical trial of BBI-355 in patients with oncogene amplified cancers, and we expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies from the POTENTIATE trial in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=~30 to 40, combination cohorts N=~20 to 50).
- ***Advance our second ecDTx, BBI-825, an RNR inhibitor through clinical development and regulatory approval in patients whose cancers harbor resistance amplifications***. We believe that an oral RNR inhibitor intentionally designed for RNR selectivity would be significantly differentiated from prior, non-selective RNR inhibitors, such as gemcitabine. In preclinical models, BBI-825 demonstrated RNR selectivity as well as inhibition of RNR. BBI-825 demonstrated tumor growth inhibition, including regressions, in both the prevention and treatment of amplification-mediated resistance in MAPK pathway-activated tumors in preclinical studies. In February 2024, we initiated the first-in-human, Phase 1/2 STARMAP clinical trial of BBI-825 in patients with resistance gene amplifications. We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-825 in combination with targeted therapies from the STARMAP trial in the second half of 2025.
- ***Advance our ecDTx 3 program to identify a development candidate and progress it into IND-enabling studies***. 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, whose inhibition is synthetic lethal to ecDNA-enabled cancer cells. Our third ecDTx program is directed to this kinesin, which is a member of a class of known druggable proteins, but for which there are no approved drugs and to our knowledge no other publicly disclosed drug discovery efforts. We have identified small molecule inhibitors of this target and are currently advancing these scaffolds through hit-to-lead generation. We are advancing our third ecDTx program through drug discovery to candidate identification and expect to submit an IND in the first half of 2026.

- ***Deploy our proprietary ecDNA diagnostic, ECHO, to identify patients most likely to benefit from our ecDTx.*** Our ecDNA diagnostic is a software algorithm intended to detect ecDNA in patient tumor samples by analyzing the genomic data of those samples available from routine NGS tests that are commonly used by commercial reference and academic laboratories for profiling patient tumors. We are working with an *in vitro* diagnostic company to develop our ecDNA diagnostic into a clinical trial assay for patient selection in clinical trials of our ecDTx, including our ongoing Phase 1/2 POTENTIATE clinical trial of BBI-355. The FDA has determined that the ecDNA diagnostic is a non-significant risk device when used in patient selection for the POTENTIATE trial, meaning that we will not be required to obtain FDA approval of an Investigational Device Exemption (IDE) for the use of the ecDNA diagnostic in this trial. To our knowledge, this will be the first ecDNA diagnostic in clinical use. As data from our ecDTx clinical studies progress, we intend to discuss with the FDA whether the ecDNA diagnostic will be appropriate or required to enable commercialization of our ecDTx.
- ***Leverage Spyglass to continue to identify and preclinically validate additional ecDNA targets to expand our pipeline of novel ecDTx.*** We utilize Spyglass to identify targets that exploit cellular vulnerabilities of ecDNA-enabled cancers. Our target identification efforts to date 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 ecDNA-enabled cancers. In addition to our three ecDTx programs described above, we have preclinically validated multiple additional ecDNA targets and have initiated ecDTx drug discovery efforts to identify potential candidates against such targets. We continue to deploy Spyglass to identify and preclinically validate additional ecDNA-essential targets, with the belief that such ecDNA targets could constitute future potential ecDTx development opportunities.
- ***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 ecDNA 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 afford an opportunity to selectively enter strategic collaborations involving ecDNA targets, our ecDTx, our ecDNA diagnostic test, 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., 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; Howard Hughes Medical Investigator; member of the National Academy of Sciences; current member of our Scientific Advisory Board.
- Ben Cravatt, Ph.D., Professor and Gilula Chair of Chemical Biology 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., Professor in the Department of Neurosurgery at Yale University School of Medicine.

In 2022, a team led by Dr. Mischel and multiple Boundless Bio scientific co-founders was declared as one of the winners of the Cancer Grand Challenges, a global initiative funded by Cancer Research UK (CRUK) and the National Cancer Institute (NCI), to further investigate the pathogenesis of ecDNA in cancer.

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, Loxo Oncology, Sierra Oncology, Halozyme Therapeutics, and Inhibrx, leading pharmaceutical companies such as Bristol-Myers Squibb, Genentech/Roche, Eli Lilly, Merck, and Novartis, and leading investment banks such as Morgan Stanley & Co. LLC and Goldman Sachs & Co. LLC.

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, Klaus Wagner, M.D., Ph.D., is a practicing oncologist who most recently served as Chief Medical Officer and Executive Vice President at Inhibrx (acquisition by Sanofi pending), where he led an integrated clinical development organization that was responsible for advancing three oncology programs from pre-IND into clinical development. Our Chief Financial Officer, Jami Rubin, most recently served as Chief Financial Officer at EQRx (acquired by Revolution Medicines) where she led the go public and capital raising process.

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 40 tyrosine kinase inhibitors (TKIs) for the treatment of cancer. This initial class of precision oncology drugs, also known as targeted therapies, generated more than $20 billion of worldwide sales in 2022. 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 benefitting relatively modest sized patient populations.

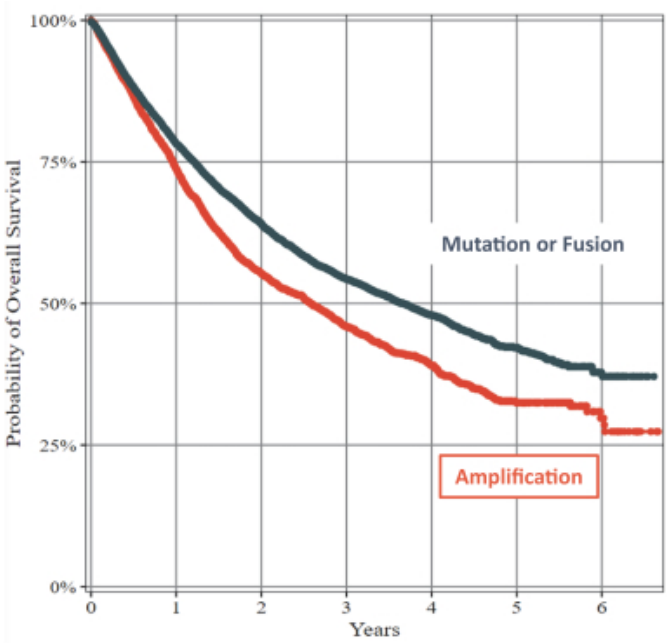
Despite these advances of the precision oncology field, treatment resistance is still an unfortunate inevitability in cancer. The predominant resistance mechanisms to targeted therapies are secondary mutations of the treatment target (e.g., $EGFR^{T790M}$, ALK^{G1202R}), other means of pathway activation, 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 forms of driver mutations of the same oncogenes.

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



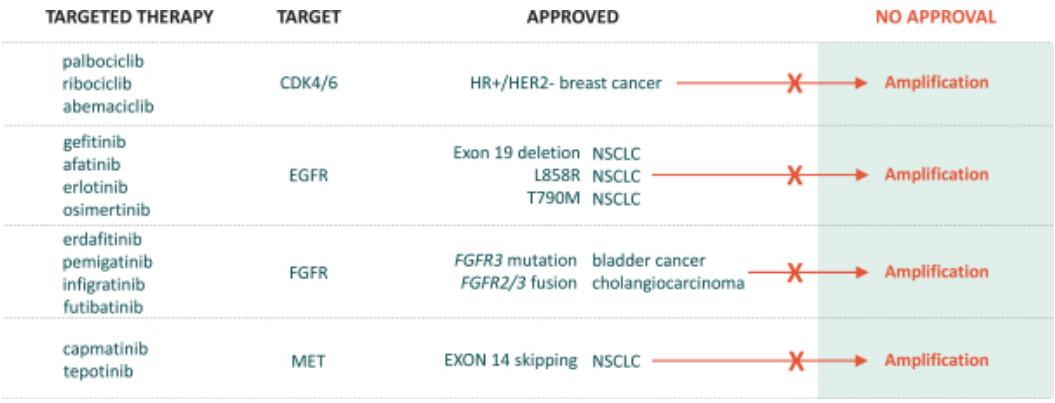
Patients with primary or metastatic cancers with amplifications, point mutations, fusions, or skipping deletions, of these genes: *AR, ALK, ARAF, BRAF, CCND1, CDK4, CDK6, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, MAP2K4, MDM2, MET, MYC, NF1, NRAS, NTRK1, NTRK2,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

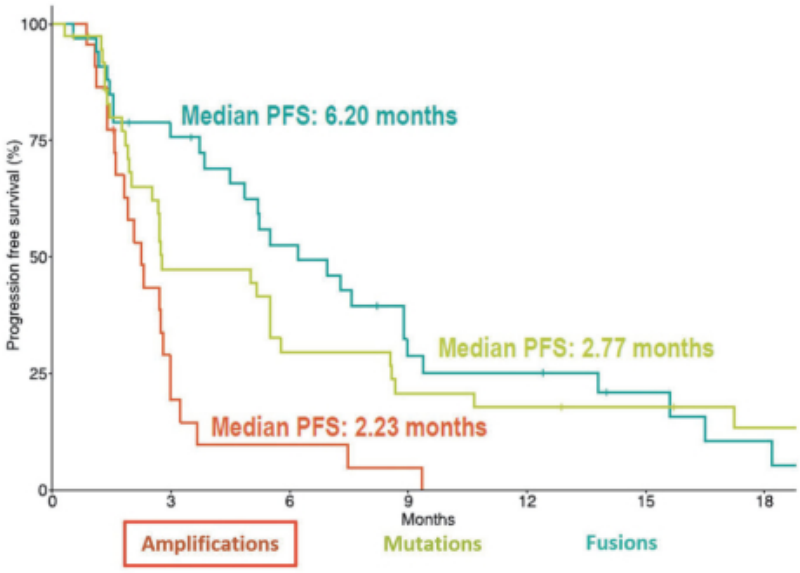
Despite the advancements in precision medicine and targeted therapies for these other forms of driver oncogene alterations, as well as immunotherapies for patients whose cancers lack driver oncogenes, both targeted therapies and immunotherapies have proven largely ineffective in oncogene-amplified cancers.

Examples of Targeted Therapies Not Approved for Oncogene Amplifications



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 is 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 170 FDA approved targeted therapies to date, only HER2 inhibitors 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)



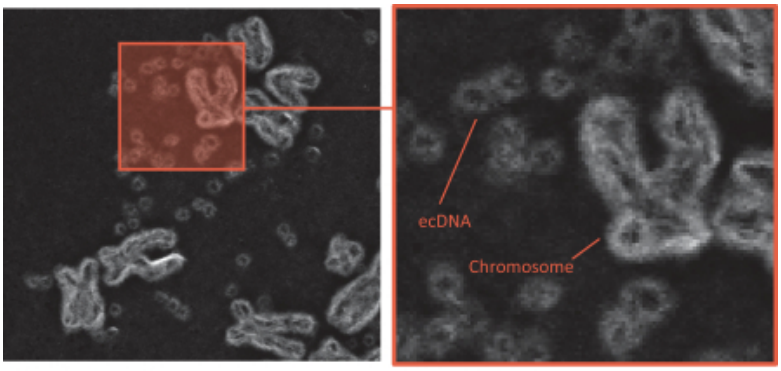
The presence of oncogene amplification is also associated with a lack of response when patients are treated with immunotherapies, for instance immune checkpoint inhibitors such as pembrolizumab. Furthermore, immune checkpoint inhibitors have been associated with rapid clinical worsening, known as hyper-progression, 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 (ecDNA) 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 have 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 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 unknown.

Microscopy Images of Chromosomes and ecDNA

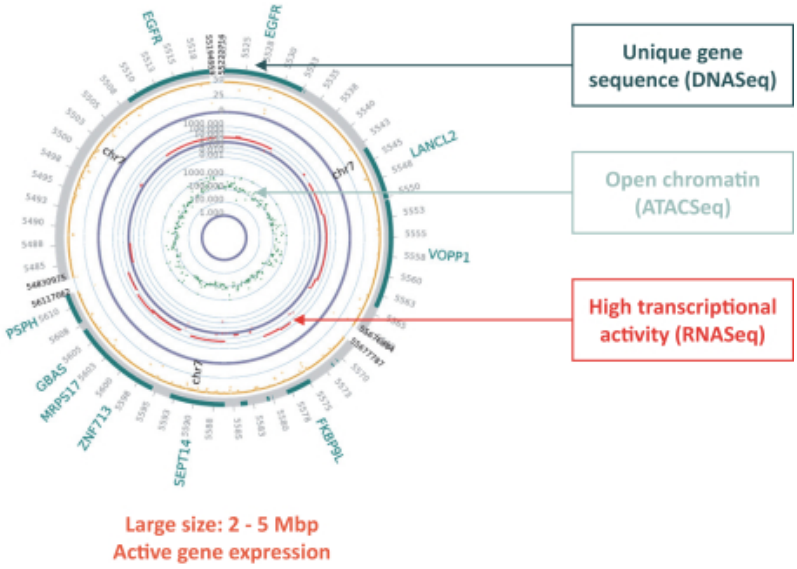


Some of the most common driver oncogenes, such as *EGFR*, *MYC*, *KRAS*, *FGFR*, etc., are found to be amplified on ecDNA and can confer a selective fitness advantage to cancer cells. Oncogenes amplified on ecDNA have several features that distinguish them from amplifications located on chromosomes,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

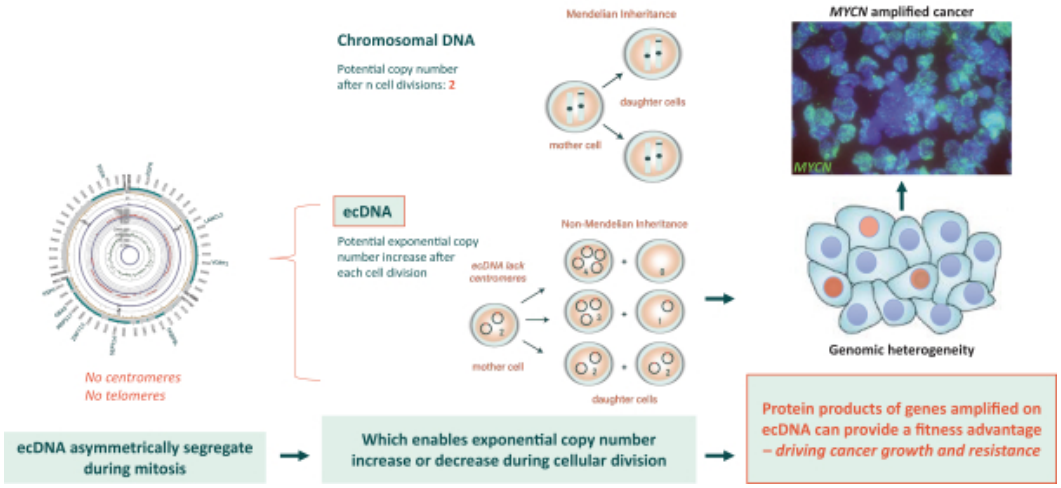
- ***Overexpression –*** Genes on ecDNA behave differently from genes on chromosomes because ecDNA are not properly regulated at the epigenetic level. ecDNA have a circular structure that is less tightly compacted compared to chromosomes, allowing easier access to their DNA. The easier access of the 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 ecDNA-bearing tumors to adapt and evade approved therapeutics such as targeted therapies.

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



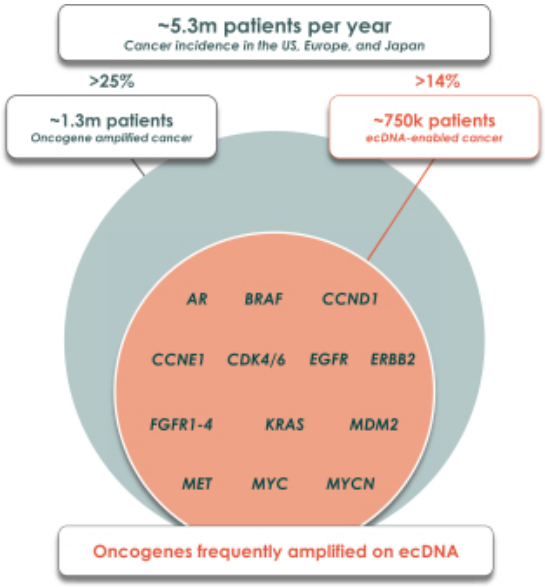
ecDNA Are Inherited via a Non-Mendelian Pattern, Leading to Genomic Heterogeneity



Until recently, the presence of ecDNA in cancer was thought to be a rare event, approximately 1.4% of cancers, and of unclear significance. 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 more than 14% of cancer patients, suggesting an incident population of approximately 750,000 new

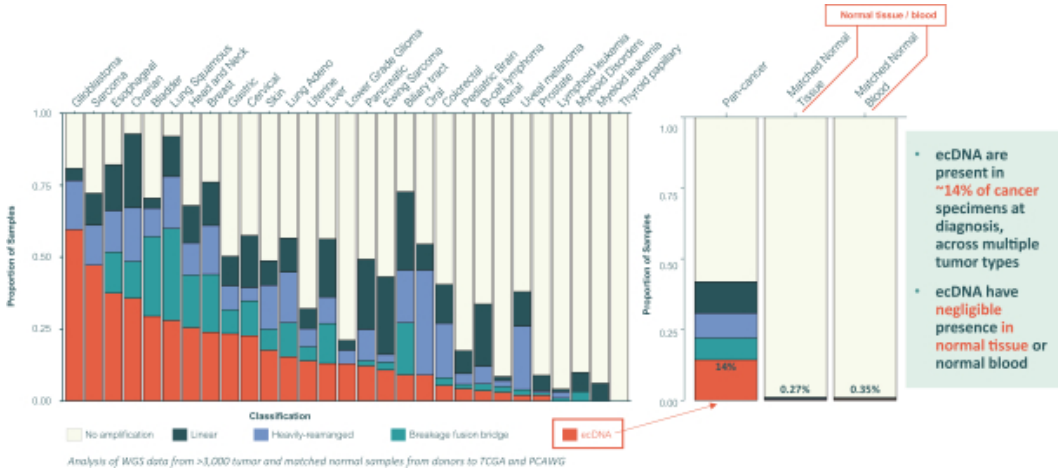
patients each year in the major addressable markets of the United States, European Union, and Japan, of which approximately 200,000 new patients are in the United States each year. More than half of all cancer cases with high-copy number gene amplification (copy number value >8) have been observed to 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



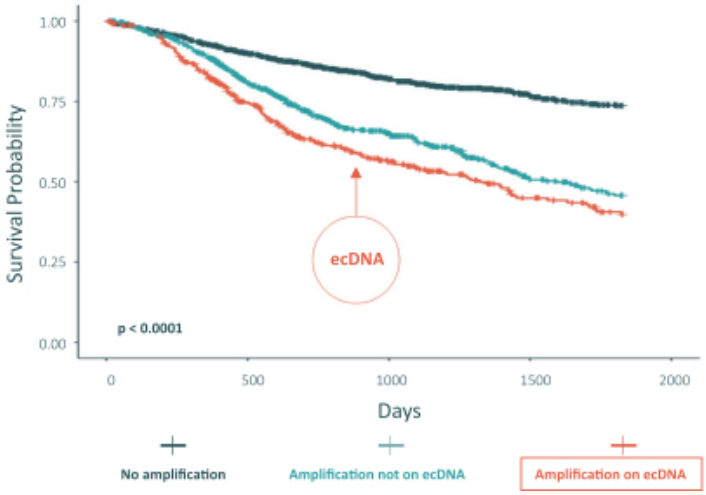
As seen in the figure below, many of the most aggressive tumor types contain the highest prevalence of ecDNA, including approximately 60% of glioblastomas and just under 50% of sarcomas. In fact, ecDNA was observed in more than 25% of the cases of the following tumor types: glioblastoma, esophageal cancer, sarcoma, ovarian cancer, bladder cancer, non-small cell lung cancer (NSCLC), squamous cell carcinoma, breast cancer, head and neck squamous cell carcinoma, and gastric cancer.

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



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

Patients with Oncogene Amplification on ecDNA Have Worse Survival

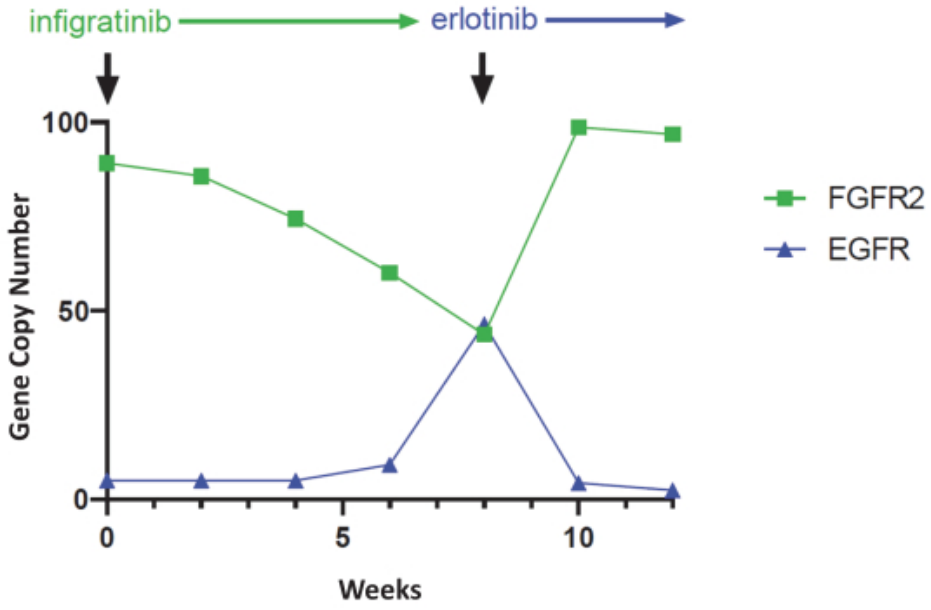


Role of ecDNA in Cancer's Resistance to Therapy

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

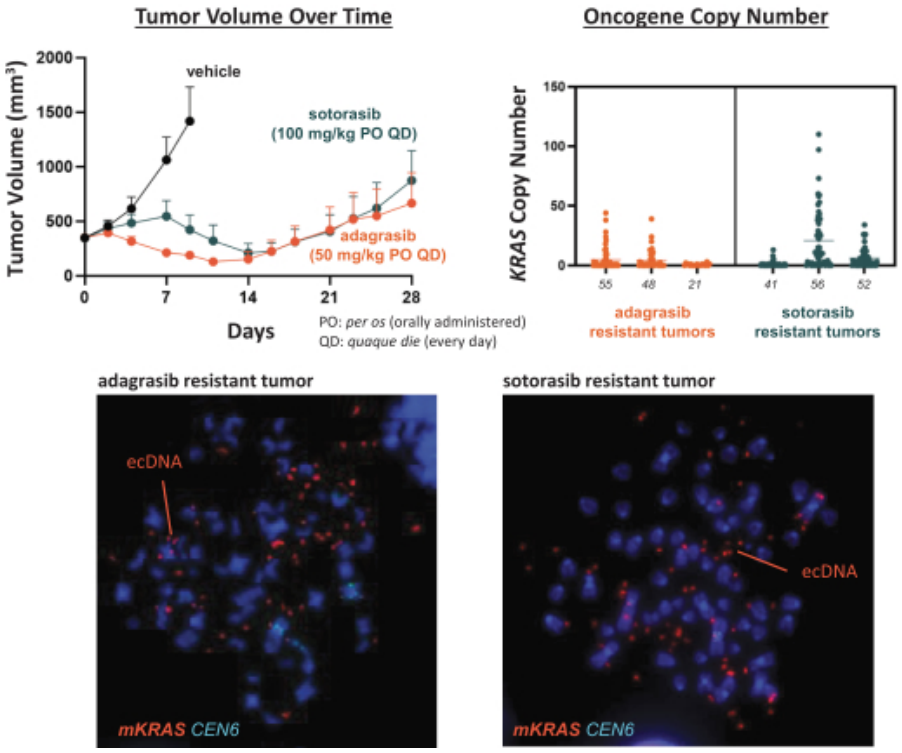
ecDNA's role in enabling resistance to molecular targeted therapies has been elucidated. For instance, as seen in the figure below, preclinical studies in a gastric cancer cell line containing *FGFR2* amplified on ecDNA demonstrated that cellular resistance to the pan-FGFR inhibitor infigratinib could 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 inhibition 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 clinically validated KRAS^{G12C} inhibitors, adagrasib and sotorasib.

Treatment of Colorectal Cancer Cells with KRAS^{G12C} Inhibitors Generated Resistance via Amplification of *KRAS^{G12C}* 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 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, resulting in a futile, clinical ‘whack-a-mole’ phenomenon. 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 developing drugs that interfere with the formation and function of ecDNA in cancer cells. 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 ecDNA 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 ecDNA-enabled tumor cell survival.

We explore the ecDNA lifecycle to identify nodes of synthetic lethality in ecDNA-enabled cancers. 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, 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 oncogene 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, replication, repair, and segregation.

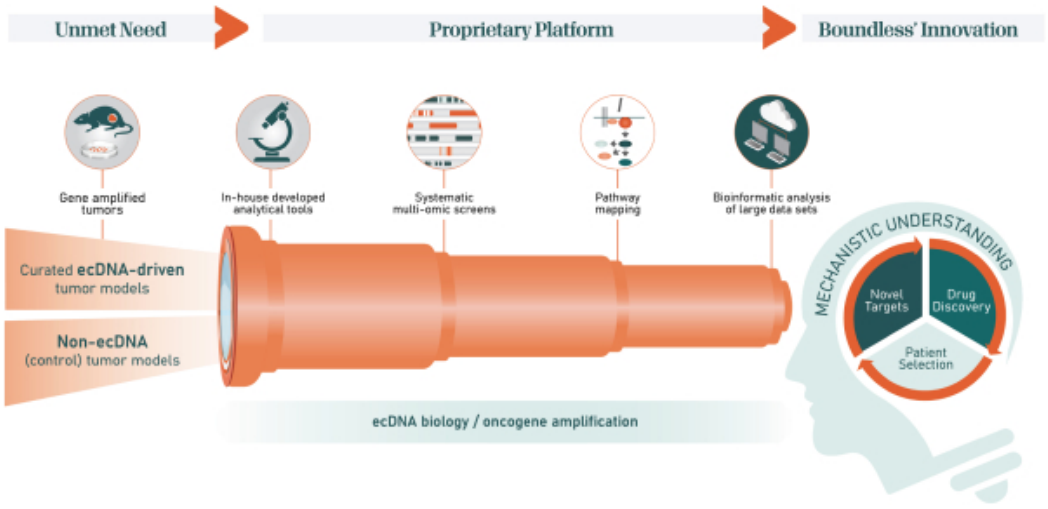
We are developing our ecDTx to be administered as single agents and in combination with other therapies. The rationale for a combination approach is based on the observation described above that applying targeted therapy, or other therapeutic, pressure to oncogene amplified cancer cells causes them to 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. Thus, our therapeutic approach is based on the concept of ecDNA-dependent synthetic lethality and uses a strategy to interfere with cancer’s ability to employ ecDNA 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 ecDNA-essential 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 ecDNA-enabled tumors.

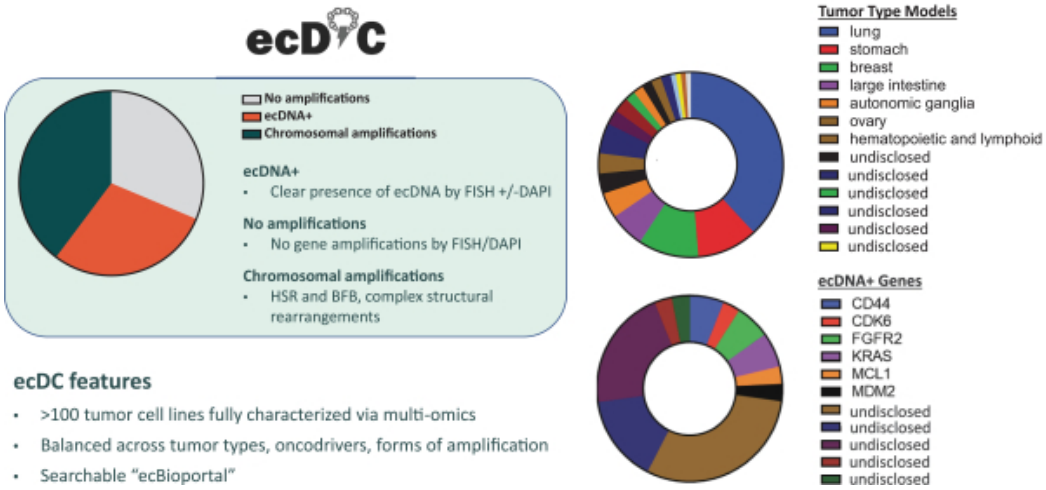
Spyglass Platform



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. We refer to this library as our ecDNA compendium (ecDC). The ecDC consists of more than 100 well characterized cancer models (*in vitro* and *in vivo*), including:
  - a panel of ecDNA-enabled models, representing multiple different tumor types, such as colorectal, gastric cancer, and sarcoma and multiple different oncodriver amplifications such as *EGFR*, *FGFR2*, *CDK4*, *KRAS*, and *MYC*;
  - a panel of matched control lines of various other states of 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.

ecDNA Compendium (ecDC)



- ***Analytical Tools –*** A suite of custom-built analytical tools designed to detect, quantify, characterize, monitor, and perturb ecDNA:
  - proprietary 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 for perturbation of ecDNA and ecDNA-enabled cancer cells.
- ***Bioinformatics Data –*** Large databases, both clinical and preclinical, to facilitate, substantiate, and contextualize ecDNA-related observations:
  - We analyze clinical databases of cancer patient genomic and clinical outcome data to support insights into ecDNA prevalence, patient populations, and clinical outcomes. Such analyses help us prioritize which tumor indications represent the largest opportunity and highest unmet need for our novel ecDTx.
  - Complementary to our use of clinical databases, we also use information from preclinical databases to support target identification, target validation, biological pathway mapping, and model library expansion.

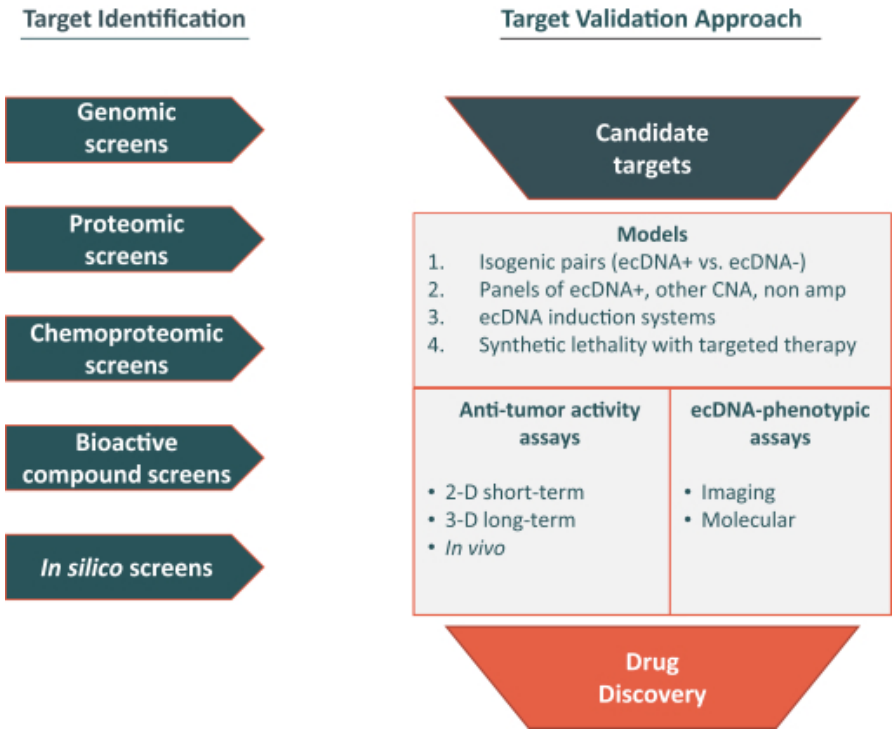
Target Identification and Validation

Through Spyglass, we have developed a sophisticated understanding of ecDNA biology and key cellular mechanisms that facilitate cancer cells' deployment of ecDNA to enable both tumor growth and development of resistance to therapeutic treatments. This understanding has given us new insight on how to disrupt ecDNA function 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 ecDNA 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 and ecDNA negative 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 gastric cancer, sarcoma, colorectal cancer, and various oncodriver amplifications, such as *EGFR*, *FGFR2*, *CDK4*, and *MYC*.

Target Identification and Validation Process



The ecDNA-essential 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 of ecDNA. 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 initiated drug discovery efforts, we also have multiple additional candidate targets for which we are currently pursuing preclinical target validation efforts. We believe that our ability to identify and pursue ecDNA-essential targets represents a unique capability and a sustainable engine for novel target identification, drug discovery, and value creation.

Our Pipeline of ecDNA-Directed Therapeutic Candidates (ecDTx)

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 and are developing novel drug candidates to intercept these nodes. Our drug discovery efforts span multiple ecDNA synthetic lethal targets, including:

- CHK1: a DNA replication checkpoint kinase target that manages the cellular response to RS arising from oncogene amplification on ecDNA;
- RNR: a cellular kinase target involved in the creation of nucleotide building blocks essential for ecDNA assembly and repair; and
- Kinesin: a target essential for ecDNA segregation and inheritance during cell division.

Our diversified ecDTx pipeline currently consists of three small molecule programs against both novel and known cancer targets. In addition, our Spyglass platform continues to yield new candidate targets for potential future drug discovery efforts.

Our Pipeline and Platform

Our Lead ecDTx: BBI-355 CHK1 Inhibitor

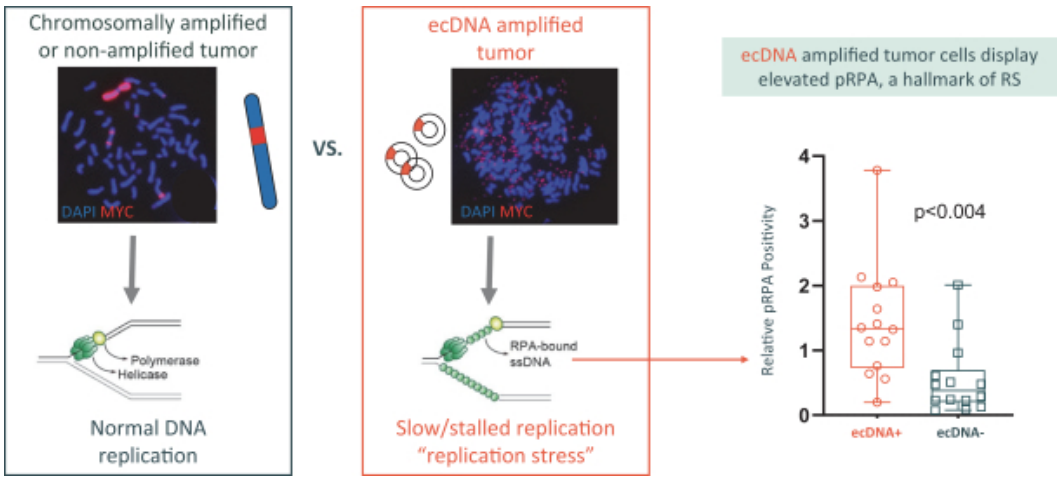
Our lead ecDTx, BBI-355, is a novel, oral, selective small molecule CHK1 inhibitor being studied in the ongoing first-in-human Phase 1/2 POTENTIATE clinical trial in patients with oncogene amplified cancers agnostic to tumor type. In preclinical models, BBI-355 showed inhibition of CHK1 in a host of tumor cell lines. CHK1 is a master regulator of cells' response to RS. RS is elevated in ecDNA-enabled oncogene amplified cancer cells and, because of this, represents a key vulnerability of those cells. BBI-355 is designed to exploit this elevated RS in ecDNA-enabled oncogene amplified cancer cells by disrupting proper CHK1 function in regulating RS and thereby facilitating catastrophic RS to preferentially kill cancer cells relative to healthy cells. We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies from the POTENTIATE trial in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=~30 to 40, combination cohorts N=~20 to 50).

CHK1 Synthetic Lethality in Oncogene Amplified Cancer

With every mammalian cell division, chromosomes comprised of billions of nucleotides must be precisely copied in coordination with the cell cycle to avoid dysregulated DNA replication or RS, which can lead to DNA damage, mis-segregation of genetic material, and, if unregulated, cell death. RS is characterized by uncoupling of the replicative helicase and DNA polymerase, slowdown of DNA synthesis, and/or replication fork stalling. These result in long stretches of fragile single stranded DNA (ssDNA) that is protected temporarily by binding to phosphorylated RPA protein (pRPA) to allow time for the rest of the cellular RS response to resolve any DNA damage. Low level RS is tolerated by cancer cells through an increased reliance on specific cellular machinery responsible for RS mitigation. In contrast, excessive RS can result in extensive DNA damage and cell death through replication and/or cell division catastrophe. Results from multiple *in vitro* studies suggest that cancer cells with gene amplifications on ecDNA exhibited elevated intrinsic levels of RS and were hypersensitive to further increases in RS, thus providing the rationale to leverage this liability as a therapeutic strategy to treat oncogene amplified cancers.

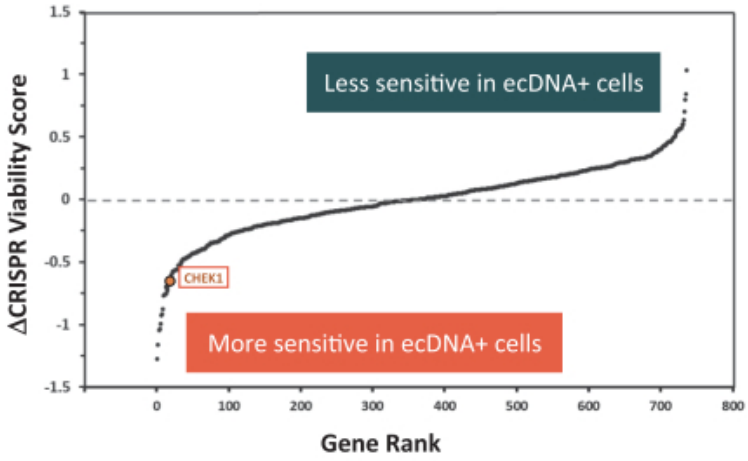
Circular ecDNA creates abnormally high accessibility of the DNA encoded on the circle, and those DNA remain accessible throughout the cell cycle. Open, accessible DNA is available to the cellular machinery for DNA replication and for RNA transcription. In healthy cells, these two processes are tightly coordinated so that cells do not replicate and transcribe the same regions of DNA at the same time. When transcription and replication do occur at the same time and place, transcription-replication collisions occur, resulting in stalled replication forks and RS. Consequently, tumor cells that have ecDNA also have colliding transcription and replication and are therefore under a great deal of RS, as detected by high pRPA levels. This elevated RS creates a unique, druggable, cancer-specific vulnerability.

ecDNA-enabled Cancer Cells Demonstrate Elevated Intrinsic Levels of RS



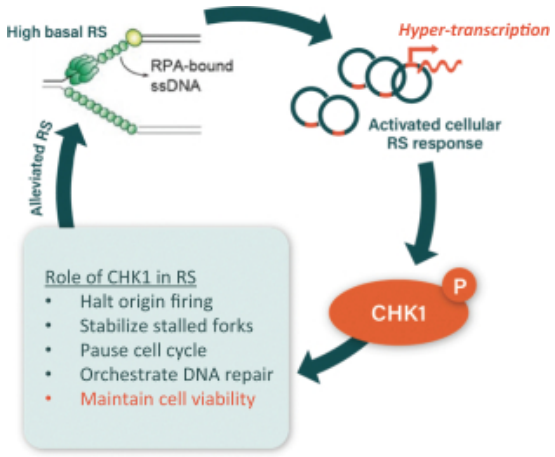
We are seeking to exploit this synthetic lethal relationship to identify druggable targets essential for survival of cells harboring ecDNA. To this end, as seen in the figure below, we conducted a CRISPR kinome screen in cancer cells resistant to the cancer drug methotrexate via amplification of the gene *DHFR* on ecDNA. In this ecDNA model system, genetic inactivation of the kinase CHK1 (encoded by *CHEK1*) resulted in enhanced cytotoxicity in ecDNA-enabled cells as compared to ecDNA negative cells, providing evidence of CHK1 as a potential drug target for ecDNA-enabled tumors.

CRISPR Kinome Screen Identified CHK1 (*CHEK1*) Inhibition as a Top Synthetic Lethality Hit in ecDNA-enabled Methotrexate Resistant (MTX-R) Cancer Cells



CHK1 is cells' master regulator of the RS response. CHK1 protects stalled DNA forks, manages DNA replication origin firing, temporarily arrests the cell cycle to allow time for DNA repair, and orchestrates repair through homologous recombination. As such, as seen in the figure below, CHK1 serves an essential role in managing RS, making it a potential therapeutic target for cancer therapy in tumors with high RS, such as those with ecDNA-enabled oncogene amplifications.

CHK1 is the Cellular Master Regulator of the Response to ecDNA-Induced RS



In our research, both genetic inactivation and pharmacological inhibition of CHK1 using structurally distinct inhibitors resulted in enhanced cytotoxicity to ecDNA-enabled cells compared to cells lacking ecDNA. This synthetic lethal relationship was observed across multiple preclinical models spanning different cancer indications and oncogene amplifications, such as *EGFR*, *FGFR2, CDK4, MYC,* and *MET*. CHK1 inhibition, both as a single agent and in combination with targeted therapy, resulted in tumor growth inhibition and tumor regressions, which correlated with reduced levels of ecDNA-based gene amplification and protein expression in ecDNA-enabled xenograft models.

Historical Challenges with CHK1 Inhibitor Development

CHK1 has been considered a cancer target for many years, and several biopharmaceutical companies have attempted to develop CHK1 inhibitors for cancer. In the past, a major challenge to developing CHK1 inhibitors to treat cancer was difficulty in accurately identifying tumors with high RS or other vulnerabilities that would respond well to this therapeutic approach. Despite strong preclinical data and preliminary evidence of clinical activity for CHK1 inhibition, including single agent responses in a small percentage of patients, no development programs have advanced to registration, which we believe is due to lack of adequate predictive biomarker(s) and optimal clinical development strategies. In addition, a range of other challenges have stalled the clinical advancement of prior CHK1 inhibitors. These challenges included suboptimal drug properties, potential compound scaffold-specific safety liabilities, such as potential cardiotoxicities and drug-drug interactions, as well as weak potency or selectivity. Furthermore, IV administered CHK1 inhibitors make continuous or chronic intermittent dosing, which we believe is critical for targeting ecDNA biology, more challenging.

Our Differentiated Approach

Through extensive preclinical studies in ecDNA-enabled oncogene amplified cancer models, we determined what we consider the optimal CHK1 inhibitor profile for targeting ecDNA-enabled tumors and designed our lead ecDTx, BBI-355, accordingly. We believe that with the optimized biochemical profile of BBI-355, alongside our differentiated precision oncology development strategy, coupled with our approach to identify patients with oncogene amplifications on ecDNA using our ecDNA diagnostic, we can overcome the challenges encountered with prior CHK1 inhibitors. BBI-355 showed picomolar biochemical inhibition of CHK1, low nanomolar activity in a host of tumor cell lines, and substantial antitumor activity in multiple ecDNA-enabled xenograft models representing several tumor types and

various driver oncogene amplifications. We are developing BBI-355 for the treatment of oncogene amplified solid tumors, including those with amplifications on ecDNA as detected by our proprietary ecDNA diagnostic.

Properties of BBI-355 observed in preclinical studies are shown below. BBI-355 is a novel, oral, selective small molecule inhibitor of CHK1, and we believe has a predicted low risk of drug-drug interaction and cardiovascular liabilities based on *in vitro* CYP and hERG/cardiomyocyte study results, respectively.

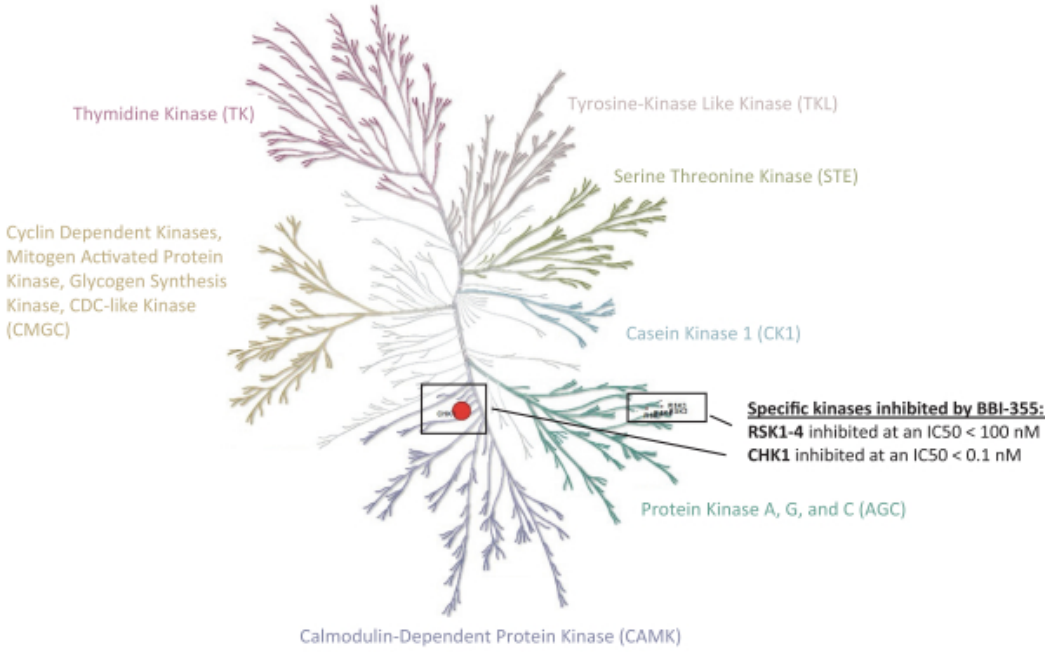
Preclinical Properties of BBI-355 CHK1 Inhibitor

PARAMETER	BBI-355
CHK1 TR-FRET IC_{50} nM	0.6
Kinase selectivity	185x CHK2
CHK1 cellular activity (target engagement, CHK1 phosphorylation, HT29) IC_{50} nM	16
Cellular activity CellTiter-Glo ecDNA+ COLO320 IC_{50} nM	13
CYP inhibition 1A2/2C9/2C19/2D6/3A4 (uM)	>30/>30/>30/22/>30
hERG inhibition (uM); cardiomyocyte assay	2.28; minimal activity @ 10 uM
CEREP/PanLabs profile	No off-target activity, 0/47 hits
PO bioavailability (rat, dog), %F	33-43

BBI-355 In Vitro Preclinical Data

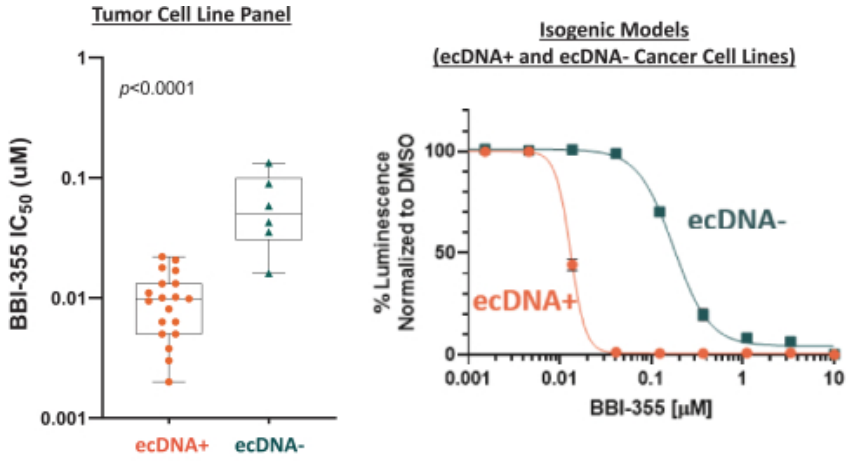
BBI-355 was first characterized extensively *in vitro*. As seen in the figure below, the kinase selectivity of BBI-355 was evaluated in a broad screen, displaying minimal off-target activity and with high selectivity across the kinome.

Kinase Selectivity of BBI-355

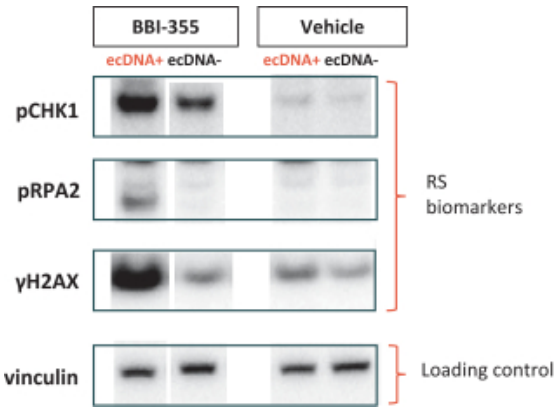


As seen in the figure below, BBI-355 demonstrated broad cytotoxicity against a host of tumor cell lines, with IC_{50} ranges from ~5 nM – 200 nM. Consistent with the enhanced reliance that ecDNA-enabled oncogene amplified cancer cells have on CHK1 due to their intrinsic elevated RS, we have observed increased sensitivity in ecDNA-enabled cancer cell lines over ecDNA negative cancer cell lines. This observation was exemplified using a near isogenic matched cell line pair of colorectal cancer cell lines (COLO320 ecDNA-enabled (+) versus COLO320 ecDNA (-)), wherein BBI-355 was approximately 10-fold more cytotoxic in ecDNA-enabled cells. Importantly, the potency of cytotoxicity in the ecDNA-enabled cancer cells paralleled the IC_{50} for cellular biomarkers of RS, including pRPA, pCHK1, and gH2AX.

BBI-355 Demonstrated Increased *In Vitro* Activity in ecDNA+ Versus ecDNA- Cancer Cells



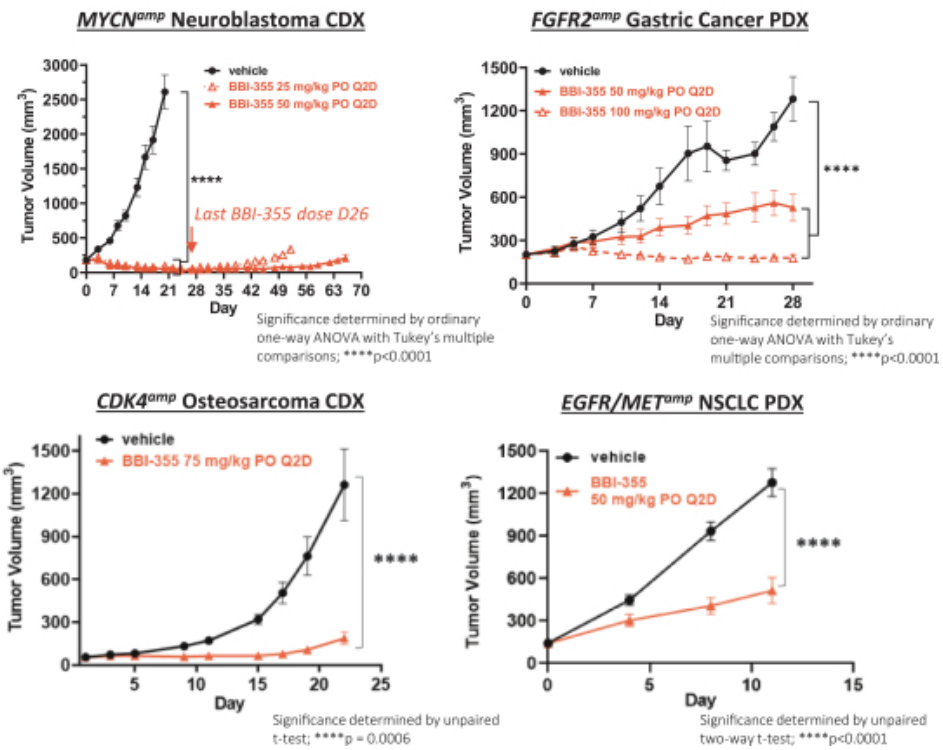
BBI-355 Preferentially Increased RS in ecDNA+ Oncogene Amplified Cancer Cells



BBI-355 Single Agent In Vivo Preclinical Data

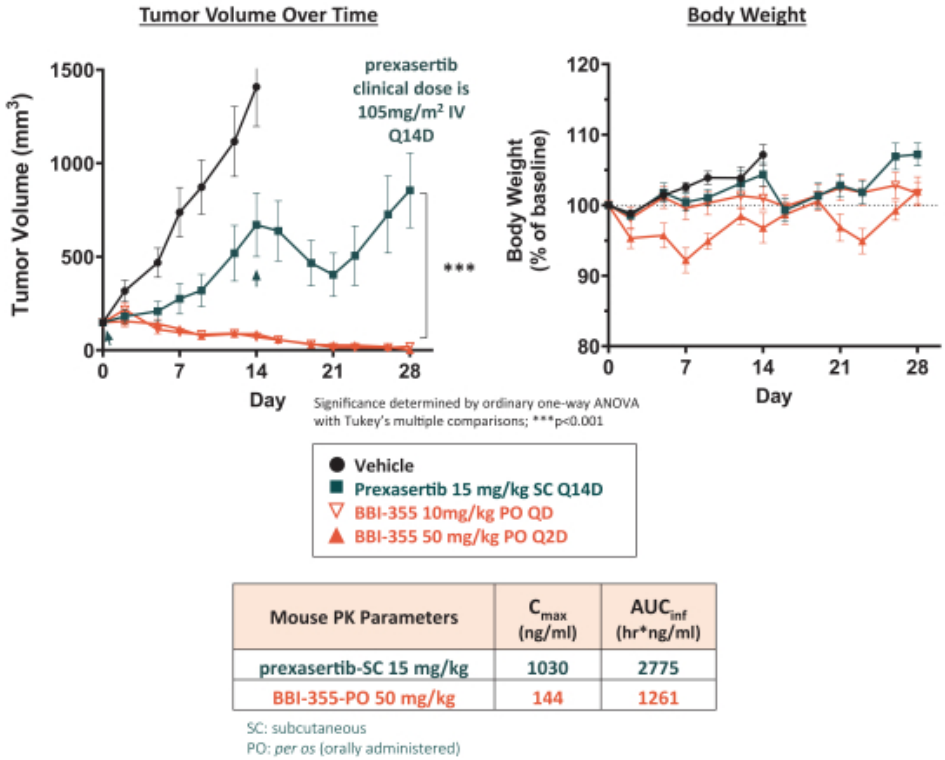
As seen in the figure below, the antitumor activity of BBI-355 was further exemplified *in vivo* in multiple ecDNA-enabled xenograft models representing several tumor types and various driver oncogene amplifications. Orally administered BBI-355 demonstrated single agent activity, including regressions in several cases, in an ecDNA-enabled *CDK4* amplified osteosarcoma CDX model, ecDNA-enabled *EGFR & MET* amplified NSCLC PDX model, ecDNA-enabled *MYCN* amplified neuroblastoma CDX model, and ecDNA-enabled *FGFR2* amplified gastric cancer PDX model.

BBI-355 Demonstrated Single Agent *In Vivo* Activity Across Multiple ecDNA+ Oncogene Amplified Models



Another CHK1 inhibitor currently in clinical development is prexasertib, which is administered IV every 14 days to patients with cancer. In order to assess the utility of oral administration of a CHK1 inhibitor, BBI-355 administered orally daily or every other day was compared to prexasertib administered subcutaneously (SC) every 14 days to mimic clinical IV administration, in a head-to-head study in a *MYCN* amplified mouse xenograft neuroblastoma model. In this preclinical study, as seen in the figure below, the more frequent oral dosing strategy of BBI-355 demonstrated statistically significant superior antitumor activity compared to both the vehicle and prexasertib, as measured by tumor growth inhibition, without increased toxicity, as measured by body weight gain. Notably, the prexasertib dose of 15 mg/kg SC every 14 days in this mouse study delivered equivalent therapeutic exposure, with matching area under the curve (AUC), to the reported clinical exposure at the human recommended Phase 2 dose (RP2D) of 105 mg/m^2 IV every 14 days.

Head-to-Head Comparison of BBI-355 and Prexasertib *In Vivo* Antitumor Activity, Tolerability, and Pharmacokinetics as a Single Agent in a *MYCN* Amplified Neuroblastoma CDX Model



Mouse PK Parameters	C_{max} (ng/ml)	AUC_{inf} (hr*ng/ml)
prexasertib-SC 15 mg/kg	1030	2775
BBI-355-PO 50 mg/kg	144	1261

SC: subcutaneous
PO: *per os* (orally administered)

BBI-355 Combination In Vivo Preclinical Data

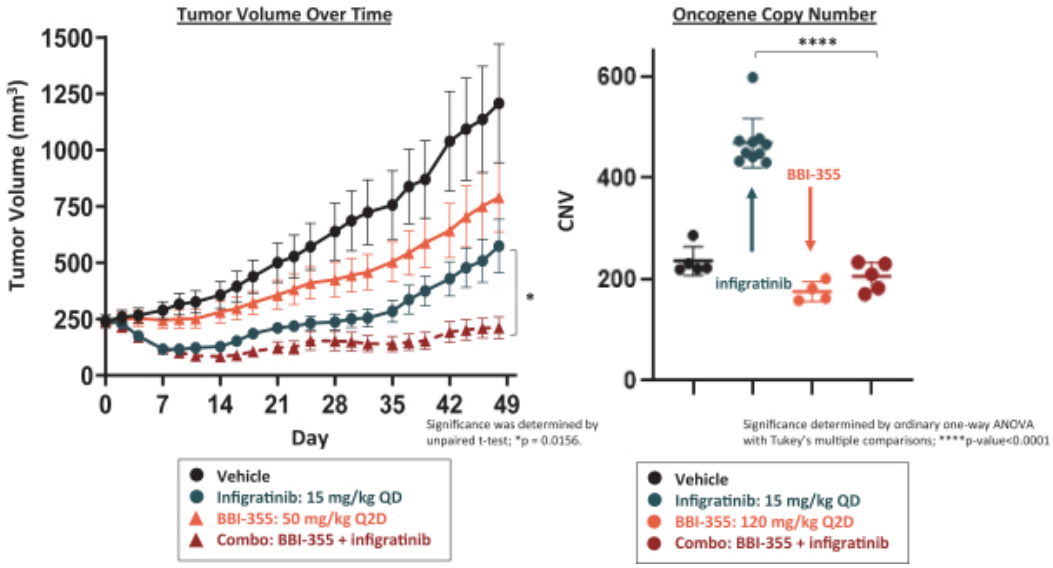
Cancers that harbor amplified oncogenes, such as *EGFR, FGFR, or CDK4*, typically do not respond well to single agent targeted therapies. We believe this is because ecDNA can facilitate rapid genomic plasticity, leading to resistance to selective therapeutic pressure. We believe this ecDNA-enabled resistance to targeted therapies can be overcome by combining our ecDTx, such as BBI-355, with targeted agents to interrupt the potential for ecDNA to facilitate resistance. We believe that this ecDTx and targeted therapy combination strategy may be effective across multiple different oncogene cargos encoded on the ecDNA and may lead to higher response rates, deeper regressions, and longer duration of responses as compared to single agent targeted therapies.

Preclinically, we have observed that applying targeted therapy pressure to tumors with ecDNA-enabled oncogene amplification induced tumor cells to evade such pressure via ecDNA-based resistance mechanisms, further increasing RS and reliance on CHK1. Accordingly, and consistent with the vice grip analogy described above, BBI-355 demonstrated combination activity when administered alongside targeted therapies in ecDNA-enabled oncogene amplified xenograft models that are generally resistant to treatment with targeted therapies alone.

As an example, in the figure below, oral administration of BBI-355 led to tumor regressions when dosed in combination with the FGFR inhibitor infigratinib in an ecDNA-enabled *FGFR2* amplified gastric cancer CDX model. In this model, treatment with single agent infigratinib led to rapid resistance via

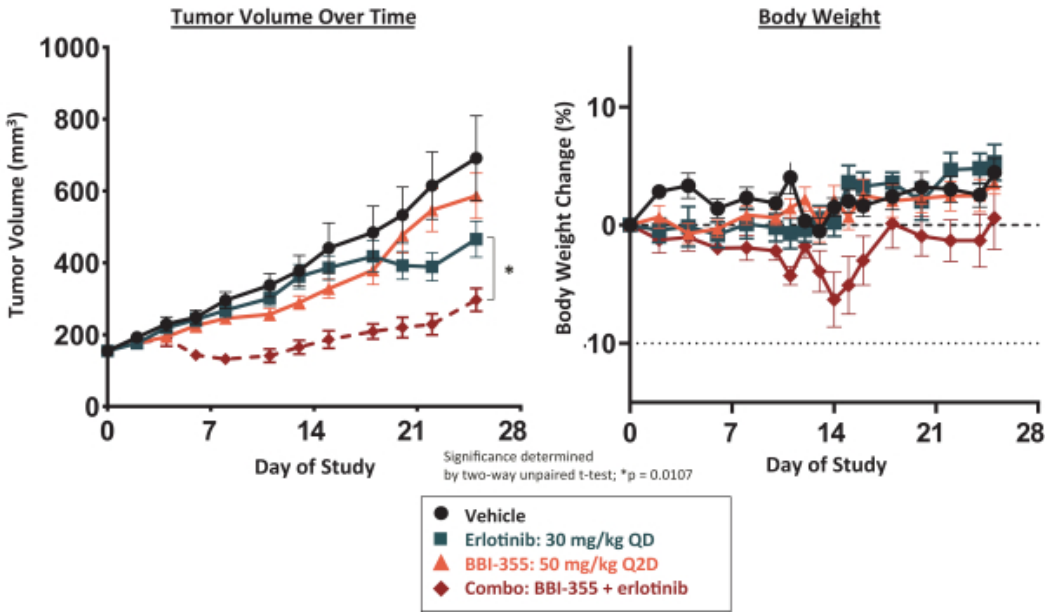
ecDNA-enabled amplification of *FGFR2*. Combining BBI-355 with infigratinib inhibited this resistance and induced tumor regressions. Pharmacodynamic (PD) analysis demonstrated that BBI-355 inhibited the expected increase in *FGFR2* copy number that would otherwise be caused by single agent infigratinib to confer resistance to infigratinib.

BBI-355 *In Vivo* Antitumor Activity in Combination with Infigratinib in an ecDNA-enabled *FGFR2* Amplified Gastric Cancer CDX Model



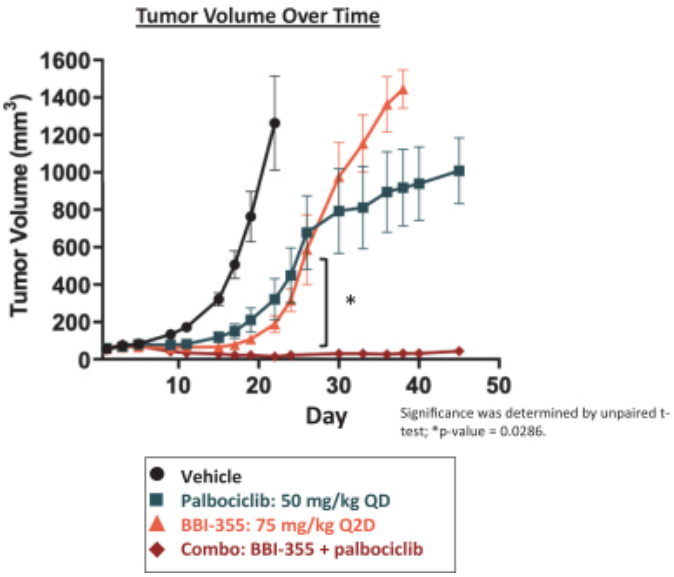
The oncogene cargo-agnostic nature of this combination approach is reflected in a second ecDNA-enabled *EGFR* amplified patient-derived gastric cancer xenograft model. In this model, monotherapy treatment with the EGFR inhibitor erlotinib resulted in limited antitumor activity, as seen in the figure below. However, combination with orally administered BBI-355 resulted in statistically significant greater and longer tumor growth inhibition, including regressions in some cases.

BBI-355 *In Vivo* Antitumor Activity in Combination with Erlotinib in an ecDNA-enabled *EGFR* Amplified Gastric Cancer PDX Model



As seen in the figure below, oral administration of BBI-355 similarly led to tumor regressions when dosed in combination with the CDK4/6 inhibitor palbociclib in an ecDNA-enabled *CDK4* amplified osteosarcoma CDX model. In this model, treatment with single agent palbociclib led to rapid resistance. Combining BBI-355 with palbociclib inhibited this resistance and induced tumor regressions.

BBI-355 *In Vivo* Antitumor Activity in Combination with Palbociclib in an ecDNA-enabled *CDK4* Amplified Osteosarcoma CDX Model



BBI-355 Clinical Development Plan

Through a comprehensive analysis of the prevalence of ecDNA-enabled gene amplifications alongside clinical outcomes associated with the use of targeted therapies, we have identified specific high unmet need patient populations with oncogene amplified cancers. For our initial targeted indications for clinical development, we are prioritizing cancers with wildtype *EGFR* amplifications, *FGFR1-4* amplifications, or *CDK4/6* amplifications.

In May 2023, we enrolled the first patient in our ongoing Phase 1/2 clinical trial of BBI-355 in patients with oncogene amplified cancers. The title of the trial (NCT05827614) is: “An Open-Label, Multicenter, First-in-Human, Dose-Escalation and Dose-Expansion, Phase 1/2 Study of BBI-355 and BBI-355 in Combination with Select Targeted Therapies in Subjects with Locally Advanced or Metastatic Solid Tumors with Oncogene Amplifications.” We also call the trial POTENTIATE, for Precision Oncology Trial Evaluating Novel Therapeutic Interrupting Amplifications Tied to ecDNA. We expect to have preliminary proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies from the POTENTIATE clinical trial in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=~30 to 40, combination cohorts N=~20 to 50).

The design of the trial is an open-label, non-randomized, three-part, Phase 1/2 clinical trial to evaluate the safety and tolerability, human pharmacokinetics (PK), PD biomarkers and preliminary

antitumor activity, as well as identify the maximum tolerated dose (MTD) and RP2D of BBI-355 administered as a single agent or in combination with select targeted therapies. In the trial, BBI-355 is administered orally every other day (Q2D) or on less frequent dosing schedules to patients with locally advanced or metastatic non-resectable solid tumors harboring oncogene amplifications, agnostic of tumor type, whose disease has progressed despite all standard therapies or for whom no further standard or clinically acceptable therapy exists. The trial has three parts: Part 1 is a dose escalation of BBI-355 as a single agent and will include a single agent dose expansion cohort at the RP2D in patients with platinum-resistant high-grade serous ovarian cancer or endometrial cancer. Parts 2 and 3 of this trial will be conducted in 3 separate modules, each module testing the combination of BBI-355 with one of the selected targeted therapies, EGFR (module 1), pan-FGFR (module 2), or CDK4/6 (module 3) inhibitors, in patients with cancers harboring amplification of *EGFR*, *FGFR1-4*, or *CDK4/6*, respectively. Notably, patients will be excluded from enrollment in any part of the trial if they harbor other pathogenic driver oncogene alterations, for example *EGFR*, *FGFR3*, *KRAS*, *BRAF* mutations or *ALK*, *NTRK*, *FGFR2, RET, ROS1* fusions.

In Part 1 of the trial, patients with amplification of driver oncogenes, as determined by standard NGS testing, are eligible for enrollment. The goal of Part 1 is to evaluate the safety, tolerability, PK and PD of single agent BBI-355, to determine the RP2D and MTD of BBI-355, and to evaluate preliminary single agent antitumor activity in patients with oncogene amplifications. Single agent BBI-355 will be further tested in a dose expansion cohort at the RP2D in platinum-resistant high-grade serous ovarian cancer or endometrial cancer patients with oncogene amplifications.

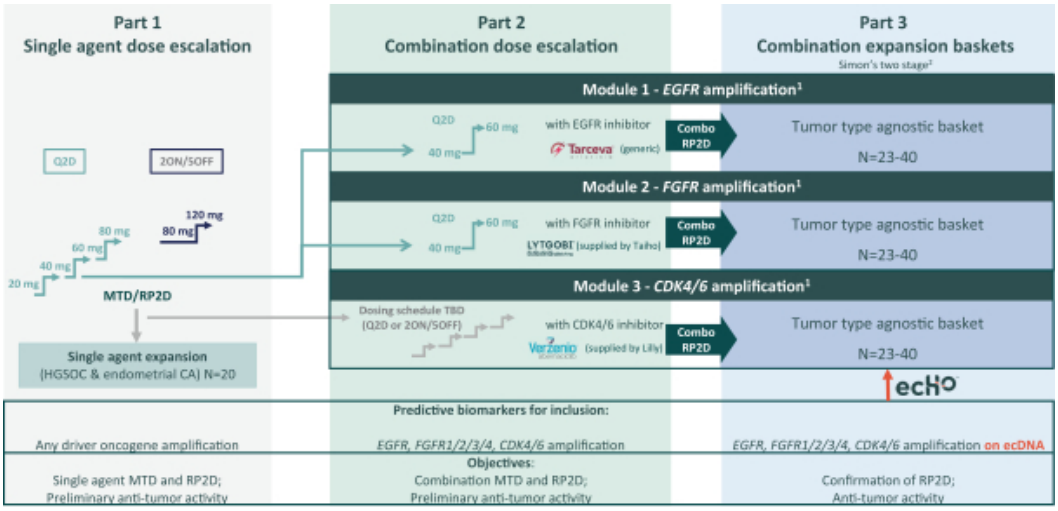
In Part 2 of the trial, patients with amplification of driver oncogenes of interest, *EGFR*, *FGFR1-4*, or *CDK4/CDK6*, as determined by standard NGS testing, will be enrolled in the corresponding module. The goal of Part 2 is to evaluate safety, tolerability, PK, and PD, as well as the RP2D and MTD, and to evaluate preliminary antitumor activity of BBI-355 in combination with the respective targeted therapy inhibitor studied in each module, that is the EGFR inhibitor erlotinib (module 1), pan-FGFR inhibitor futibatinib (module 2), or CDK4/CDK6 inhibitor abemaciclib (module 3).

In Part 3 of the trial, patients with amplification of oncogenes of interest, *EGFR*, *FGFR1-4*, or *CDK4/CDK6*, enabled by ecDNA as determined by testing with our ecDNA diagnostic clinical trial assay (see “Our Precision Medicine Approach” below), will be enrolled. The goal of Part 3 is to further evaluate combination antitumor activity at the combination RP2D.

We have entered into clinical trial collaboration and supply agreements with each of Taiho Oncology and Eli Lilly providing for no-cost supply of futibatinib and abemaciclib, respectively, for use in the applicable modules of Parts 2 and 3 of this trial (which agreements also provide for the sharing of certain clinical trial data but have no financial obligations and terminate upon conclusion of the trial).

It is anticipated that approximately 200 to 300 patients will be enrolled in total in this trial. Should any cohort of the trial demonstrate compelling signs of clinical antitumor activity, along with acceptable safety and tolerability, we would seek to engage with the FDA and other global regulatory bodies to discuss potential registrational paths, including the designs of any additional clinical trials we may need to conduct to support potential registrations for BBI-355. We may also consider expanding this trial with additional matched targeted agent and oncogene amplification cohorts based on our ongoing research and the dynamic clinical therapeutic landscape.

Design of BBI-355 Phase 1/2 POTENTIATE Clinical Trial



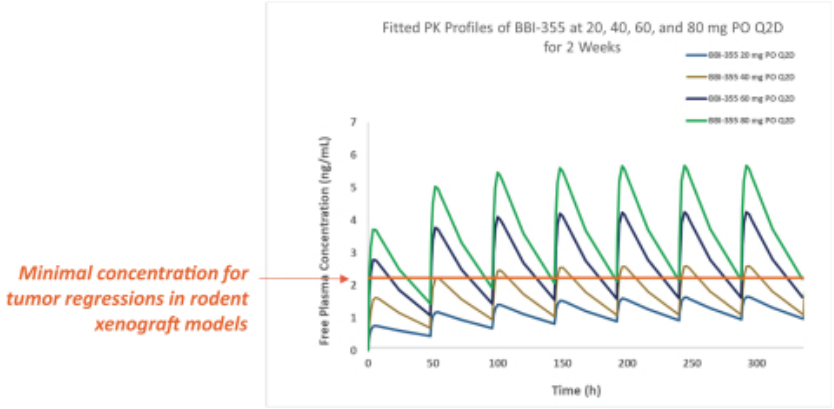
Preliminary Results from Part 1 of the POTENTIATE trial

Preliminary data from the ongoing POTENTIATE trial as of the dates noted below have been obtained from 22 subjects enrolled across six dosing cohorts in Part 1 of the trial. Subjects have been treated or are ongoing on an oral Q2D dosing regimen in escalating dose cohorts of 20 mg (N=3), 40 mg (N=4), 60 mg (N=3), and 80 mg (N=4), and on an oral 2 days on and 5 days off weekly dosing regimen (2ON/5OFF) at 80 mg (N=5) and 120 mg (N=3).

Phase 1 Preliminary PK, PD, and Antitumor Activity Data

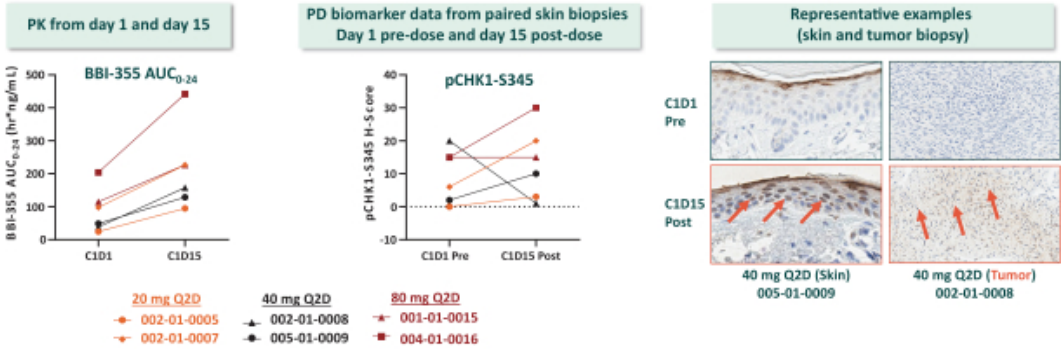
Preliminary PK data analysis as of February 21, 2024, revealed good oral bioavailability of BBI-355 across the dosing range, including a dose proportional increase of Cmax and AUC values, with some inter-subject variability. The average half-life of BBI-355 was approximately 40 hours, and average drug accumulation was approximately 2 to 3-fold from day 1 to steady state. Average PK exposures at the 40 mg, 60 mg, and 80 mg Q2D doses achieved or exceeded the minimum PK concentration required for tumor regression in certain rodent cancer xenograft models.

BBI-355 Preliminary Multi-Dose Fitted Human PK Data



A clinical PD assay measuring pCHK1 by immunohistochemistry (IHC) showed CHK1 target engagement in skin punch biopsies across the dosing range as well as in tumor tissue of one patient who consented to serial tumor biopsy.

BBI-355 Preliminary Human PD Data (pCHK1 in serial biopsy)



As for preliminary clinical antitumor activity, stable disease (per RECIST 1.1 criteria) has been observed in five of eighteen RECIST evaluable subjects, including regression of target lesions by approximately 20% in a patient with metastatic breast cancer harboring oncogene amplifications who has been a subject in the POTENTIATE trial for approximately six months and is continuing in the trial.

Phase 1 Safety and Tolerability Data

Preliminary clinical safety data as of the data cut-off date of March 4, 2024, showed that, BBI-355 has been generally well-tolerated at the first three dose levels (20 mg, 40 mg, 60 mg) administered Q2D, without any dose-limiting toxicities (DLTs) or drug-related serious adverse events (SAEs). At the 80 mg Q2D dose level, DLTs, specifically Grade 4 platelet count decreased and neutrophil count decreased, occurred in two of four subjects, and this dose level was determined to exceed the target toxicity rate. Therefore, 60 mg was determined to be the MTD with this dosing regimen.

BBI-355 was also evaluated on a 2ON/5OFF dosing regimen. Preliminary clinical safety data in this dosing regimen, showed that, as of the data cut-off date of March 4, 2024, BBI-355 has been generally well tolerated at the first dose level (80mg), with one DLT, specifically, administration of less than 70% of the intended dose in the DLT evaluation period due to an adverse event of Grade 4 neutrophil count decreased, in one out of five subjects at this dose level. At the 120 mg 2ON/5OFF dose level, DLTs occurred in two of three subjects, specifically one subject experienced a Grade 4 platelet count decreased and a second subject experienced an administration of less than 70% of the intended dose in the DLT evaluation period following Grade 4 neutrophil count decreased, and therefore this dose level was determined to exceed the target toxicity rate or MTD.

We may consider evaluating other dose levels or dosing schedules to further inform the single agent RP2D and dosing schedule before proceeding to Part 1 dose expansion in platinum-resistant high-grade serous ovarian cancer or endometrial cancer. We anticipate that in the enrolled subjects continuing in the trial as well as those we may enroll in potential future dose escalation cohorts, we may observe toxicities that are novel or on-target class effects for CHK1 inhibitors, which may also constitute DLTs and/or drug-related SAEs.

The most common reported drug-related adverse events (i.e., number of subjects with a specific adverse event) and across all dosing cohorts were neutrophil count decreased or neutropenia (N=4), fatigue (N=4), nausea (N=4), platelet count decreased (N=3), lymphocyte count decreased (N=3), white blood cell count decreased (N=3), diarrhea (N=3), vomiting (N=2), urinary frequency (N=2), headache (N=2), anorexia or loss of appetite (N=2), and dry skin (N=2). Two subjects experienced drug-related SAEs; a Grade 4 platelet count decreased and Grade 4 neutrophil count decreased in one subject, while the other subject experienced Grade 3 anemia leading to hospitalization. All observed hematologic toxicities were asymptomatic, are considered an on-target class effect for CHK1 inhibitors, and have been reported for several other clinical stage CHK1/2 inhibitors.

Based on the totality of the clinical safety, PK, PD, and antitumor activity observed to date, the POTENTIATE trial has recently advanced into Part 2 of the study, with BBI-355 40 mg Q2D to be administered with the respective combination therapies, and with the intention to escalate to BBI-355 60 mg Q2D to be administered with the respective combination therapies. Based on our preclinical pharmacology data and human PK data, we believe 60 mg Q2D to be in the therapeutically active exposure range.

Addressable Patient Populations for BBI-355

We estimate that BBI-355, if approved for the combination indications we are targeting in the POTENTIATE trial, could address an initial potential U.S. patient population of approximately 30,000 new patients per year with *EGFR*, *FGFR1-4*, or *CDK4/6* amplifications on ecDNA across a broad range of tumor types. Beyond the United States, we estimate that BBI-355, if approved for such indications, could address approximately 40,000 such patients in the European Union and over 10,000 such patients in Japan, representing a total potential addressable patient population of 80,000 new patients annually in the United States, European Union, and Japan. Our goal is to achieve a tumor agnostic label for BBI-355 in combination with targeted therapies (e.g., an EGFR inhibitor, a pan-FGFR inhibitor, and a CDK4/6 inhibitor) for each of these settings. Guided by our ecDNA diagnostic test, we are evaluating basket trial cohorts of each of these indications and treatment settings.

- ***EGFR Amplified Tumor Types*** – Using U.S. SEER incidence data by tumor type and adjusting for ecDNA prevalence, we estimate a potential patient population of approximately 5,000 new patients annually in the United States alone for *EGFR* amplifications. This estimate includes patients with esophageal and gastric cancer, head and neck squamous cell carcinoma, NSCLC squamous cell carcinoma, and other tumor

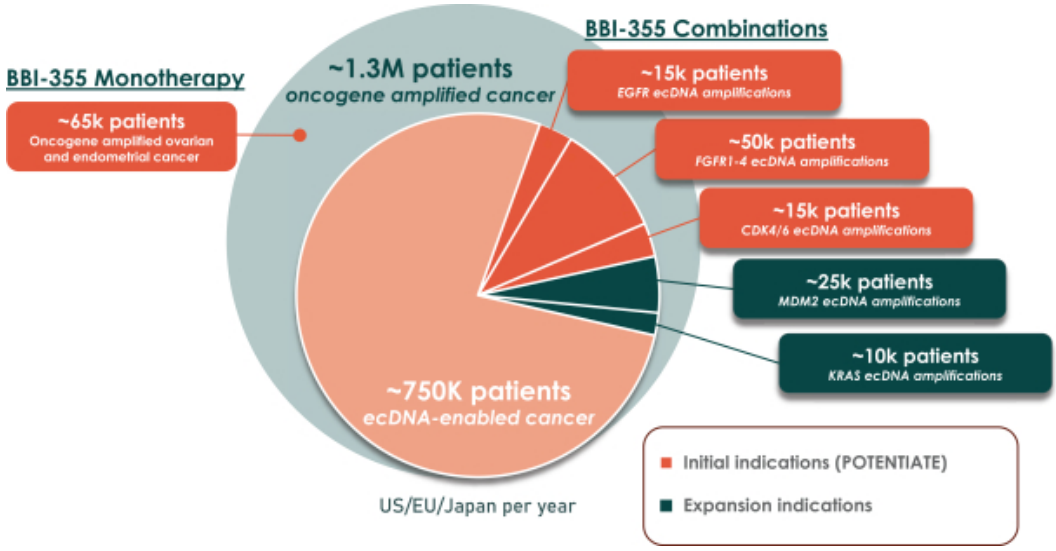
types that exhibit *EGFR* driver oncogene amplifications on ecDNA, with the potential to expand to glioblastoma, which has high ecDNA prevalence.

- ***FGFR1-4 Amplified Tumor Types*** – The potential *FGFR1-4* amplified patient population, including early and late stage metastatic, represents up to approximately 18,000 new patients annually in the United States alone. This population includes patients with breast cancer, NSCLC squamous cell carcinoma, esophageal and gastric cancer, bladder cancer, and other tumor types that exhibit *FGFR1-4* driver oncogene amplifications on ecDNA.
- ***CDK4/6 Amplified Tumor Types*** – The potential *CDK4/6* amplified patient population, including early and late stage metastatic, represents approximately 6,000 new patients annually in the United States alone. This population includes patients with liposarcoma, NSCLC squamous cell carcinoma, esophageal and gastric cancer, and other tumor types that exhibit *CDK4/6* driver oncogene amplifications on ecDNA, with the potential to expand to glioblastoma.

We also estimate that BBI-355, if approved for the monotherapy indications we are targeting in the POTENTIATE trial, could address a total potential patient population of approximately 65,000 new patients per year with high-grade serous ovarian cancer or endometrial cancer, each with oncogene amplification, in the United States, European Union, and Japan.

In addition to the gene amplified cancer types described above, we are currently conducting preclinical studies of BBI-355 in *MDM2* amplified cancers and non-mutated *KRAS* amplified cancers; in the future, we intend to pursue additional gene amplified tumor settings as well. Clinical success in one or more of these indications could expand the potential addressable patient population for BBI-355.

Initial Indications for BBI-355 May Represent a Total Addressable Population of 145,000 New Patients in the United States, the European Union, and Japan Each Year



Central Nervous System (CNS) Penetrant CHK1 Inhibitor Program: BBI-098

In addition to BBI-355, we have also identified a second CHK1 inhibitor candidate with a differentiated profile from BBI-355. This novel ecDTx compound, BBI-098, is orally available, selective,

has shown picomolar biochemical inhibition of CHK1, and has demonstrated CNS penetrance in preclinical models. We have nominated BBI-098 as a development candidate and have completed non-Good Laboratory Practice (non-GLP) dose range finding toxicology studies. We are currently conducting *in vivo* studies in multiple glioblastoma pharmacology models. If those studies are successful and we are able to demonstrate clinical activity of CHK1 inhibition in ecDNA-bearing cancers with our BBI-355 ecDTx, then we intend to advance BBI-098 into GLP toxicology studies and formulation development to pursue ecDNA-bearing oncology CNS indications such as glioblastoma or brain metastases. Properties of BBI-098 observed in preclinical studies are shown below.

Preclinical Properties of BBI-098 CNS Penetrant CHK1 Inhibitor

PARAMETER	BBI-098
CHK1 biochemical inhibition (TR-FRET) IC_{50} nM	0.7
Kinase selectivity	>200x CHK2
CHK1 cellular activity (target engagement, CHK1 phosphorylation, HT29) IC_{50} nM	15
Cellular activity CellTiter-Glo COLO320 ecDNA+ IC_{50} nM	20
CYP inhibition 1A2/2C9/2C19/2D6/3A4 (uM)	>50/48/>50/4.9/50
hERG inhibition (uM); cardiomyocyte assay	2.7; minimal activity @ 10 uM
CEREP/PanLabs profile	No off-target activity, 0/47 hits
PO bioavailability (dog, rat), %F	22-64
CNS penetration Brain:plasma AUC - mouse, rat	2.1, 1.9
Brain Kp_{uu} (unbound partition coefficient)- mouse, rat	0.35, 0.19

Our Second ecDTx: BBI-825 RNR Inhibitor

Our second ecDTx, BBI-825, is a novel, selective, oral small molecule inhibitor of RNR. RNR is a rate-limiting enzyme responsible for cellular production of dNTPs, the building blocks of DNA, and is essential to the assembly and repair of ecDNA. We have demonstrated that inhibition of RNR with BBI-825 starved ecDNA-reliant cancer cells of dNTPs, depleted ecDNA, and was synthetic lethal in multiple ecDNA-bearing cancers, including both driver oncogene and resistance settings. In January 2024, we received allowance from the FDA to initiate the first-in-human, Phase 1/2 STARMAP clinical trial in patients with resistance gene amplifications. We initiated the STARMAP trial in February 2024 and expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-825 in combination with targeted therapies from the STARMAP trial in the second half of 2025.

RNR Synthetic Lethality in ecDNA-enabled Cancer

RNR is a rate-limiting enzyme responsible for cellular *de novo* synthesis of dNTPs and is essential to the assembly and repair of ecDNA. The premise for this ecDTx program is based on the

preclinical observation that RNR inhibition starved ecDNA-reliant cancer cells of dNTPs, depleted ecDNA, and was synthetic lethal in amplification-bearing cancer cells.

We have observed particular sensitivity to RNR inhibition in cancer cells harboring certain oncodriver mutations, for instance *KRAS*^{G12C} and *BRAF*^{V600}, previously shown to have hyperactive dNTP synthesis that promotes the activity of key *de novo* nucleotide biosynthesis pathway enzymes, including RNR. Critically, *KRAS*, *BRAF*, and other genes involved in MAPK pathway signaling are frequently amplified on ecDNA, potentially further compounding the demand for dNTPs and reliance on RNR for tumor cell survival.

Limitations with Prior RNR Inhibitors

RNR inhibition as a pharmacological strategy for treating cancer has been clinically validated by approved drugs with RNR inhibitory activity, such as gemcitabine and hydroxyurea. These drugs, however, are not selective for RNR and were not originally intended for, nor optimized for, RNR inhibitor properties. They have several shortcomings, including poor PK properties, IV delivery (gemcitabine), weak potency (hydroxyurea), polypharmacology, and other metabolic liabilities. Despite these limitations, drugs with RNR inhibitory activity have shown clinical activity in multiple settings, with anecdotal evidence supporting synthetic lethality for gemcitabine in high-RS tumors with oncogene amplification. To date, no selective RNR inhibitor has either been approved, nor to our knowledge is being actively developed. Additionally, no compounds with RNR inhibitory properties have been previously approved with a biomarker for patient selection. Therefore, we believe there is a significant opportunity for a precision medicine approach to pursuing this clinically validated cancer target via an intentionally designed, selective, oral RNR inhibitor, with a biomarker-enabled approach for selection of patients with cancers most likely to benefit from this therapeutic strategy.

Our Differentiated Approach

To this end, we have designed BBI-825, a novel, RNR-selective inhibitor optimized for ecDNA-enabled cancers, including those with MAPK pathway activation (e.g., *BRAF*^{V600E} and *KRAS*^{G12C} mutations). BBI-825 is orally available and has demonstrated selective, low double digit nanomolar biochemical inhibition of RNR, encouraging PK properties in higher species, and a favorable profile for hERG interaction. Properties of BBI-825 observed in preclinical studies are shown below.

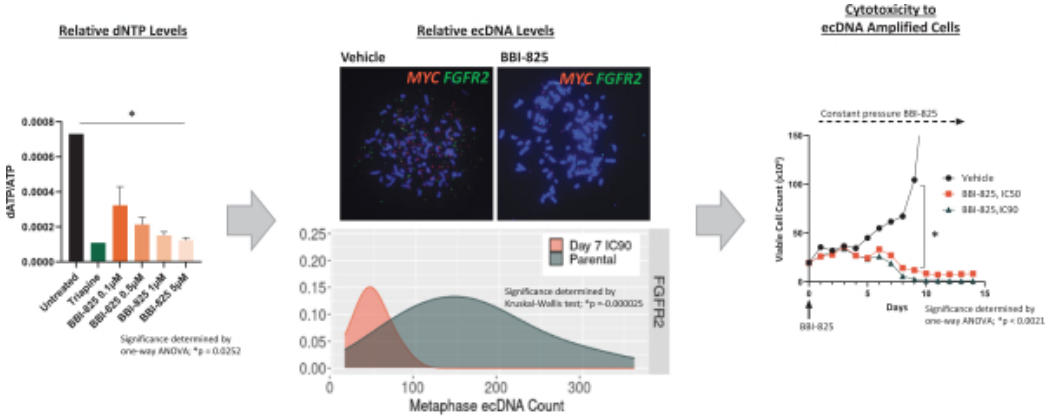
Preclinical Properties of BBI-825 Selective RNR Inhibitor

PARAMETER	BBI-825
RNR biochemical inhibition (RF-MS) IC50 nM	20
RNR cellular activity (dNTP lowering, COLO320) IC50 nM	<100
Cytotoxicity COLO320 ecDNA+ IC50 nM	1365
CYP inhibition 1A2/2C9/2C19/2D6/3A4-M/3A4-T (uM)	>100/15.8/8.6/31.7/0.7/2.0
hERG inhibition (uM); cardiomyocyte assay	>10, no activity @10 uM
CEREP/PanLabs profile	Minimal off target activity, 1/47 hits
PO bioavailability (rat, dog), %F	47-73

BBI-825 In Vitro Preclinical Data

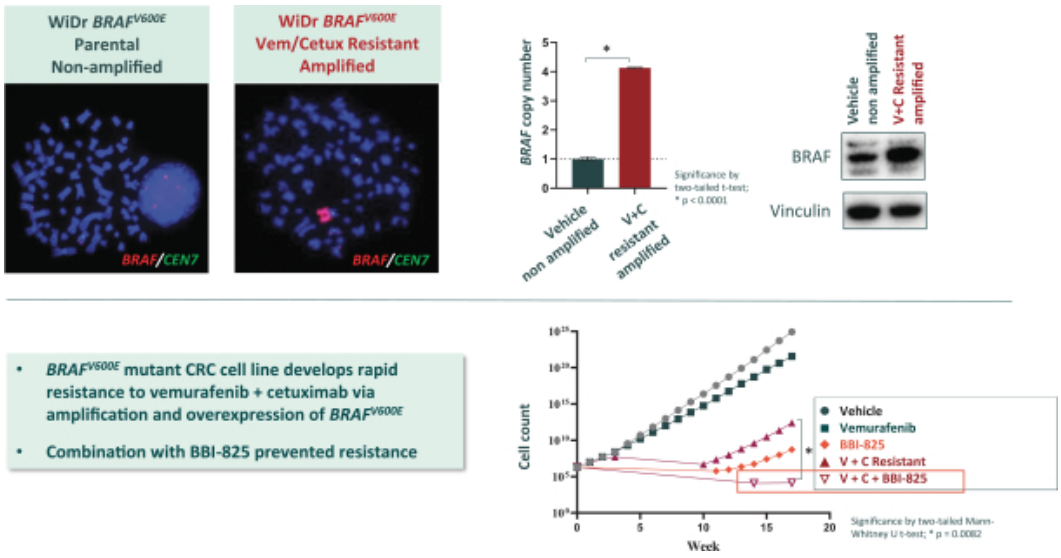
BBI-825 was first characterized extensively *in vitro*. As seen in the figure below, dysregulation of cellular dNTP levels in ecDNA-enabled *FGFR2* amplified gastric cancer cells treated with BBI-825 resulted in a substantial reduction of ecDNA compared to untreated cells. Reduction in ecDNA levels correlated directly with tumor cell cytotoxicity in both a concentration and temporal-dependent manner. Similar effects on ecDNA levels and cell viability were observed in other tumor cell lines irrespective of the specific ecDNA amplified oncogene, consistent with RNR representing an ecDNA-essential drug target.

Selective Inhibition of RNR with BBI-825 Resulted in dNTP Depletion, ecDNA Reduction, and Cytotoxicity in ecDNA Amplified Colorectal Cancer Cells



As seen in the figure below, similar to the results observed in *KRAS*^{G12C} mutant models, BBI-825 also demonstrated antitumor activity in WiDr *BRAF*^{V600E} mutant colorectal cancer cells. In this *in vitro* model, WiDr cells were initially sensitive to the combination of the BRAF inhibitor vemurafenib and the EGFR inhibitor cetuximab, but cells developed resistance through amplification and subsequent overexpression of *BRAF*^{V600}. Consistent with the results observed in the mutant KRAS setting, the addition of BBI-825 to the vemurafenib and cetuximab therapy resulted in complete inhibition of WiDr tumor cell growth. In contrast, cells treated with either BBI-825 alone, or vemurafenib and cetuximab alone, eventually resumed growth after several weeks in culture.

BBI-825 Overcame Amplification-based Resistance Arising from Combination BRAF and EGFR Inhibition in *BRAF*^{V600E} Mutated Colorectal Cancer Cells

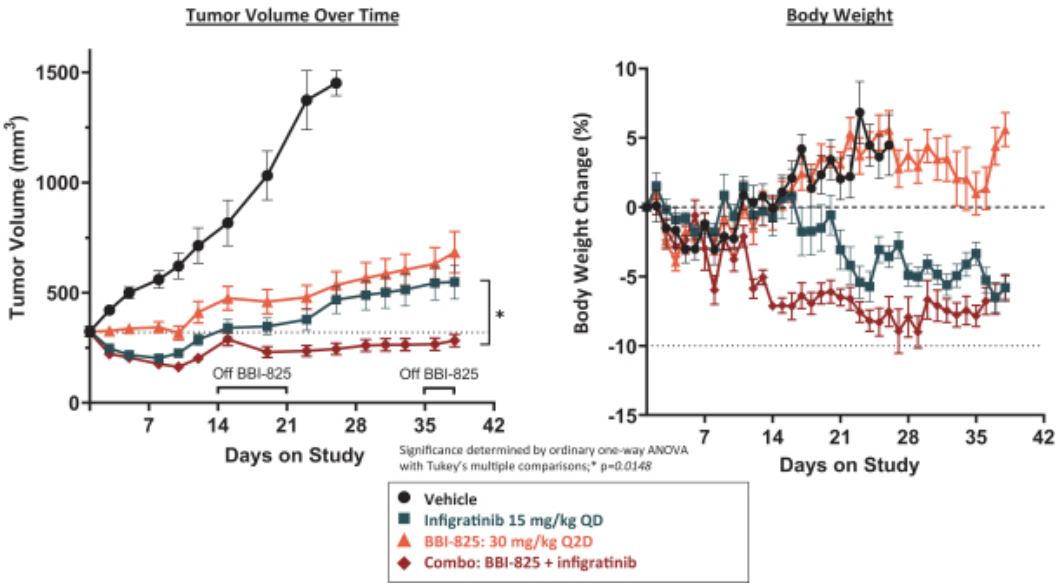


BBI-825 In Vivo Preclinical Data

Pharmacological inhibition of RNR using BBI-825 in tumor xenograft models reinforces the potential of this ecDTx to treat amplification-enabled oncogene-dependent cancers. BBI-825 demonstrated antitumor activity in models that have driver oncogene amplifications and models that developed resistance amplifications in response to MAPK pathway targeting therapies such as KRAS^{G12C} inhibitors. The *in vivo* antitumor activity of BBI-825 has been demonstrated in an ecDNA-enabled *FGFR2* amplified gastric cancer xenograft model and an ecDNA-enabled *KRAS*^{G12C}-addicted syngeneic colorectal cancer xenograft model.

As seen in the figure below, in the *FGFR2* amplified gastric cancer xenograft model, BBI-825 showed single agent antitumor activity, and the combination of BBI-825 and infigratinib yielded significantly deeper tumor regressions than either single agent alone.

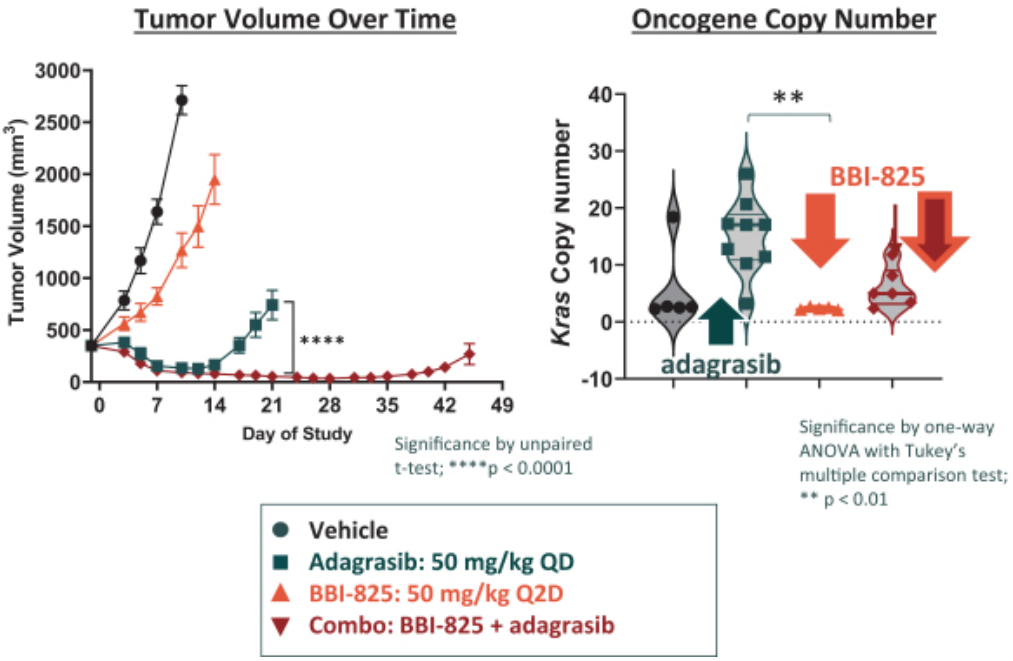
BBI-825 *In Vivo* Antitumor Activity as a Single Agent and in Combination with Infigratinib in an ecDNA-enabled *FGFR2* Amplified Gastric Cancer CDX Model



Prevention of Amplification-Mediated Resistance in MAPK Pathway-Activated Tumors

As seen in the figure below, in an ecDNA-enabled $KRAS^{G12C}$ inhibitor induced resistance colorectal cancer xenograft model, $KRAS^{G12C}$ inhibition by adagrasib induced ecDNA amplification harboring $KRAS^{G12C}$ concurrent with development of drug resistance and tumor regrowth. This resistance mechanism was consistent with recurrent clinical observations where *KRAS* amplification was associated with disease progression in patients following treatment with the combination of $KRAS^{G12C}$ inhibition by adagrasib and EGFR inhibition by cetuximab. The combination of BBI-825 with adagrasib in $KRAS^{G12C}$ colorectal cancer xenograft models led to robust tumor regressions and inhibited the development of amplification-mediated resistance to adagrasib.

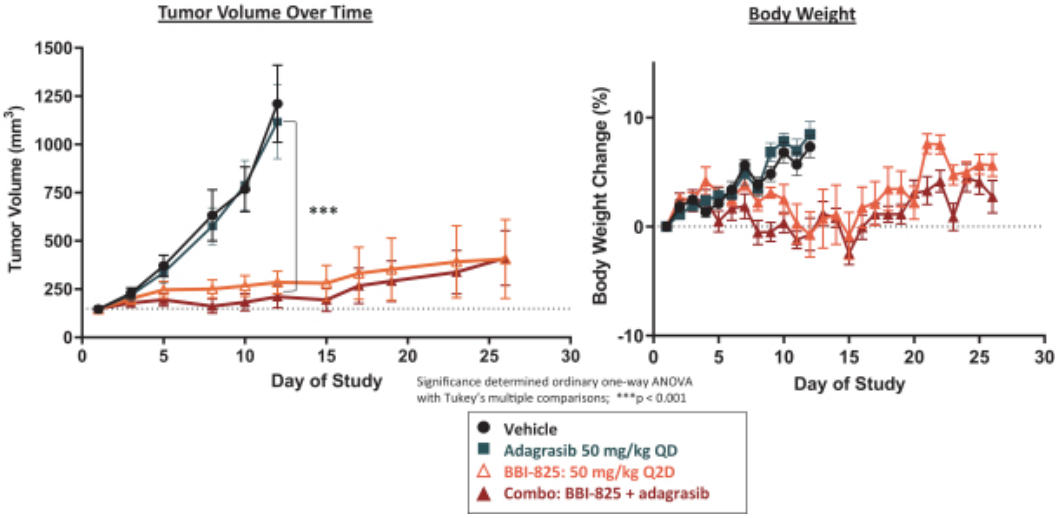
BBI-825 *In Vivo* Antitumor Activity in Combination with Adagrasib in $KRAS^{G12C}$ Mutated Colorectal Cancer CDX Model: Prevention of Resistance



Treatment of Amplification-Mediated Resistance in MAPK Pathway-Activated Tumors

As seen in the figure below, BBI-825 also demonstrated significant antitumor activity in an *in vivo* $KRAS^{G12C}$ colorectal cancer CDX model that had already developed amplification-mediated resistance to adagrasib. In this model where amplification-mediated resistance to $KRAS^{G12C}$ inhibitor treatment was already established, BBI-825 significantly inhibited tumor growth as monotherapy, showing 92% tumor growth inhibition compared to vehicle or adagrasib alone, including tumor regressions in multiple animals.

BBI-825 *In Vivo* Antitumor Activity as a Single Agent in Adagrasib-Resistant $KRAS^{G12C}$ Mutated and Amplified Colorectal Cancer CDX Model: Treatment of Resistance



BBI-825 Clinical Development Plan

For the initial clinical development of BBI-825, we prioritized indications based on the preclinical antitumor activity we have observed for BBI-825 to date and our understanding of the evolving unmet medical need in cancer. BRAF and $KRAS^{G12C}$ inhibitors have shown the capacity to drive deeper and more durable responses than conventional chemotherapy regimens while minimizing unwanted side effects and damage to normal healthy tissues in patients with $BRAF^{V600E}$ or $KRAS^{G12C}$ mutated cancers. Unfortunately, resistance to BRAF and $KRAS^{G12C}$ inhibitors is almost always inevitable. The predominant resistance mechanisms to these targeted therapies, including when administered in combination with EGFR inhibitors in colorectal cancer, are secondary mutations of the oncodriver targets ($BRAF^{V600E}$ or $KRAS^{G12C}$), other MAPK pathway activation, and resistance gene amplifications. Thus, we initially intend to explore the antitumor activity of BBI-825 in patients with locally advanced or metastatic non-resectable colorectal cancer with MAPK pathway alterations, specifically $BRAF^{V600E}$ and $KRAS^{G12C}$ mutations, and co-occurring resistance gene amplifications.

In February 2024, we initiated a first-in-human, Phase 1/2 clinical trial of BBI-825 and BBI-825 in combination with select targeted therapies in subjects with locally advanced or metastatic solid tumors with resistance gene amplifications. The title of the trial (NCT pending) is: “An open-label, multicenter, first-in-human, dose-escalation and dose expansion, Phase 1/2 study of BBI-825 and BBI-825 in combination with select targeted therapies in subjects with locally advanced or metastatic solid tumors with resistance gene amplifications.” We also call the trial STARMAP, for “Study Treating Acquired

Resistance: MAPK Amplifications". We expect to have preliminary proof of concept safety and antitumor activity data of BBI-825 in combination with targeted therapies from the STARMAP trial in the second half of 2025.

The design of the trial is an open-label, non-randomized, three-part Phase 1/2 clinical trial to evaluate the safety and identify the MTD and RP2D of BBI-825 administered as a single agent or in combination with select targeted therapies. The trial has three parts: Part 1 is a dose escalation of BBI-825 as a monotherapy, while Parts 2 and 3 of this trial will be conducted in two separate modules, each module testing the combination of BBI-825 with two targeted therapies, encorafenib and cetuximab (module 1), or adagrasib and cetuximab (module 2), in patients with amplification-based resistance in *BRAF*^{V600E} mutant colorectal cancer or *KRAS*^{G12C} mutant colorectal cancer, respectively.

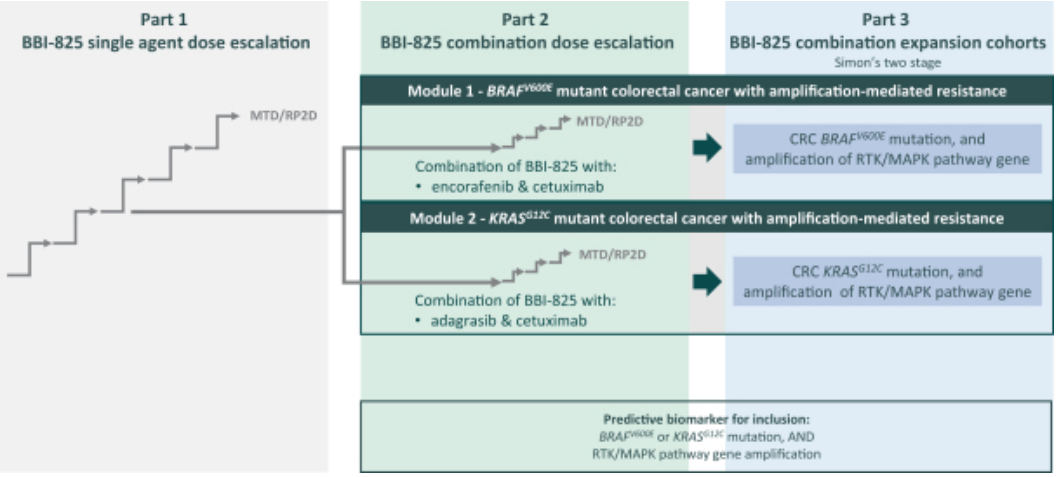
In Part 1 of the trial, patients with solid tumors will be eligible for enrollment. The goal of Part 1 is to identify the single agent RP2D and MTD of BBI-825 and to evaluate preliminary single agent antitumor activity.

In Part 2 of the trial, patients with locally advanced or metastatic non-resectable colorectal cancer with MAPK pathway alterations, specifically *BRAF*^{V600E} and *KRAS*^{G12C} mutations, and co-occurring resistance gene amplifications, as determined by standard NGS testing, will be enrolled in the corresponding module. The goal of Part 2 is to identify the RP2D and MTD of BBI-825, as well as initial antitumor activity, in combination with the respective targeted therapies studied in each module, that is encorafenib and cetuximab (module 1), or adagrasib and cetuximab (module 2), in patients with amplification-based resistance in BRAF^{V600E} mutant colorectal cancer or KRAS^{G12C} mutant colorectal cancer, respectively.

In Part 3 of the trial, patients with locally advanced or metastatic non-resectable colorectal cancer with MAPK pathway alterations, specifically BRAF^{V600E} and KRAS^{G12C} mutations, and co-occurring resistance gene amplifications, as determined by standard NGS testing, will be enrolled in the corresponding module. The goal of Part 3 is to evaluate preliminary combination antitumor activity at the combination RP2Ds.

We expect to enroll a total of approximately 140 to 190 patients in this trial. Should any cohort of the trial demonstrate compelling signs of clinical antitumor activity, along with acceptable safety and tolerability, we would seek to engage with the FDA and other global regulatory bodies to discuss potential registrational paths, including the designs of any additional clinical trials we may need to conduct to support potential registrations for BBI-825. Based on ongoing preclinical studies as well as the future clinical data for BBI-825, we may also consider expanding this trial to pan-tumor, pan-RAS, and/or pan-RAF evaluation.

Design of BBI-825 Phase 1/2 STARMAP Clinical Trial

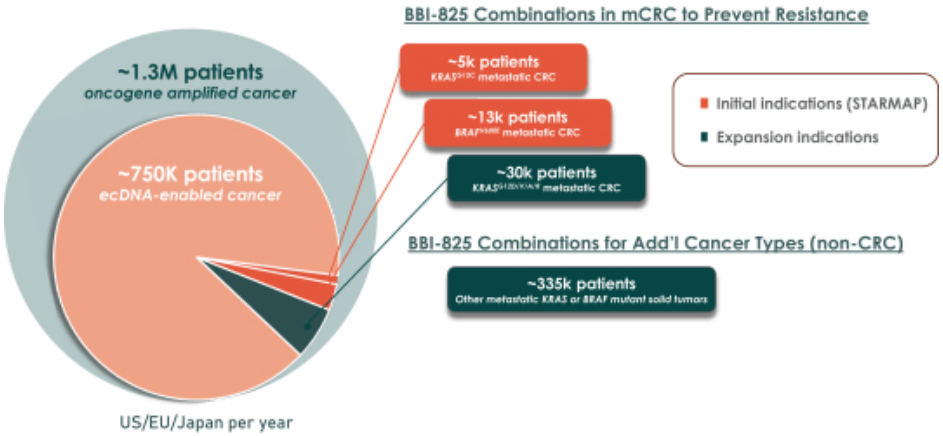


Addressable Patient Populations for BBI-825

We estimate that BBI-825, if approved for the indications we are targeting in the STARMAP trial, could address an initial U.S. patient population of approximately 7,000 new metastatic colorectal cancer patients per year with *BRAF*^{V600E} or *KRAS*^{G12C} mutations, in addition to over 9,000 new patients in the European Union and 3,000 new patients in Japan, representing a total potential addressable patient population of nearly 20,000 new patients per year in the United States, European Union, and Japan; although at this early juncture it is difficult to know how many patients eventually develop resistance to targeted therapy treatment via resistance gene amplification.

In addition to the indications currently being evaluated in the STARMAP trial described above, we are also currently conducting preclinical studies to evaluate BBI-825 in additional MAPK pathway activated cancer indications, including resistance associated with other KRAS activations (e.g., *KRAS*^{G12C} non-colorectal cancers and *KRAS*^{G12D} colorectal cancer), *BRAF*^{V600E} non-colorectal cancers, and others. Clinical success in one or more of these indications could expand the potential addressable patient population for BBI-825. In the future, we estimate that expansion into additional non-colorectal metastatic KRAS and BRAF solid tumors (e.g., *KRAS*^{G12C}, *KRAS*^{G12D}, *KRAS*^{G12V}, *KRAS*^{G12A}, *KRAS*^{G12R}, *BRAF*^{V600E}, and *BRAF*^{V600K} mutations) could further expand the total potential addressable patient population by approximately 335,000 new patients per year in the United States, European Union, and Japan.

Initial Indications for BBI-825 May Represent a Total Addressable Population of Nearly 20,000 New Patients in the United States, the European Union, and Japan Each Year, with Indication Expansion Possibility of 365,000 Additional New Patients

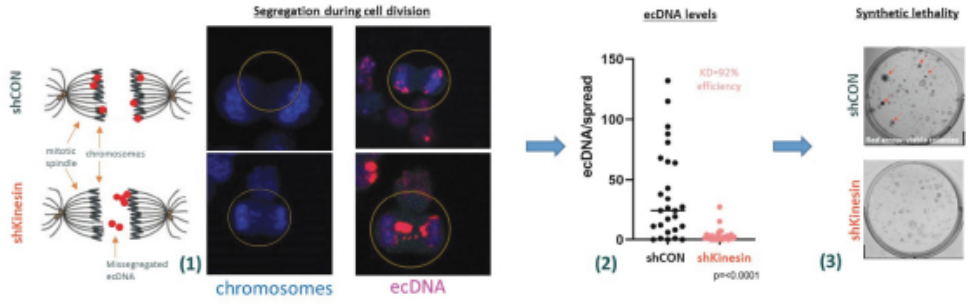


Our Third ecDTx Program

Our third ecDTx program is directed against a novel member of a class of druggable proteins, the kinesins. This ecDTx target has no approved drugs and, to our knowledge, no other publicly disclosed drug discovery efforts. This kinesin is involved with ecDNA segregation during cellular division and leverages the fact that ecDNA, unlike chromosomes, lack centromeres.

The cell has evolved numerous redundant mechanisms governing the interactions of chromosomes with the mitotic spindle, the highly coordinated network of factors that separates chromosomes equally into daughter cells during cell division. The primary and essential attachment point for chromosomes to the mitotic spindle is via the centromere, although additional non-essential factors can assist in shepherding chromosomes independently of the centromere. Whereas these centromere-independent segregation factors are non-essential to chromosome segregation, they may be required for ecDNA due to ecDNA's lack of centromeres. Consistent with this hypothesis, when certain proteins are genetically deactivated, it results in abnormal ecDNA segregation during cell division. As shown below, this leads to aggregation and eventual loss of ecDNA that is statistically significant. This defect in the segregation process during cell division is directly correlated with significant cytotoxicity in ecDNA-enabled tumor cells while demonstrating minimal impact on cells without ecDNA, where the target is non-essential.

Genetic Inhibition of Novel Kinesin Target Was Associated with (1) Abnormal ecDNA Segregation, (2) Depleted ecDNA Levels, and (3) Cytotoxicity in Tumor Cells



Through Spyglass, we identified a novel kinesin essential for ecDNA segregation during cellular division. We preclinically validated this target *in vitro* by demonstrating that its inhibition was associated with statistically significant differential sensitivity and reduction of ecDNA levels in multiple ecDNA tumor cell lines compared to non-ecDNA-bearing tumor cell lines. We also preclinically validated this target *in vivo* by demonstrating that its inhibition led to statistically significant tumor growth inhibition in an ecDNA amplified tumor model. We have generated nanomolar inhibitors against this target and are currently advancing these scaffolds through hit-to-lead generation. We are advancing our third ecDTx program through drug discovery to candidate identification and expect to submit an IND in the first half of 2026.

Ongoing Discovery Efforts for Future Programs

In addition to our three ecDTx programs described above, we continue to leverage Spyglass to identify and preclinically validate additional ecDNA-essential targets. These candidate targets span multiple, diverse ecDNA synthetic lethal nodes in oncogene amplified cancers. We have preclinically validated multiple additional ecDNA targets and have initiated ecDTx drug discovery efforts to identify candidates against such targets. We expect to continue to identify and preclinically validate additional ecDNA targets using our Spyglass platform in the future.

Our Precision Medicine Approach – ecDNA Diagnostic Test

Precision medicine aims to identify and treat patients with specific biomarkers to maximize the likelihood of therapeutic benefit while minimizing side effects. We developed an ecDNA diagnostic test, internally called ECHO, to detect ecDNA in patient tumor specimens and identify patients most likely to benefit from our ecDTx. Our ecDNA diagnostic is a proprietary software algorithm designed to detect the presence of ecDNA by analyzing genomic data in the form of raw data output format files, such as FASTQ or binary sequence alignment map (BAM) files, generated from routine clinical NGS assays that are commonly used by commercial reference laboratories and academic laboratories to profile patient tumor samples. We are working with an *in vitro* diagnostic company to develop our ecDNA diagnostic into a clinical trial assay for patient selection in clinical trials of our ecDTx, including our Phase 1/2 POTENTIATE clinical trial. The FDA has determined the ecDNA diagnostic is a non-significant risk device when used in our Phase 1/2 POTENTIATE trial, meaning that we will not be required to obtain FDA approval of an IDE for the use of the ecDNA diagnostic in this trial. To our knowledge, this will be the first ecDNA diagnostic in clinical use. As data from our clinical studies mature, we intend to discuss with the FDA whether the ecDNA diagnostic will be appropriate or required to enable commercialization of our ecDTx.

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 substantial 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 the 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-355, Acrivon Therapeutics, Esperas Pharma, and PharmaEngine have CHK1 inhibitors in clinical development. BenevolentAI, Fosun Pharma, and Impact Therapeutics have publicly disclosed preclinical-stage CHK1 inhibitors.

For BBI-825, there are several generic approved agents that inhibit RNR as part of their broader mechanism of action, including gemcitabine and hydroxyurea.

For our pipeline of ecDTx programs, potential competition includes established companies as well as emerging biotechnology companies that launch programs against ecDNA targets. However, we are not aware of any companies with ecDNA-directed therapeutic programs in clinical development and a patient selection strategy for ecDNA-enabled oncogene amplification. We are aware of one early-stage private company that is focused on research in ecDNA, Econic Biosciences.

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 all 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 February 23, 2024, our intellectual property portfolio included 25 patent families solely owned by us, which include 12 pending US provisional applications, 10 pending US non-provisional patent applications, 3 issued US patents, pending applications in Australia, Brazil, Canada, China, Eurasia, Europe, India, Israel, Japan, Korea, Mexico, Singapore, South Africa and Taiwan, as well as 6 pending applications filed pursuant to the Patent Cooperation Treaty (PCT).

We continually assess and refine our intellectual property strategy as we discover and validate new ecDNA targets, develop new ecDTx product candidates, and make improvements to our Spyglass platform and our ecDNA diagnostic test. 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 CHK1 Program

With regard to our CHK1 program including our BBI-355 and BBI-098 product candidates, as of February 23, 2024, we owned 10 patent families (including 2 of which also cover our RNR program), including 5 pending US provisional patent applications, 4 pending US non-provisional patent applications, 2 issued US patents, pending applications in Australia, Brazil, Canada, China, Eurasia, Europe, India, Israel, Japan, Korea, Mexico, Singapore, South Africa and Taiwan, as well as 3 pending applications filed pursuant to the Patent Cooperation Treaty (PCT). 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 2041-2044 without accounting for any patent term adjustment or extension that may be available.

Intellectual Property Relating to Our RNR Program

With regard to our RNR program, as of February 23, 2024, we owned 8 families (including 2 of which also cover our CHK1 program), including 2 pending US provisional patent applications, 4 pending US non-provisional patent applications, pending applications in Australia, Brazil, Canada, China, Europe, Japan, Korea, Mexico, and Taiwan, as well as 3 pending applications filed pursuant to the Patent Cooperation Treaty (PCT). These patent rights relate to the compositions of matter, as well as methods of treating diseases using RNR inhibitors. 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.

Intellectual Property Relating to Our Precision Medicine Program

With regard to our precision medicine program, we have developed a proprietary ecDNA diagnostic to detect ecDNA based on the data outputs from NGS tests routinely used to profile patient tumor samples. As of February 23, 2024, we owned 1 patent family related to methods of detecting ecDNA signatures in cancers that is currently pending in the US, China, Europe, and Japan. Additionally, we own 1 pending US provisional patent application related to our ecDNA 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 US 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 US. The patent situation outside of the US is even more uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the US 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 any of our ecDTx obtain 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, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the New Drug Application (NDA) process before it may be legally marketed in the United States.

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. 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 drug may be marketed in the United States generally involves the following:

- completion of certain preclinical laboratory tests, animal studies and formulation studies in accordance with GLPs and other applicable regulations;

- submission to the FDA of an 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;
- 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 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.

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 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.

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 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.
- 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 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.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing 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.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are 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 a standard NDA for a new molecular entity to 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 a recommendation 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. 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 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 of 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, such as an additional clinical trial 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 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 a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy (REMS), to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products.

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 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 safe and effective. The sponsor or FDA may request 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.

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 a 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.

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.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is 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 a 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. 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.

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 period for FDA review or approval will not be shortened.

Post-Approval Requirements

Any products 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, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. 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 cGMPs and other laws and regulations. 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 company can make only 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.

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 on the basis of 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 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.

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. On August 6, 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 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 trial, if the trial meets both the requirements of applicable IDE regulations and the IND regulations. The guidance provides that, depending on the details of the trial plan and degree of risk posed to subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

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, in order 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.

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 by third-party payors, such as government health programs or 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. 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 for coverage). 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 reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could have a material adverse effect on our sales, results of operations, and financial condition.

General legislative 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.

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, 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 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. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus the ACA will remain in force in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which 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. Moreover, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

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 designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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.

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.

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 1, 2024, we had 72 full-time employees, including a total of 24 employees with M.D. or Ph.D. degrees. Of these full-time employees, 55 employees are engaged in research and development and 17 are engaged in finance, legal, business development, and general management and administration. 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 ensure we remain competitive and attractive to potential new hires.

Facilities

Our corporate headquarters are currently located in San Diego, California, where we lease approximately 28,700 square feet of laboratory and office space. This lease commenced in the first quarter of 2022 and is expected to end upon the commencement of our new lease described below. We have entered into an agreement to lease a new corporate headquarters consisting of approximately 80,168 square feet of laboratory and office space that will be located in La Jolla, California. The lease for the new corporate headquarters is expected to commence once buildout of the facilities is complete and we may take occupancy of the new facility. We believe that our existing facilities are adequate for our current needs and that our future facilities will be suitable for our needs at that time.

Legal Proceedings

We are not currently a party to any material proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age, and position of each of our executive officers and directors as of March 1, 2024.

Name	Age	Position(s)
Executive Officers		
Zachary D. Hornby	45	President, Chief Executive Officer, and Director
Jami Rubin	60	Chief Financial Officer
Klaus Wagner, M.D., Ph.D.	52	Chief Medical Officer
Chris Hassig, Ph.D.	52	Chief Scientific Officer
Neil Abdollahian	51	Chief Business Officer
Jessica Oien	53	Chief Legal Officer and Corporate Secretary
Non-Employee Directors		
Jonathan E. Lim, M.D.(1)(2)	52	Chairman and Co-Founder
Christine Brennan, Ph.D.(2)(3)	55	Director
Kristina Burow(1)(3)	50	Director
Jamie Christensen, Ph.D.(1)	56	Director
Jennifer Lew(1)(2)	51	Director
Jakob Loven, Ph.D.(4)	46	Director
Fabio Pucci, Ph.D.(5)	39	Director
Nancy Whiting, Pharm.D.(3)	51	Director

(1) Member of the compensation committee.
(2) Member of the audit committee.
(3) Member of the nominating and corporate governance committee.
(4) Dr. Loven resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(5) Dr. Pucci resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Executive Officers

Zachary D. Hornby has served as our President, Chief Executive Officer, and as a member of our board of directors since May 2019. Previously, Mr. Hornby served in several executive positions at Ignyta, Inc. (acquired by Roche/Genentech), a publicly traded precision oncology company, including as its Chief Operating Officer from June 2014 to July 2018 and prior to that as its Chief Financial Officer from July 2013 to May 2014 and Vice President of Corporate Development from August 2012 to July 2013. In these roles, Mr. Hornby led the operational team responsible for the development of entrectinib (Rozlytrek™) and the efforts ultimately leading to the acquisition by Roche in February 2018. Prior to Ignyta, Mr. Hornby served as Senior Director of Business Development at Fate Therapeutics, a cellular immunotherapy company focused on oncology and immunology, and various business and corporate development roles at Halozyme Therapeutics, Inc.. Mr. Hornby held earlier roles in new product planning, marketing, and strategy at Neurocrine Biosciences and L.E.K. Consulting. In addition, Mr. Hornby serves as a member of the board of directors for Novome Biotechnologies, Inc., Aardvark Therapeutics, Inc., and Radionetics Oncology, Inc. Mr. Hornby received a B.S in Biology and a M.S. in Biology from Stanford University and an MBA from Harvard Business School. Mr. Hornby's knowledge of our business, his background in corporate strategy and finance, and his extensive executive experience at multiple biopharmaceutical companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Jami Rubin has served as our Chief Financial Officer since July 2023. Previously, Ms. Rubin was a venture partner in ARCH Venture Partners, a venture capital firm, from May to July 2023, and continues to serve in such role on a part-time basis. Prior to that, Ms. Rubin served as Chief Financial Officer of EQRx (acquired by Revolution Medicines), Inc., a publicly traded biotechnology company, from April 2021 to March 2023. From May 2019 to April 2021, Ms. Rubin served as a partner at PJT Partners, a global advisory-focused investment bank. Prior to that, Ms. Rubin spent more than 25 years as an equity analyst following the pharmaceutical industry. Most recently, Ms. Rubin was an equity research analyst and then partner at Goldman Sachs & Co. LLC managing the global healthcare research team from September 2008 to October 2018. In addition, Ms. Rubin currently serves as a member of the board of directors of Relay Therapeutics, Inc., a publicly traded precision medicine company. Ms. Rubin received a B.A. from Vassar College.

Klaus Wagner, M.D., Ph.D. has served as our Chief Medical Officer since February 2022. Prior to joining Boundless, Dr. Wagner served as Chief Medical Officer and Executive Vice President of Inhibrx, Inc. (acquisition by Sanofi pending), a publicly traded biopharmaceutical company, where he led the development of multiple oncology candidates from pre-IND to late-stage clinical trials from August 2015 to February 2022. Prior to Inhibrx, Dr. Wagner served as a Medical Oncologist at the Banner MD Anderson Cancer Center and as Adjunct Assistant Professor in the Department of Thoracic, Head & Neck Medical Oncology at MD Anderson Cancer Center from November 2012 to August 2015. During that time, Dr. Wagner led multiple targeted therapy and cancer immunotherapy trials in non-small cell lung cancer as a Principal Investigator. From October 2003 to 2006, and from September 2011 to 2012, Dr. Wagner was at Genentech, Inc., where he served in various roles including Scientist and Diagnostic Development Team Leader, and Assistant Medical Director; and from November 2000 to 2003, Dr. Wagner was a Post-doctoral Associate at the Genomics Institute of the Novartis Research Foundation. Dr. Wagner sees patients as a Medical Oncologist on a volunteer basis up to five hours per week in the General Medical Oncology Clinic at the VA Medical Center in San Diego. Dr. Wagner was Board-certified in Medical Oncology and Internal Medicine and completed his internal medicine training at the Indiana University School of Medicine and medical oncology training at MD Anderson Cancer Center. Dr. Wagner received an M.D. and a Ph.D. from Friedrich-Alexander University School of Medicine.

Christian "Chris" Hassig, Ph.D. has served as our Chief Scientific Officer since November 2019. Before Boundless, Dr. Hassig was with Sierra Oncology, Inc. (acquired by GlaxoSmithKline), a publicly traded precision oncology company where he served in various leadership roles including Chief Scientific Officer and Senior Vice President of Research, from June 2016 to November 2019. Prior to Sierra, Dr. Hassig served as Vice President of Drug Discovery at the Sanford Burnham Prebys Medical Discovery Institute where he led the discovery and development of novel small molecule therapeutics against innovative targets. Dr. Hassig also held several positions within the Biology and Lead Discovery departments at Kalypsys, Inc., a private biopharmaceutical company specializing in small molecule drug discovery and development. Dr. Hassig received a B.A. in Chemistry and Biochemistry from the University of California, San Diego, a Ph.D. in Molecular and Cellular Biology from Harvard University, and also completed a Postdoctoral Fellowship at the University of California, Berkeley.

Neil Abdollahian has served as our Chief Business Officer since August 2021. Prior to Boundless, Mr. Abdollahian served as Chief Business Officer of Cidara Therapeutics, Inc., a publicly traded biopharmaceutical company, from July 2016 to August 2021. Prior to Cidara, Mr. Abdollahian was Managing Director of Clarity Point Partners, LLC, a strategic advisory firm focused on corporate development initiatives including biopharmaceutical product acquisitions and licensing. Previously, Mr. Abdollahian served in various leadership roles including Vice President of Business Development at Trius Therapeutics, Inc., where he led the efforts resulting in the acquisition by Cubist Pharmaceuticals. Mr. Abdollahian also served earlier in various business and corporate development roles at Emerging Growth Capital Pty, Avanir Pharmaceuticals, and Isis Pharmaceuticals.

Mr. Abdollahian received a B.S in Biology from the George Washington University, a M.S. in Biomedical Sciences from University of New Mexico Medical School, and an MBA from Pepperdine University.

Jessica Oien has served as our Chief Legal Officer and Corporate Secretary since January 2024 and as our General Counsel and Corporate Secretary from August 2021 through December 2023. Prior to joining Boundless, Ms. Oien served as General Counsel and Corporate Secretary at Cidara Therapeutics, Inc., a publicly traded biopharmaceutical company, from September 2018 to August 2021. Before Cidara, Ms. Oien served as Vice President, Legal and Compliance at Otonomy, Inc., a publicly traded biopharmaceutical company, where she was the legal lead for the commercial business from 2015 to 2018 and spearheaded the commercial compliance program. She served in similar roles as Vice President, Legal and Compliance for Pernix Therapeutics; Vice President, Legal Affairs & Compliance for Somaxon Pharmaceuticals; and Senior Director, Legal Affairs for Verus Pharmaceuticals, and Senior Director, Legal Affairs at Elan Pharmaceuticals. Ms. Oien began her legal career as corporate counsel at national law firms including Brobeck, Phleger & Harrison LLP and Milbank, Tweed, Hadley & McCloy LLP. Ms. Oien received a B.A. in Economics and Political Science from North Dakota State University and a J.D. from Loyola Law School.

Non-Employee Directors

Jonathan E. Lim, M.D. co-founded Boundless and has served as our Chairman since December 2018. Dr. Lim also co-founded Erasca, Inc., a publicly traded precision oncology company, in July 2018, joined as Executive Chairman in October 2018, and has served as Chairman and Chief Executive Officer since March 2019. Dr. Lim has also served as a Venture Partner at ARCH Venture Partners since December 2018 and as Managing Partner at City Hill, LLC since founding it in 2010. Prior to co-founding each of Boundless and Erasca in 2018, Dr. Lim co-founded and served as Chairman of Ignyta, Inc., a publicly traded precision oncology company, and led it from 2012 as Chairman, Chief Executive Officer, and President through its acquisition by Roche in February 2018 and subsequent integration into Roche and Genentech in July 2018. During his tenure at Ignyta, Dr. Lim co-founded Bonti, Inc., a privately held pain management and anesthetics company, and served as its Chairman from February 2016 until its acquisition by Allergan plc in October 2018. Prior to joining Ignyta, Dr. Lim served as Chairman and Chief Executive Officer of Eclipse Therapeutics, Inc., a privately held oncology company targeting cancer stem cells that he co-founded in March 2011 as a spinout from Biogen Idec and that was sold to Bionomics Ltd. in 2012. Prior to Eclipse, Dr. Lim served as the President, Chief Executive Officer, and a Director (including as Chairman from 2004 to 2005) of Halozyme Therapeutics, Inc., a publicly traded biotechnology company, from May 2003 to December 2010. Prior to Halozyme, Dr. Lim's experience included management consulting at McKinsey & Company, a National Institutes of Health Postdoctoral Fellowship at Harvard Medical School and the Dana-Farber Cancer Institute, and two years of general surgery residency at New York Hospital-Cornell and Memorial Sloan Kettering Cancer Center. Dr. Lim has also served as a member of the board of directors of Maze Therapeutics, Inc., a private company advancing precision medicines for both rare and common diseases, since October 2019. Dr. Lim has been a member of the Board of Overseers at Scripps Research since October 2018, a member of the Board of Visitors of the Moores Cancer Center at the University of California, San Diego since 2015, and a member of the Stanford Interdisciplinary Biosciences Council since 2014. Dr. Lim has B.S. and M.S. degrees from Stanford University, an M.D. from McGill University, and an M.P.H. from Harvard University. Dr. Lim's intimate knowledge of our business as a co-founder and his extensive experience as an executive officer and director of multiple public and private biotechnology companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Christine Brennan, Ph.D. has served as a member of our board of directors since February 2022. Dr. Brennan is a Managing Director at Vertex Ventures HC since 2022 and previously Partner at MRL Ventures Fund from 2017 to 2021 and Principal at the Novartis Venture Fund from 2013 to 2017.

During her career as a venture capital investor, Dr. Brennan has served on the board of directors of biotechnology companies, including Alector, Inc., Entrada Therapeutics, Inc., and Altimmune, Inc. (while the companies were privately held). Prior to the Novartis Venture Fund, Dr. Brennan was Chief Business Officer at Vitae Pharmaceuticals, from 2010 to 2013, and subsequently acquired by Allergan in December 2016. Dr. Brennan received a B.S. in Biochemistry from the University of New Hampshire and a Ph.D. in Neuroscience from Dartmouth Medical School and conducted a postdoctoral fellowship in developmental neurobiology at the National Institutes of Health. Dr. Brennan's extensive investment experience in the biopharmaceutical industry, as well as her experience on numerous public and private company boards of directors, contributed to our board of directors' conclusion that she should serve as a director of our company.

Kristina Burow has served as a member of our board of directors since June 2019. Ms. Burow has served as a Managing Director of ARCH Venture Partners, a venture capital firm, since November 2011 and previously held positions of increasing responsibility at ARCH from August 2002 to November 2011. Ms. Burow currently serves on the board of directors of several biopharmaceutical and biotechnology companies, including: Beam Therapeutics Inc., a publicly traded biotechnology company; Scholar Rock Holding Corporation, a publicly traded biopharmaceutical company; Autobahn Therapeutics, Inc., a privately held biopharmaceutical company; ROME Therapeutics, Inc., a privately held biopharmaceutical company; Asteroid Therapeutics, Inc., a privately held biopharmaceutical company; Metsera Therapeutics, Inc., a privately held biopharmaceutical company; Treeline Therapeutics Inc., a privately held biopharmaceutical company; and Pretzel Therapeutics, Inc., a privately held biopharmaceutical company. Ms. Burow is a co-founder and director of Neumora Therapeutics, Inc., a publicly traded biopharmaceutical company and Orbital Therapeutics Inc., a privately held biotechnology company. Ms. Burow previously was a co-founder and member of the board of directors of Receptos Inc., a publicly traded pharmaceutical company, until its acquisition by Celgene Corporation, a global biopharmaceutical company, and of Sapphire Energy, Inc., an energy company. Ms. Burow previously served as a member of the board of directors of Boragen, Inc., a privately held biotechnology company; Gossamer Bio, Inc., a publicly traded biopharmaceutical company; Unity Biotechnology, Inc., a publicly traded biopharmaceutical company; AgBiome Inc., a privately held biotechnology company; Metacrine, Inc., a publicly traded pharmaceutical company; Vir Biotechnology Inc., a publicly traded biotechnology company; BlackThorn Therapeutics, Inc., a privately held biopharmaceutical company; Sienna Biopharmaceuticals, Inc.; a publicly traded biopharmaceutical company; and Epirium Bio, a privately held pharmaceutical company. Ms. Burow has participated in a number of other ARCH portfolio companies including: Erasca, Inc.; Dewpoint Therapeutics, Inc.; Aledade, Inc.; Kythera Biopharmaceuticals, Inc.; Mindstrong Inc.; Kura Oncology, Inc.; and Ikaria, Inc., acquired by Madison Dearborn Partners, a private equity firm. Prior to joining ARCH, Ms. Burow served as an associate with the Novartis BioVenture Fund and was an early employee at the Genomics Institute of the Novartis Research Foundation. Ms. Burow received a B.S. in Chemistry from the University of California, Berkeley, an M.A. in Chemistry from Columbia University, and an M.B.A. from the University of Chicago. Ms. Burow's extensive experience serving on the board of directors of clinical-stage biotechnology companies and her investment experience in the life sciences industry contributed to our board of directors' conclusion that she should serve as a director of our company.

James "Jamie" Christensen, Ph.D. has served as a member of our board of directors since October 2023. Dr. Christensen has been the Chief Scientific Officer of Mirati Therapeutics, an oncology-focused biopharmaceutical company, since January 2014. Mirati was acquired by Bristol Myers Squibb (BMS) in 2024 and is now its wholly owned subsidiary. Dr. Christensen continues at BMS and is responsible for its drug discovery, translational research, drug manufacturing, and companion diagnostics research support for the Mirati pipeline. Dr. Christensen leads activities related to the discovery and advancement of the company's clinical and preclinical programs. At Mirati, Dr. Christensen previously served as Senior Vice President from January 2014 through December 2018,

and Vice President, Research from June 2013 through January 2014. Prior to Mirati, Dr. Christensen was the Head of Oncology Precision Medicine and a member of the executive leadership team in the Oncology Research Unit at Pfizer. He joined Pfizer in 2003, where his responsibilities included leading oncology nonclinical research and translational sciences for programs including Sutent® (sunitinib malate) and Xalkori® (crizotinib). Prior to Pfizer, Dr. Christensen held positions at Sugen Inc. (acquired by Pharmacia), as a group leader in preclinical research and exploratory development. He began his career in the pharmaceutical industry at Warner Lambert/Parke-Davis. Dr. Christensen has authored or co-authored numerous peer-reviewed research articles in scientific journals including Science, Nature, Cancer Cell, Cancer Discovery, New England Journal of Medicine, and many others. He received his Ph.D. and M.S. in Pharmacology and Toxicology at North Carolina State University and his B.S. in Biology from Northern Illinois University. Dr. Christensen's extensive executive and research experience in the biopharmaceutical industry, contributed to our board of directors' conclusion that he should serve as a director of our company.

Jennifer Lew has served as a member of our board of directors since January 2022. Ms. Lew has been the EVP and Chief Financial Officer of Annexon Inc., a publicly traded biotechnology company, since June 2019. Prior to Annexon, she served as Chief Financial Officer and previously Senior Vice President, Finance for Aduro Biotech, which merged with Chinook Therapeutics, Inc. (a Novartis company), from 2013 to May 2019. Prior to Aduro, Ms. Lew held various finance roles at Dynavax Technologies Corp., a publicly traded biotechnology company, from 2004 to 2013, and QRS Corporation, a publicly held technology company, from 2000 to 2004. Ms. Lew began her career in the audit practice at Ernst & Young from 1994 to 1999. Ms. Lew received a B.A. in Economics/Accounting and Government from Claremont McKenna College and is a Certified Public Accountant (inactive status). Ms. Lew's background in leadership, finance, and accounting at privately held and publicly traded biotechnology companies contributed to our board of directors' conclusion that she should serve as a director of our company.

Jakob Loven, Ph.D. has served as a member of our board of directors since April 2021. Dr. Loven joined Nextech Invest in 2017 and is currently a Managing Partner focused on precision oncology investments. Previously, Dr. Loven participated in the creation of Relay Therapeutics, Inc. and Syros Pharmaceuticals, Inc. and currently serves on the board of directors of A2 Biotherapeutics, Inc., Arrakis Therapeutics, IconOVir Bio, Hexagon Bio, and Flare Therapeutics Inc and serves as a board observer for IDRx. In the past, Dr. Loven has served on the board of directors for Vividion Therapeutics (acquired by Bayer) and Turning Point Therapeutics (acquired by Bristol Myers Squibb) as well as a number of public companies, including Kronos Bio, Inc., Arvinas Inc, Kinnate Biopharma Inc., and Autolus Therapeutics PLC. Dr. Loven received a B.A. in Biomedical Sciences from the Anglia Ruskin University of Cambridge and received a Ph.D. in Medical Sciences focused on oncology from Karolinska Institute and conducted his post-doctoral fellowship at the Whitehead Institute for Biomedical Research (WIBR) and Massachusetts Institute of Technology (MIT). Dr. Loven's background as a director and venture capital investor in precision oncology companies, as well as his extensive experience with biotechnology platform companies, contributed to our board of directors' conclusion that she should serve as a director of our company.

Fabio Pucci, Ph.D. has served as a member of our board of directors since April 2023. Dr. Pucci is currently the Senior Director, Venture Investments at Leaps by Bayer since October 2021. Dr. Pucci has also served as a board member for Lyterian Therapeutics since February 2023, Mozart Therapeutics, Inc. since November 2022, Indapta Therapeutics since January 2022, and Immunitas Therapeutics since December 2021, all of which are privately held life sciences companies. Dr. Pucci has also served as a board observer for Capstan Therapeutics since July 2022, and at Kojin Therapeutics since December 2021, and until June 2023, at Azitra Inc. Previously, Dr. Pucci worked as an Associate/Senior Associate at RA Capital Management, LLC, a multi-stage investment manager specializing in life sciences, from October 2019 to September 2021, for which he also served as board

observer at Hemab Therapeutics, until September 2021. Before his tenure at RA Capital Management, Dr. Pucci was an MBA Venture Capital Consultant for F-Prime Capital, an investment group specializing in healthcare and technology, from October 2018 to April 2019. Dr. Pucci has earned his Ph.D. in Cellular Biology from the University of Edinburgh and an MBA from the London Business School and conducted his postdoctoral fellowship at the Francis Crick Institute. Dr. Pucci's experience as a director of numerous biopharmaceutical companies, as well as his experience in the venture capital industry, contributed to our board of directors' conclusion that he should serve as a director of our company.

Nancy Whiting, Pharm.D. has served as a member of our board of directors since October 2023. Since September 2021, Dr. Whiting has been the Chief Executive Officer and a member of the board of directors of Recludix Pharma, a privately held company developing novel treatments for inflammatory disease and cancer. Prior to Recludix, Dr. Whiting held various positions at Seagen Inc. (formerly Seattle Genetics, Inc.) for approximately 15 years (from March 2007 to September 2021), where she served most recently as Executive Vice President of Corporate Strategy, Alliances, and Communication. Prior to this role at Seagen, Dr. Whiting served as Executive Vice President of Late Stage Development, Senior Vice President of Clinical Development and Medical Affairs, and Head of Experimental Medicine. During her tenure at Seagen, Dr. Whiting played a central role in the development and regulatory approvals of cancer medicines Adcetris® (brentuximab vedotin), Padcev® (enfortumab vedotin-ejfv), Tukysa® (tucatinib) and Tivdak® (tisotumab vedotin). Prior to her career in the pharmaceutical industry, Dr. Whiting practiced as a clinical oncology pharmacist at the Seattle Cancer Care Alliance. Dr. Whiting has served as a member of the board of directors of Caribou Biosciences, a publicly traded biopharmaceutical company, since August 2021. She received her Pharm.D. from the University of Washington and her B.Sc. in Pharmaceutical Sciences from the University of British Columbia. Dr. Whiting's extensive experience in all phases of drug development, contributed to our board of directors' conclusion that she should serve as a director of our company.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of seven members. Our board of directors has determined that all of our directors other than Mr. Hornby are independent directors in accordance with the listing requirements of the Nasdaq Stock Market (Nasdaq). The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of the director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors

whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Dr. Brennan and Dr. Whiting, and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Ms. Burow and Dr. Christensen, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Mr. Hornby, Ms. Lew, and Dr. Lim and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our board of directors or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock then entitled to vote in an election of directors.

Board Leadership Structure

Our board of directors is currently chaired by Dr. Lim. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the Company continues to grow. We separate the roles of chief executive officer and chairman of the board of directors in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for our company and the day-to-day leadership and performance of our company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company. Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business, and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management, and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic, and reputational risk.

The audit committee reviews information regarding liquidity and operations and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention, and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor, or control such exposures. The compensation committee is responsible for assessing whether any of our

compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

Board Committees and Independence

Our board of directors has established three standing committees – audit, compensation. and nominating and corporate governance – each of which operates under a charter that has been approved by our board of directors.

Audit Committee

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence, and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy, and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing, overseeing, and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board of directors any changes to such investment policy;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement;
- review our policies with respect to risk assessment and management and oversee management of our information technology risks, including cybersecurity and data privacy risks;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are Dr. Brennan, Ms. Lew, and Dr. Lim. Ms. Lew serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that Ms. Lew is an "audit committee financial expert" as defined by applicable

SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq listing standards. Our board of directors has determined that each of Dr. Brennan, Ms. Lew, and Dr. Lim is independent under the applicable rules of the SEC and Nasdaq. Upon the listing of our common stock on Nasdaq, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Compensation Committee

Our compensation committee approves policies relating to compensation and benefits of our officers and employees. The compensation committee approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives, and approves the compensation of these officers based on such evaluations. The compensation committee also approves the issuance of stock options and other awards under our equity plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Ms. Burow, Dr. Christensen, Ms. Lew, and Dr. Lim. Dr. Lim serves as the chairperson of the committee. Our board of directors has determined that each of Ms. Burow, Dr. Christensen, Ms. Lew, and Dr. Lim is independent under the applicable Nasdaq listing standards and is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. Upon the listing of our common stock on Nasdaq, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board of directors’ responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting, and making recommendations to our board of directors concerning governance matters, reviewing, and assisting the Board with oversight of matters relating to environmental, social and governance matters affecting the Company, and oversight of the evaluation of our board of directors. The members of our nominating and corporate governance committee are Dr. Brennan, Ms. Burow, and Dr. Whiting. Dr. Brennan serves as the chairperson of the committee. Our board of directors has determined that each of Dr. Brennan, Ms. Burow, and Dr. Whiting is independent under the applicable Nasdaq listing standards. Upon the listing of our common stock on Nasdaq, the nominating and corporate governance committee will operate under a written charter, which the nominating and corporate governance committee will review and evaluate at least annually.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Board Diversity

Upon the closing of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills, and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members) for election or appointment, the nominating and corporate governance committee and the board of directors will take into account many factors, including the following:

- personal and professional integrity, ethics, and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly-held company;
- experience as a board member or executive officer of another publicly-held company;
- strong finance experience;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence, and specialized experience;
- experience relevant to our business industry and with relevant social policy concerns; and
- relevant academic expertise or other proficiency in an area of our business operations.

Currently, our board of directors evaluates, and following the closing of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

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, which will be effective upon the closing of this offering. Upon the closing of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at www.boundlessbio.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. We have included our website address in this prospectus solely as an inactive textual reference. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

Overview

Our named executive officers for 2023, which consist of our principal executive officer during 2023 and our two next most highly compensated executive officers during 2023, were:

- Zachary D. Hornby, President and Chief Executive Officer;
- Klaus Wagner, M.D., Ph.D., Chief Medical Officer; and
- Chris Hassig, Ph.D., Chief Scientific Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

The following table sets forth information regarding compensation earned with respect to the fiscal year ended December 31, 2023 by our named executive officers.

2023 Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)(2)	Total ($)
Zachary D. Hornby President and Chief Executive Officer	2023	495,000	—	1,651,813	222,750(3)	3,300	2,372,863
	2022	476,100	—	—	214,245(4)	3,050	693,395
Klaus Wagner, M.D., Ph.D. Chief Medical Officer	2023	465,840	—	363,572	163,044(3)	4,200	996,656
	2022	383,654	—	825,982	138,600(4)	—	1,348,236
Chris Hassig, Ph.D. Chief Scientific Officer	2023	415,000	—	339,960	145,250(3)	3,300	903,510

(1) The amounts reported in the "Option Awards" column represent the aggregate grant date fair value of the stock options awarded to our named executive officers during the applicable fiscal year, calculated in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. The amounts reported in the "Option Awards" column also include the incremental fair value associated with the modification in 2023 of the exercise prices of the options granted to our named executive officers in 2021 and 2022 in connection with our option repricing in June 2023, computed in accordance with FASB ASC Topic 718 as follows: Mr. Hornby, $170,293, Dr. Wagner, $65,334, and Dr. Hassig, $41,722. The assumptions used in calculating the grant date fair value of the awards and the incremental fair value reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and do not reflect the actual economic value that will be realized by our named executive officers upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such awards. See the subsection titled "—Narrative to Summary Compensation Table—Equity-Based Incentive Awards" below.

(2) Amounts reflect 401(k) matching contributions for each of our named executive officers ($3,300 for 2023 and $3,050 for Mr. Hornby for 2022) and a $900 cell phone reimbursement for Dr. Wagner.

(3) Amounts reflect performance bonuses earned by each executive in 2023, which were paid in early 2024.

(4) Amounts reflect performance bonuses earned by each executive in 2022, which were paid in early 2023.

Narrative to Summary Compensation Table

Annual Base Salary

The compensation of our named executive officers is generally determined and approved by our board of directors. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Our named executive officers' annual base salaries in effect for 2023 were as follows: $495,000 for Mr. Hornby, $465,840 for Dr. Wagner, and $415,000 for Dr. Hassig. Effective January 1, 2024, the annual base salaries for Mr. Hornby, Dr. Wagner, and Dr. Hassig were increased to $515,000, $482,144, and $431,600, respectively.

In connection with this offering and pursuant to their amended and restated offer letters (as described in the subsection below titled "—Employment Arrangements with Our Named Executive Officers"), the annual base salaries for Mr. Hornby, Dr. Wagner, and Dr. Hassig will be increased to $620,000, $500,000, and $460,000, respectively, effective upon the closing of this offering.

Annual Bonus

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is based on the extent to which we achieve the corporate goals that our board of directors establishes each year. At the end of the year, our board of directors reviews our performance against each corporate goal and determines the extent to which we achieved each of our corporate goals.

For 2023, Mr. Hornby, Dr. Wagner, and Dr. Hassig were each eligible to receive a target annual bonus for 2023 equal to 45%, 35%, and 35% of their respective annual base salaries.

The corporate goals the board of directors established for 2023 related to clinical and development goals, as well as operational objectives. Bonuses are usually determined and paid in the first quarter of the following year. Actual amounts paid to each named executive officer ($222,750 for Mr. Hornby, $163,044 for Dr. Wagner, and $145,250 for Dr. Hassig) are set forth in the "Non-Equity Incentive Plan Compensation" column of the "Summary Compensation Table" above.

In connection with this offering and pursuant to their amended and restated employment offer letters (as described in the subsection below titled "—Employment Arrangements with Our Named Executive Officers"), the target annual bonuses for Mr. Hornby, Dr. Wagner, and Dr. Hassig will be increased to 55%, 40%, and 40%, effective upon the closing of this offering.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees, including our executive officers. The board of directors or an authorized committee thereof is responsible for approving equity grants.

Prior to this offering, we have granted stock options pursuant to our Amended and Restated 2018 Equity Incentive Plan (the 2018 Plan). Following this offering, we will grant equity awards under the terms of our 2024 Incentive Award Plan (the 2024 Plan). The terms of our equity plans are described in the subsection titled "—Equity Incentive Plans" below. All options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award as determined by our board of directors based on an independent third-party valuation. Our stock option grants generally vest over a four-year period and may be subject to acceleration of vesting and exercisability under certain termination and change in control events.

On June 13, 2023, we granted to Mr. Hornby, Dr. Wagner, and Dr. Hassig options to purchase 471,282, 94,871, and 94,871 shares of our common stock, respectively. The options have an exercise price of $4.10 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The options vest over a period of four years in equal monthly installments beginning on the first monthly anniversary of the vesting commencement date (June 13, 2023), subject to the named executive officer's continuous service with us as of each such vesting date.

On June 13, 2023, in order to retain and properly incentivize our employees to continue our growth, we approved a repricing of stock options held by current employees with exercise prices in excess of $4.10 per share, including each of our named executive officers, whereby the exercise price per share of each outstanding stock option with an exercise price higher than $4.10 per share was lowered to $4.10 per share (our fair market value per share on the date of the repricing as determined by our board of directors based on an independent third-party valuation).

On February 15, 2024, we granted to Mr. Hornby, Dr. Wagner, and Dr. Hassig options to purchase 257,207, 68,080, and 76,173 shares of our common stock, respectively. The options have an exercise price of $8.19 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The options vest in substantially equal monthly installments over a period of four years following the grant date, in each case subject to the named executive officer's continuous service with us as of each such vesting date; provided, that in no event will the options vest if this offering is not completed on or prior to December 31, 2024 (or such later date as our board of directors or compensation committee may determine). In the event this offering is not completed on or prior to such deadline, the options will no longer be eligible to vest and will be forfeited.

In connection with this offering, our board of directors has approved a grant of stock options to our named executive officers pursuant to our 2024 Plan, which grants became effective as of the effective date of the registration statement of which this prospectus is part. The number of shares of our common stock subject to the options that we will grant to Mr. Hornby, Dr. Wagner, and Dr. Hassig, respectively, will equal approximately 0.70%, 0.18% and 0.21% of the shares of our common stock to be outstanding after this offering (calculated on an as-converted basis and after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares). The options will be granted with an exercise price per share equal to the initial price to the public of our common stock in this offering. The options will vest over a period of four years in equal monthly installments beginning on the first monthly anniversary of the vesting commencement date, subject to the named executive officer's continuous service with us as of each such vesting date.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table presents information regarding the outstanding stock options held by each of our named executive officers as of December 31, 2023.

		Option Awards			
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable(1)	Option Exercise Price	Option Expiration Date
Zachary D. Hornby	06/10/2020	112,179	16,025	$3.1200	06/09/2030
	06/07/2021	160,256	96,153	$4.1000	06/06/2031
	6/13/2023	58,910	412,371	$4.1000	6/12/2033
Klaus Wagner, M.D., Ph.D.	02/24/2022	47,008	55,555	$4.1000	02/23/2032
	12/13/2022	2,408	7,226	$4.1000	12/12/2032
	6/13/2023	11,858	83,012	$4.1000	6/12/2033
Chris Hassig, Ph.D.	12/3/2019	38,461	—	$3.1200	12/2/2029
	12/2/2020	7,478	2,777	$3.7100	12/1/2030
	6/7/2021	39,262	23,557	$4.1000	6/6/2031
	6/13/2023	11,858	83,012	$4.1000	6/12/2033

(1) These awards are subject to potential acceleration of vesting in connection with a qualifying termination of employment following a change in control, as described in the subsection titled “Employment Arrangements with our Named Executive Officers” below.

(2) On June 10, 2020, our board of directors granted Mr. Hornby an option to purchase 128,204 shares of our common stock under our 2018 Plan, which vests in 48 substantially equal monthly installments beginning on the first monthly anniversary of the vesting commencement date of June 10, 2020, subject to Mr. Hornby’s continuous service with us as of each such vesting date.

(3) On June 7, 2021, our board of directors granted Mr. Hornby an option to purchase 256,409 shares of our common stock under our 2018 Plan, which vests in 48 substantially equal monthly installments beginning on the first monthly anniversary of the vesting commencement date of June 7, 2021, subject to Mr. Hornby’s continuous service with us as of each such vesting date.

(4) The exercise price of each of these options was repriced to $4.10 per share in June 2023.

(5) On June 13, 2023, our board of directors granted to Mr. Hornby, Dr. Wagner, and Dr. Hassig options to purchase 471,282 shares, 94,871 shares, and 94,871 shares of our common stock, respectively, under our 2018 Plan. Each option vests in 48 substantially equal monthly installments beginning on the first monthly anniversary of the vesting commencement date of June 13, 2023, subject to the named executive officer’s continuous service with us as of each such vesting date.

(6) On February 24, 2022, our board of directors granted Dr. Wagner an option to purchase 102,563 shares of our common stock under our 2018 Plan, with 25% of such shares vesting on the first anniversary of the vesting commencement date of February 22, 2022 and the remaining shares vesting in 36 substantially equal monthly installments thereafter, subject to Dr. Wagner’s continuous service with us as of each such vesting date.

(7) On December 13, 2022, our board of directors granted Dr. Wagner an option to purchase 9,634 shares of our common stock under our 2018 Plan, which vests in 48 substantially equal monthly installments beginning on the first monthly anniversary of the vesting commencement date of December 13, 2022, subject to Dr. Wagner’s continuous service with us as of each such vesting date; provided none of the options were eligible to vest prior to the first anniversary of Dr. Wagner’s commencement of employment.

(8) On December 2, 2020, our board of directors granted Dr. Hassig an option to purchase 10,255 shares of our common stock under our 2018 Plan, with 25% of such shares vesting on the first anniversary of the vesting commencement date of January 1, 2021, and the remaining shares vesting in 36 substantially equal monthly installments thereafter, subject to Dr. Hassig’s continuous service with us as of each such vesting date.

(9) On June 7, 2021, our board of directors granted Dr. Hassig an option to purchase 62,819 shares of our common stock under our 2018 Plan, which vests in 48 substantially equal monthly installments beginning on the first monthly anniversary of the vesting commencement date of June 7, 2021, subject to Dr. Hassig’s continuous service with us as of each such vesting date.

Employment Arrangements with Our Named Executive Officers

We have entered into amended and restated employment offer letters with each of our named executive officers, which will become effective upon the consummation of this offering, and which will govern certain terms of their employment with us following this offering. Upon the effectiveness of their amended and restated employment offer letters, Mr. Hornby, Dr. Wagner, and Dr. Hassig will be

entitled to an annual base salary of $620,000, $500,000, and $460,000, respectively. In addition, Mr. Hornby, Dr. Wagner, and Dr. Hassig will be eligible to receive an annual bonus at a target amount of 55%, 40%, and 40%, respectively, of their base salaries actually paid for the year to which such annual bonus relates based on the achievement of performance objectives as determined by our board of directors.

Regardless of the manner in which our named executive officers' employment terminates, they are entitled to receive amounts previously earned during their employment, including unpaid salary, reimbursement of expenses owed, and any continuation of benefits required by applicable law. In addition, upon the consummation of our initial public offering, Mr. Hornby will be entitled to "Tier 1 Covered Employee" level severance benefits under our Severance Plan (as defined below) and Drs. Wagner and Hassig will be entitled to "Tier 2 Covered Employee" level severance benefits under our Severance Plan, as described below.

Severance and Change in Control Severance Plan

In connection with this offering, our board of directors adopted a Severance and Change in Control Severance Plan (the "Severance Plan") for the benefit of certain management-level employees of the Company or its subsidiaries as designated by our compensation committee (the "Covered Employees"). The severance benefits under the Severance Plan, which will become effective upon the consummation of our initial public offering, will supersede any severance benefits otherwise payable under the Covered Employees' employment offer letters.

The Severance Plan provides assurances of specified severance benefits to Covered Employees whose employment is subject to involuntary termination by us other than for cause (as defined below) or the Covered Employee resigns for good reason (as defined below) under the circumstances described in the Severance Plan, including, but not limited to, following a change in control (as defined below). The severance benefits each Covered Employee could be entitled to receive under the Severance Plan are determined pursuant to each Covered Employee's classification as a Tier 1 Covered Employee, a Tier 2 Covered Employee, or a Tier 3 Covered Employee. Covered Employees are classified as follows:

- "Tier 1 Covered Employee" means an employee of the Company who has been designated by our compensation committee as eligible to participate under Tier 1 in the Severance Plan.
- "Tier 2 Covered Employee" means an employee of the Company who has been designated by our compensation committee as eligible to participate under Tier 2 in the Severance Plan.
- "Tier 3 Covered Employee" means an employee of the Company who has been designated by our compensation committee as eligible to participate under Tier 3 in the Severance Plan.

Pursuant to the Severance Plan, if, at any time before or after the end of the 12-month period beginning on the date of a change in control, we (or any of our subsidiaries) terminate a Covered Employee's employment other than for cause (and other than due to death or disability (as defined in the Severance Plan)) or the Covered Employee resigns for good reason, then the Covered Employee will be entitled to receive the following severance benefits, subject to his or her execution of a release of claims and compliance with certain restrictive covenants, including with respect to non-solicitation and non-disparagement:

- An amount equal to the Covered Employee's annualized Base Pay (as defined in the Severance Plan) for 12 months, 9 months, or 6 months following termination in the case of a Tier 1 Covered Employee, a Tier 2 Covered Employee, or a Tier 3 Covered Employee, respectively, paid in a lump sum.

- Company-paid COBRA coverage for 12 months, 9 months, or 6 months following termination in the case of a Tier 1 Covered Employee, a Tier 2 Covered Employee, or a Tier 3 Covered Employee, respectively.
- The accelerated vesting of the time-based equity compensation awards (as defined in the Severance Plan) that would have vested and become exercisable within 12 months following termination in the case of a Tier 1 Covered Employee; provided, however, that any performance-based equity compensation awards will continue to be governed by the terms of the applicable equity compensation award agreement.

Pursuant to the Severance Plan, if, at any time within the 12-month period following a change in control, we (or any of our subsidiaries) terminate a Covered Employee's employment other than for cause (and other than due to death or disability) or the Covered Employee resigns for good reason, then the Covered Employee will be entitled to receive the following severance benefits, subject to his or her execution of a release of claims and compliance with certain restrictive covenants, including with respect to non-solicitation and non-disparagement:

- The following aggregate cash amount paid in a lump sum:
  - In the case of a Tier 1 Covered Employee, the sum of 18 months of annualized base pay and 1.5 times his or her target bonus (as defined in the Severance Plan);
  - In the case of a Tier 2 Covered Employee, the sum of 12 months of annualized base pay and 1.0 times his or her target bonus; and
  - In the case of a Tier 3 Covered Employee, the sum of 9 months of annualized base pay and 0.75 times his or her target bonus.
- Company-paid COBRA coverage for 18 months, 12 months, or 9 months following termination in the case of a Tier 1 Covered Employee, a Tier 2 Covered Employee, or a Tier 3 Covered Employee, respectively.
- 100% accelerated vesting of the Covered Employee's time-based equity compensation awards; provided, that any performance-based equity compensation awards will vest assuming "target" level of performance, unless the terms of the applicable equity compensation award agreement provide otherwise, in which case the applicable equity compensation award agreement will govern.

For purposes of the Severance Plan:

"Cause" means, unless otherwise defined in a Covered Employee's participation agreement, any of the following: (i) the Covered Employee's commission of an act of fraud, embezzlement or dishonesty, or the commission of some other illegal act by the Covered Employee, that has a demonstrable adverse impact on the Company or any successor or affiliate thereof; (ii) the Covered Employee's conviction of, or plea of "guilty" or "no contest" to, a felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (iii) any intentional, unauthorized use or disclosure by the Covered Employee of confidential information or trade secrets of the Company or any successor or affiliate thereof; (iv) the Covered Employee's gross negligence, insubordination or material violation of any duty of loyalty to the Company or any successor or affiliate thereof, or any other demonstrable material misconduct on the Covered Employee's part; (v) the Covered Employee's ongoing and repeated failure or refusal to perform or neglect of the Covered Employee's duties as required by any offer or employment letter with the Company or the Covered Employee's ongoing and repeated failure or refusal to comply with the lawful instructions given to him or her by the CEO or, with respect to the CEO, the board of directors, which failure, refusal or neglect continues for 15 days following receipt of written notice from the board of directors stating with specificity the nature of such failure, refusal or neglect; or (vi) the Covered Employee's willful, material breach of any Company policy or any material provision of any offer or

employment letter or any confidential information agreement, proprietary information and inventions agreement. Prior to the determination that "Cause" under clauses (iv), (v) or (vi) has occurred, the Company shall (A) provide to the Covered Employee in writing, in reasonable detail, the reasons for the determination that such "Cause" exists, (B) afford the Covered Employee a reasonable opportunity to remedy any such conditions, if capable of being cured, (C) provide the Covered Employee an opportunity to be heard prior to the final decision to terminate his or her employment hereunder for such "Cause" and (D) make any decision that such "Cause" exists in good faith.

"Change in Control" has the same meaning as set forth in the Company's 2024 Incentive Award Plan, as described below.

"Good Reason" means, unless otherwise defined in a Covered Employee's Participation Agreement, the occurrence of any of the following events or conditions without a Covered Employee's written consent: (i) a material diminution in the Covered Employee's authority, duties or responsibilities; (ii) a material diminution in the Covered Employee's base compensation, unless such a reduction is imposed across-the-board to all senior management of the Company; (iii) a material change in the geographic location at which the Covered Employee must perform his or her duties from the location that was designated as the Covered Employee's primary location immediately prior to such change (and he or she and the Company agree that a change of more than thirty-five (35) miles shall be material for this purpose); or (iv) any other action or inaction that constitutes a material breach by the Company or any successor or affiliate of its obligations to the Covered Employee under any agreement between the Covered Employee and the Company or any of its affiliates. The Covered Employee must provide written notice to the Company of the occurrence of any of the foregoing events or conditions without his or her written consent within sixty (60) days of the occurrence of such event. The Company or any successor or affiliate shall have a period of thirty (30) days to cure such event or condition after receipt of written notice of such event. The Covered Employee's termination of employment by reason of resignation from employment with the Company for Good Reason must occur within thirty (30) days following the expiration of the foregoing thirty (30)-day cure period.

Health and Welfare Benefits; Perquisites

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, disability, and life insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Code. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Under the 401(k) plan, we provide matching contributions equal to 25% of the first 4% of eligible compensation deferred by our employees, not to exceed 1% of an employee's eligible compensation. Our board of directors may elect to adopt qualified or nonqualified retirement plans in the future, if it determines that doing so is in our best interests.

Clawback Policy

In connection with this offering, we have adopted a compensation recovery policy that is compliant with the Nasdaq Listing Rules, as required by the Dodd-Frank Act, to be effective upon the consummation of this offering.

Equity Incentive Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the applicable plan, each of which is or will be filed as an exhibit to the registration statement of which this prospectus is a part.

2024 Incentive Award Plan

In connection with this offering, our board of directors has adopted and our stockholders have approved the Boundless Bio, Inc. 2024 Incentive Award Plan (2024 Plan), which became effective in connection with this offering. Under the 2024 Plan, we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate, and retain the talent for which we compete. The material terms of the 2024 Plan are summarized below.

Eligibility and administration. Our employees, consultants, and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2024 Plan. Following this offering, the 2024 Plan will generally be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2024 Plan, Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2024 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2024 Plan, including any vesting and vesting acceleration conditions.

Limitation on awards and shares available. The number of shares initially available for issuance under awards granted pursuant to the 2024 Plan will be the sum of (i) a number of shares equal to 12% of the shares of our common stock to be outstanding after this offering (on an as-converted basis and after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares), plus (ii) any shares of our common stock which, as of the effective date of the 2024 Plan, remain available for issuance under the 2018 Plan, plus (iii) any shares subject to outstanding awards under the 2018 Plan as of the effective date of the 2024 Plan that become available for issuance under the 2024 Plan thereafter in accordance with its terms. The number of shares initially available for issuance will be increased on January 1 of each calendar year beginning on and including January 1, 2025 and ending on and including January 1, 2034, by an amount equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year, or (b) such smaller number of shares as determined by our board of directors. No more than 200,000,000 shares of common stock may be issued upon the exercise of incentive stock options under the 2024 Plan. Shares issued under the 2024 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2024 Plan or the 2018 Plan expires, lapses, or is terminated, exchanged for, or settled in cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited, in any case, in a manner that results in us acquiring shares covered by the award at a price

not greater than the price paid by the participant for such shares or not issuing any shares covered by the award, any shares subject to such award will, as applicable, become or again be available for new grants under the 2024 Plan. Awards granted under the 2024 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2024 Plan.

Awards. The 2024 Plan provides for the grant of stock options, including incentive stock options, or ISOs within the meaning of Section 422 of the Code, and nonqualified stock options, or NSOs; restricted stock; dividend equivalents; restricted stock units, or RSUs; stock appreciation rights, or SARs; and other stock or cash-based awards. Certain awards under the 2024 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2024 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock options.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance, and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any.
- *SARs.* SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.
- *Restricted stock and RSUs.* Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.
- *Other stock or cash-based awards.* Other stock or cash-based awards are awards of cash, fully vested shares of our common stock, and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash-based awards may be granted to participants and may also be available as a payment form

in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees, or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

- *Dividend equivalents.* RSUs or other stock and cash-based awards may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Such dividend equivalents will be paid out only to the extent that any vesting conditions are subsequently satisfied, unless otherwise determined by the plan administrator. No dividend equivalents will be payable on stock options or SARs.

Performance awards. Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including, but not limited to, gross profits, net profits, profit growth, net operation profit, or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs, and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion, or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human capital management (including diversity and inclusion); supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability, or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to our performance or the performance of a subsidiary, division, business segment, or business unit, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies.

Director compensation. The 2024 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2024 Plan's limitations. In connection with this offering, we intend to adopt and ask our stockholders to approve the initial terms of our non-employee director compensation program, which is described in the subsection titled "Non-Employee Director Compensation" below. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in its discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it deems relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value (as determined in accordance with FASB ASC 718, or any successor thereto) of any equity awards granted as compensation for services as a

non-employee director during any calendar year may not exceed $1,000,000, increased to $1,500,000 in the calendar year of a non-employee director's initial service as a non-employee director or during which a non-employee director serves as chair of our board of directors or lead independent director (which limits will not apply to the compensation for any non-employee director who serves in any capacity in addition to that of a non-employee director for which he or she receives additional compensation or any compensation paid to any non-employee director prior to the calendar year following the calendar year in which this offering occurs). The plan administrator may make exceptions to this limit for individual non-employee directors in such circumstances as the plan administrator may determine in its discretion.

Certain transactions. In connection with certain transactions and events affecting our common stock, including a change in control (as defined below), or change in any applicable laws or accounting principles, the plan administrator has broad discretion to act under the 2024 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards in exchange for either an amount in cash or other property with a value equal to the amount that would have been obtained upon exercise or settlement of the vested portion of such award or realization of the participant's rights under the vested portion of such award, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available, replacing awards with other rights or property or terminating awards under the 2024 Plan. In the event of a change in control where the acquirer does not assume awards granted under the 2024 Plan, awards issued under the 2024 Plan will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable. In addition, in the event of certain non-reciprocal transactions with our stockholders (an equity restructuring) the plan administrator will make equitable adjustments to the 2024 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

For purposes of the 2024 Plan, a "change in control" means and includes each of the following:

- a transaction or series of transactions whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than our company or our subsidiaries or any employee benefit plan maintained by us or any of our subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of our securities possessing more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition; or
- during any period of two consecutive years, individuals who, at the beginning of such period, constitute our board of directors together with any new directors (other than a director designated by a person who has entered into an agreement with us to effect a change in control transaction) whose election by our board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or
- the consummation by us (whether directly or indirectly) of (i) a merger, consolidation, reorganization, or business combination or (ii) a sale or other disposition of all or substantially all of our assets in any single transaction or series of related transactions or (iii) the acquisition of assets or stock of another entity, in each case other than a transaction:
    - which results in our voting securities outstanding immediately before the transaction continuing to represent either by remaining outstanding or by being converted into

voting securities of the company or the person that, as a result of the transaction, controls, directly or indirectly, the company or owns, directly or indirectly, all or substantially all of our assets or otherwise succeeds to our business, directly or indirectly, at least a majority of the combined voting power of the successor entity's outstanding voting securities immediately after the transaction, and

- after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the successor entity; provided, however, that no person or group will be treated as beneficially owning 50% or more of the combined voting power of the successor entity solely as a result of the voting power held in our company prior to the consummation of the transaction.

Foreign participants, clawback provisions, transferability, and participant payments. With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any clawback policy implemented by us and to the extent set forth in such clawback policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations, and the laws of descent and distribution, awards under the 2024 Plan are generally nontransferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2024 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2024 Plan, the plan administrator may, in its discretion, accept cash, wire transfer, or check, shares of our common stock that meet specified conditions (a market sell order) or such other consideration as it deems suitable or any combination of the foregoing.

Plan amendment and termination. Our board of directors may amend, suspend, or terminate the 2024 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2024 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its exercise price per share or cancel outstanding stock options or SARs (including those that have an exercise price in excess of fair market value) in exchange for cash, other award or stock option or SARs with an exercise price per share that is less than the exercise price per share of the original stock option or SARs. No award may be granted pursuant to the 2024 Plan after the tenth anniversary of the date on which our board of directors adopts the 2024 Plan.

2018 Equity Incentive Plan

Our board of directors and our stockholders have adopted and approved the 2018 Equity Incentive Plan.

A total of 4,226,659 shares of our common stock are reserved for issuance under the 2018 Plan. As of December 31, 2023, 2,813,937 shares of our common stock were subject to outstanding awards granted under the 2018 Plan, and 861,155 shares of our common stock remained available for future issuance under the 2018 Plan.

After the effective date of the 2024 Plan, no additional awards will be granted under the 2018 Plan. However, the 2018 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of our common stock subject to awards granted under the 2018 Plan that expire, lapse or are terminated, exchanged for cash, surrendered, repurchased, or forfeited following the effective date of the 2018 Plan will be available for issuance under the 2024 Plan in accordance with its terms.

Administration. Our board of directors administers the 2018 Plan unless it delegates authority for administration of the plan. Subject to the terms and conditions of the 2018 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2018 Plan. The plan administrator is also authorized to establish, adopt, amend, or revise rules relating to administration of the 2018 Plan, subject to certain restrictions.

Eligibility. Awards under the 2018 Plan may be granted to individuals who are then our employees, consultants, and members of our board of directors and our subsidiaries. Only employees may be granted ISOs.

Awards. The 2018 Plan provides that our administrator may grant or issue stock options (including NSOs and ISOs), restricted stock, RSUs, other stock-based awards, or any combination thereof. The administrator considers each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms, and conditions of the award.

Certain Transactions. The plan administrator has broad discretion to equitably adjust the provisions of the 2018 Plan and the terms and conditions of existing and future awards, including with respect to aggregate number and type of shares subject to the 2018 Plan and awards granted pursuant to the 2018 Plan, to prevent the dilution or enlargement of intended benefits and/or facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations, and other corporate transactions. The plan administrator may also provide for the acceleration, cash-out, termination, assumption, substitution, or conversion of awards in the event of a change in control or certain other unusual or nonrecurring events or transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an “equity restructuring,” the plan administrator will make equitable adjustments to the 2018 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

In the event of a change of control where the acquirer does not assume awards granted under the 2018 Plan, awards issued under the 2018 Plan held by persons who have not experienced a termination of service will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, immediately prior to the change in control. Under the 2018 Plan, a change of control is generally defined as: (i) a merger or consolidation of our company with or into any other corporation or other entity or person; (ii) a sale, lease, exchange, or other transfer in one transaction or a series of related transactions of all or substantially all of our company’s assets; or (iii) any other transaction, including the sale by us of new shares of our capital stock or a transfer of existing shares of our capital stock, the result of which is that a third party that is not an affiliate of us or our stockholders (or a group of third parties not affiliated with us or our stockholders) immediately prior to such transaction acquires or holds capital stock representing a majority of our outstanding voting power immediately following such transaction; provided that the following events shall not constitute a “change in control” under the 2018 Plan: (a) a transaction (other than a sale of all or substantially all of our assets) in which the holders of our voting securities immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (b) a sale, lease, exchange, or other transaction in one transaction or a series of related transactions of all or substantially all of our assets to an affiliate of ours; (c) an initial public offering of any of our securities; (d) a reincorporation solely to change our jurisdiction; or (e) a transaction undertaken for the primary

purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held our securities immediately before such transaction.

Plan Amendment and Termination. Our board of directors may terminate, amend, or modify the 2018 Plan. Additionally, the plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its exercise price per share. However, stockholder approval of any amendment to the 2018 Plan must be obtained to the extent necessary and desirable to comply with any applicable law, regulation, or stock exchange rule, or for any amendment to the 2018 Plan that increases the number of shares available under the 2018 Plan.

2024 Employee Stock Purchase Plan

In connection with this offering, our board of directors has adopted and our stockholders have approved the Boundless Bio, Inc. 2024 Employee Stock Purchase Plan (the ESPP), which became effective in connection with this offering. The material terms of the ESPP are summarized below.

The ESPP is comprised of two distinct components in order to provide increased flexibility to grant options to purchase shares under the ESPP to U.S. and to non-U.S. employees. Specifically, the ESPP authorizes (i) the grant of options to U.S. employees that are intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Code, (the Section 423 Component), and (ii) the grant of options that are not intended to be tax-qualified under Section 423 of the Code to facilitate participation for employees located outside of the U.S. who do not benefit from favorable U.S. federal tax treatment and to provide flexibility to comply with non-U.S. law and other considerations (the Non-Section 423 Component). Where permitted under local law and custom, we expect that the Non-Section 423 Component will generally be operated and administered on terms and conditions similar to the Section 423 Component.

Shares available for awards; administration. The number of shares initially available for issuance pursuant to the ESPP will be equal to a number of shares equal to 1% of the shares of our common stock to be outstanding after this offering (on an as-converted basis and after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares). In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning on and including January 1, 2025 and ending on and including January 1, 2034, by an amount equal to the lesser of (i) 1% of the shares outstanding on the final day of the immediately preceding calendar year, or (ii) such smaller number of shares as is determined by the plan administrator, provided that no more than 100,000,000 shares of our common stock may be issued under the Section 423 Component. Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the ESPP (referred to as the plan administrator below).

Eligibility. We expect that all of our employees will be eligible to participate in the ESPP. However, an employee may not be granted rights to purchase stock under the ESPP if the employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

Grant of rights. Stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to twenty-seven months long and may consist of one or more purchase periods. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in each purchase period under an offering period. Offering periods under the ESPP will commence when determined by the plan administrator. The plan

administrator may, in its discretion, modify the terms of future offering periods. In non-U.S. jurisdictions where participation in the ESPP through payroll deductions is prohibited, the plan administrator may provide that an eligible employee may elect to participate through contributions to the participant's account under the ESPP in a form acceptable to the plan administrator in lieu of or in addition to payroll deductions.

The ESPP permits participants to purchase common stock through payroll deductions of up to a specified percentage of their eligible compensation. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any purchase period or offering period. In addition, no employee will be permitted to accrue the right to purchase stock under the Section 423 Component at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period and will be exercised on each applicable purchase date during an offering period to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the ESPP at any time during a specified period prior to the end of the applicable offering period and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the ESPP other than by will or the laws of descent and distribution, and such rights are generally exercisable only by the participant.

Certain transactions. In the event of certain non-reciprocal transactions or events affecting our common stock, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods, or (v) the termination of all outstanding rights.

Plan amendment. The plan administrator may amend, suspend, or terminate the ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP or changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP.

Non-Employee Director Compensation

We provide a $25,000 cash retainer, paid in quarterly installments, to certain directors for their service on our board. We also have a policy of reimbursing all of our non-employee directors for their reasonable out-of-pocket expenses in connection with attending board of directors and committee meetings.

In addition, we also from time to time provide equity compensation to certain directors for their service on our board. On June 13, 2023, we granted to Dr. Lim, Dr. Cravatt (who ceased serving as a

director in September 2023), and Ms. Lew options to purchase 17,435, 22,564, and 9,743 shares of our common stock, respectively. The options have an exercise price of $4.10 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The options vest over a period of three years in equal monthly installments beginning on the first monthly anniversary of the vesting commencement date of June 13, 2023, subject to the director's continuous service with us as of each such vesting date.

On June 13, 2023, we approved a repricing of outstanding stock options held by Dr. Lim, Dr. Cravatt, and Ms. Lew, whereby the exercise price per share of each outstanding stock option held by them was lowered to $4.10 (our fair market value per share on the date of the repricing as determined by our board of directors based on an independent third-party valuation).

On October 2, 2023, we granted Drs. Christensen and Whiting each an option to purchase 27,692 shares of our common stock. The options have an exercise price of $4.49 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The options vest over a period of three years in equal monthly installments beginning on the first monthly anniversary of the vesting commencement date of October 1, 2023, subject to the director's continuous service with us as of each such vesting date.

On February 15, 2024, we granted Drs. Lim, Christensen, and Whiting and Ms. Lew each an option to purchase 13,846 shares of our common stock. The options have an exercise price of $8.19 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The options vest in substantially equal monthly installments over a period of three years following the grant date, subject to the director's continuous service with us as of each such vesting date; provided, that in no event will the options vest if this offering is not completed on or prior to December 31, 2024 (or such later date as our board of directors or compensation committee may determine). In the event the offering is not completed on or prior to such deadline, the options will no longer be eligible to vest and will be forfeited.

In connection with this offering, our board of directors has approved a grant of stock options to Dr. Lim, Dr. Brennan, Ms. Burow, Dr. Christensen, Ms. Lew, and Dr. Whiting pursuant to our 2024 Plan, which grants became effective as of the effective date of the registration statement of which this prospectus is part. The number of shares of our common stock subject to the options that we will grant to each such director is 0.057% (or with respect to each of Dr. Brennan and Ms. Burow, 0.114%) of the shares of our common stock to be outstanding after this offering (on an as-converted basis and after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' options to purchase additional shares). The options will be granted with an exercise price per share equal to the initial price to the public of our common stock in this offering. The options vest over a period of three years in equal monthly installments beginning on the first monthly anniversary of the vesting commencement date, subject to the director's continuous service with us as of each such vesting date.

The following table sets forth information regarding compensation earned with respect to the fiscal year ended December 31, 2023 by each individual who served as a non-employee director during such fiscal year.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Jonathan Lim, M.D.[2]	—	61,165	—	61,165
Christine Brennan, Ph.D	—	—	—	—
Kristina Burow	—	—	—	—
James Christensen, Ph.D. [2][3]	6,250	96,487	—	102,737
Ben Cravatt, Ph.D. [2][4]	18,750	73,534	—	92,284
Jennifer Lew[2]	25,000	41,549	—	66,549
Jakob Loven, Ph.D. [5]	—	—	—	—
Fabio Pucci, Ph.D. [6]	—	—	—	—
Nancy Whiting, Pharm.D. [2][3]	—	6,250	96,487	102,737

(1) The amounts reported in the "Option Awards" column represent the aggregate grant date fair value of the stock options awarded to our non-employee directors during the fiscal year ending December 31, 2023, calculated in accordance with FASB ASC Topic 718. For Drs. Lim and Cravatt and Ms. Lew, the amounts reported in the "Option Awards" column also include the incremental fair value associated with the modification in 2023 of the exercise prices of the options granted to them in 2021 and 2022 in connection with our option repricing in June 2023 computed in accordance with FASB ASC Topic 718 as follows: Dr. Lim, $7,078, Dr. Cravatt, $3,539, and Ms. Lew, $11,323. The assumptions used in calculating the grant date fair value and incremental fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and do not reflect the actual economic value that will be realized by the individual upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such awards.

(2) As of December 31, 2023, each of Dr. Lim and Ms. Lew held options to purchase 27,691 shares of our common stock and each of Drs. Cravatt, Christensen and Whiting held options to purchase 27,692 shares of our common stock.

(3) Drs. Christensen and Whiting were appointed as directors commencing October 2, 2023.

(4) Dr. Cravatt ceased serving as a director in September 2023.

(5) Dr. Loven resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(6) Dr. Pucci was appointed as a director commencing April 5, 2023. Dr. Pucci resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Post-IPO Director Compensation Program

In connection with this offering, our board of directors has adopted and our stockholders have approved the initial terms of our non-employee director compensation program. The material terms of the non-employee director compensation program are summarized below.

The non-employee director compensation program will provide for annual retainer fees and equity awards for our non-employee directors. We expect each non-employee director will receive an annual retainer of $40,000, with the non-employee director serving as chair of the board of directors or lead independent director receiving an additional annual retainer of $30,000. The non-employee directors serving as the chairs of the audit, compensation, and nominating and corporate governance committees will receive additional annual retainers of $15,000, $10,000 and $8,000, respectively. Non-employee directors serving as members of the audit, compensation, and nominating and corporate governance committees will receive additional annual retainers of $7,500, $5,000 and $4,000, respectively. Non-employee directors commencing service following this offering will also receive initial grants of options to purchase 27,000 shares of our common stock, vesting in substantially equal monthly installments over three years following the date of initial election or appointment to the board of directors. Each year on the date of each annual meeting, each non-employee director will receive an annual grant of options to purchase 13,500 shares of our common stock, vesting in substantially equal monthly installments over the 12 months following the date of grant (or, in the event the next annual meeting of our stockholders occurs prior to the first anniversary of the date of grant, any remaining unvested portion of the annual award will vest on the date of such annual meeting of our stockholders). Awards to our non-employee directors will also vest in the event of a change in control or upon a non-employee director's death or disability.

Compensation under our non-employee director compensation program will be subject to the annual limits on non-employee director compensation set forth in the 2024 Plan, as described above (which limits will not apply to any non-employee director that serves in any additional capacity with the company for which he or she receives compensation or any compensation paid to any non-employee director prior to the calendar year following the calendar year in which this offering occurs). As provided in the 2024 Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors as the board of directors or its authorized committee may determine in its discretion.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines, and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus is a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit

against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2021 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 and one percent of the average of our total assets as of December 31, 2022 and 2023, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control, and other arrangements, which are described in the section titled "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers, and stockholders.

Convertible Preferred Stock Financings

Series A Convertible Preferred Stock Financings. In July 2020, we sold to investors in private placements an aggregate of 33,189,295 shares of Series A convertible preferred stock, pursuant to a Series A preferred stock purchase agreement originally entered into in August 2018, as amended in June 2019, to provide for additional closings. The per share purchase price was $0.70, and we received gross proceeds of approximately $23.2 million. In previous closings in August 2018 and June 2019, we sold to investors, in private placements, an aggregate of 33,189,295 shares of Series A convertible preferred stock at the same per share purchase price for additional gross proceeds of $23.2 million.

Series B Convertible Preferred Stock Financings. In April 2021, we entered into a Series B preferred stock purchase agreement, pursuant to which we sold to investors, in private placements, an aggregate of 78,211,116 shares of Series B convertible preferred stock. The per share purchase price was $1.35, and we received gross proceeds of approximately $105.6 million.

Series C Convertible Preferred Stock Financings. In April 2023, we entered into a Series C preferred stock purchase agreement, pursuant to which in April and May 2023 we sold to investors, in private placements, an aggregate of 142,857,138 shares of Series C convertible preferred stock. The per share purchase price was $0.70, and we received gross proceeds of approximately $100.0 million.

The following table sets forth the aggregate number of shares acquired by the listed directors, executive officers, or holders of more than 5% of our capital stock, or their affiliates. Each outstanding share of convertible preferred stock, including the shares identified in the table below, will convert into shares of common stock at a ratio of 19.5-for-one immediately prior to the closing of this offering.

Participants	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Series C Convertible Preferred Stock
5% or Greater Stockholders[1]			
Entities affiliated with ARCH Venture Partners[2]	28,571,428	4,444,445	14,285,713
Entities affiliated with Fidelity[3]	—	14,814,815	31,285,714
Entities affiliated with RA Capital Management, L.P.[4]	—	20,000,000	16,428,571
Bayer HealthCare LLC[5]	—	—	28,571,428
Entities affiliated with Nextech VI Oncology SCSp[6]	—	14,814,815	8,157,544
Vertex Global HC Fund II Pte. Ltd[7]	10,000,000	1,851,852	6,526,035
Officers and Directors			
Jonathan E. Lim, M.D.[8]	10,000,000	100,000	142,857

(1) Additional details regarding these stockholders and their equity holdings are provided in the section titled "Principal Stockholders."

(2) Represents shares acquired by ARCH Venture Fund IX, L.P., ARCH Venture Fund IX Overage, L.P., and ARCH Venture Fund X Overage, L.P. Ms. Burow is a Managing Director of ARCH Venture Partners and a member of our board of directors. Dr. Lim, our Chairman and Co-founder, and Ms. Rubin, our Chief Financial Officer, are Venture Partners of ARCH Venture Partners.
(3) Represents shares acquired by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund, Fidelity Capital Trust: Fidelity Flex Small Cap Fund – Small Cap Growth Subportfolio, Fidelity Growth Company Commingled Pool, Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, Fidelity Securities Fund: Fidelity Small Cap Growth Fund, Fidelity Mt. Vernon Street Trust : Fidelity Growth Company K6 Fund, Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, Fidelity Securities Fund: Fidelity Small Cap Growth K6 Fund, Fidelity Capital Trust: Fidelity Stock Selector Small Cap Fund and Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund.
(4) Represents shares acquired by RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund II, L.P.
(5) Dr. Pucci is Senior Director, Venture Investments at Leaps by Bayer HealthCare LLC and a member of our board of directors. Dr. Pucci resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(6) Includes shares acquired by Nextech VI GP S.à r.l. Nextech VI Oncology SCSp is an affiliate of Nextech Invest Ltd. Dr. Loven is a Managing Partner of Nextech Invest Ltd. and a member of our board of directors. Dr. Loven resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(7) Vertex Global HC Fund II Pte. Ltd. is an affiliate of Vertex Ventures HC. Dr. Brennan is a Managing Director of Vertex Ventures HC and a member of our board of directors.
(8) Represents shares acquired by City Hill, LLC. Dr. Lim is the Managing Partner of City Hill, LLC and our Chairman and Co-founder.

Investors' Rights Agreement

We entered into an investors' rights agreement in August 2018, as last amended and restated in April 2023 (the Investors' Rights Agreement), with the holders of our convertible preferred stock and certain holders of our common stock, including the holders of more than 5% of our capital stock listed above as well as entities with which certain of our directors are affiliated. This agreement provides for certain rights relating to the registration of their shares of common stock issuable upon conversion of their convertible preferred stock and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the Investors' Rights Agreement), all rights under this agreement will terminate upon closing of this offering. The registration rights will continue following this offering and will terminate four years after the closing of this offering. See the section titled "Description of Capital Stock—Registration Rights" for more information regarding these registration rights.

Voting Agreement

We entered into a voting agreement in August 2018, as last amended and restated in April 2023 (the Voting Agreement), with the holders of our convertible preferred stock and certain holders of our common stock, including the holders of more than 5% of our capital stock listed above as well as entities with which certain of our directors are affiliated, pursuant to which the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Christine Brennan, Ph.D., Kristina Burow, Jamie Christensen, Ph.D., Zachary D. Hornby, Jennifer Lew, Jonathan Lim, M.D., Jakob Loven, Ph.D., Fabio Pucci, and Nancy Whiting, Pharm.D. Pursuant to the Voting Agreement, Mr. Hornby, as our Chief Executive Officer, serves on our board of directors as the CEO director. Mr. Hornby was initially selected to serve on our board of directors as representative of the holders of our common stock, Dr. Brennan and Ms. Burow were initially selected to serve on our board of directors as representatives of the holders of our Series A convertible preferred stock, Dr. Loven was initially selected to serve on our board of directors as a representative of the holders of our Series B convertible preferred stock, and Mr. Pucci was initially selected to serve on our board of directors as a representative of the holders of our Series C convertible preferred stock.

The Voting Agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed, or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail in the section titled "Management—-Board Composition and Election of Directors."

Right of Refusal and Co-Sale Agreement

We entered into a right of first refusal and co-sale agreement in August 2018, as last amended and restated in April 2023 (the ROFR Agreement), with holders of our common stock affiliated with our executive officers, which entities are referred to in the ROFR Agreement as key holders, and certain other holders of convertible preferred stock, including the holders of more than 5% of our capital stock listed above. Pursuant to the ROFR Agreement, we have a right of first refusal on certain transfers of our shares by the key holders, holders of our convertible preferred stock have a secondary right of first refusal on such transfers, and such convertible preferred stockholders have a right of co-sale in respect of such transfers. The ROFR Agreement will terminate upon the closing of this offering.

Director and Officer Indemnification

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines, and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement, or payment of a judgment under certain circumstances. For further information, see the section titled "Executive and Director Compensation—Limitations of Liability and Indemnification Matters."

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness, and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of February 15, 2024, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 16,003,886 shares of common stock outstanding on February 15, 2024, which gives effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of our common stock immediately prior to the closing of this offering and includes 1,481 shares subject to forfeiture or a right of repurchase. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or other rights held by such person that are currently exercisable or that will become exercisable or otherwise vest within 60 days of February 15, 2024 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. The table below excludes any potential purchases in this offering by the beneficial owners identified in the table below.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Boundless Bio, Inc., 9880 Campus Point Drive, Suite 120, San Diego, CA 92121. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% or Greater Stockholders			
Entities affiliated with ARCH Venture Partners(1)	2,494,095	15.6%	11.2%
Entities affiliated with Fidelity(2)	2,364,125	14.8%	10.6%
Entities affiliated with RA Capital Management, L.P.(3)	1,868,131	11.7%	8.4%
Bayer HealthCare LLC(4)	1,465,201	9.2%	6.6%
Entities affiliated with Nextech VI Oncology SCSp(5)	1,178,069	7.4%	5.3%
Vertex Global HC Fund II Pte. Ltd(6)	942,455	5.9%	4.2%
Named Executive Officers and Directors			
Zachary D. Hornby(7)	669,795	4.1%	3.0%
Klaus Wagner, M.D., Ph.D.(8)	79,229	*	*
Chris Hassig, Ph.D.(9)	139,869	*	*
Jonathan E. Lim, M.D.(10)	669,347	4.2%	3.0%
Christine Brennan, Ph.D.	—	—	*
Kristina Burow	—	—	*
Jamie Christensen, Ph.D.(11)	28,461	*	*
Jennifer Lew(12)	21,423	*	*
Jakob Loven, Ph.D.(13)	—	—	*
Fabio Pucci, Ph.D.(14)	—	—	*
Nancy Whiting, Pharm.D.(15)	28,461	*	*
All executive officers and directors as a group (14 persons)(16)	1,769,827	10.5%	7.7%

* Less than 1%.

(1) Consists of 617,092 shares of common stock held by ARCH Venture Fund IX, L.P. (AVF IX), 828,570 shares of common stock held by ARCH Venture Fund IX Overage, L.P. (AVF IX Overage), and 1,048,433 shares of common stock held by ARCH Venture Fund X Overage, L.P. (AVF X Overage). ARCH Venture Partners IX, L.P. (AVP IX LP) is the sole general partner of AVF IX. ARCH Venture Partners IX Overage, L.P. (AVP IX Overage LP) is the sole general partner of AVF IX Overage. ARCH Venture Partners IX, LLC (AVP IX LLC) is the sole general partner of each of AVP IX LP and AVP IX Overage LP. Keith Crandell, Robert Nelsen, and Clinton Bybee comprise the managing directors of AVP IX LLC (the AVP IX Managing Directors). AVP IX LP may be deemed to beneficially own the shares held by AVF IX; AVP IX Overage LP may be deemed to beneficially own the shares held by AVF IX Overage; AVP IX LLC may be deemed to beneficially own the shares held by AVF IX and AVF IX Overage; and each of the Managing Directors may be deemed to beneficially own the shares held by AVF IX and AVF IX Overage. ARCH Venture Partners X Overage, L.P. (AVP X Overage LP) is the sole general partner of AVF X Overage. ARCH Venture Partners X, LLC (AVP X LLC) is the sole general partner of AVP X Overage LP. Keith Crandell, Kristina Burow, Steven Gillis, and Robert Nelsen comprise the investment committee of AVP X LLC (the AVP X Committee Members). AVP X Overage LP may be deemed to beneficially own the shares held by AVF X Overage; AVP X LLC may be deemed to beneficially own the shares held by AVF X Overage; and each of the AVP X Committee Members may be deemed to share the power to direct the disposition and vote of the shares held by AVF X Overage. Each of AVP IX LP, AVP IX Overage LP, AVP IX LLC, the Managing Directors, AVP X Overage LP, AVP X LLC, and the AVP X Committee Members disclaims beneficial ownership except to any pecuniary interest therein. The address of the ARCH Venture Funds is 8755 W. Higgins Road, Suite 1025, Chicago, IL 60631. Ms. Burow, a member of our board of directors, owns an interest in AVP IX LP and AVP IX Overage LP but does not have voting or dispositive power over the shares held by AVF IX and AVF IX Overage and disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein.

(2) All of the securities listed in the table above are beneficially owned, or may be deemed to be beneficially owned, by FMR LLC, certain of its subsidiaries and affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman, and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners,

directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.

(3) Consists of 1,587,912 shares of common stock held by RA Capital Healthcare Fund, L.P. (RA Healthcare) and 280,219 shares of common stock held by RA Capital Nexus Fund II, L.P. (Nexus II). RA Capital Management, L.P. is the investment manager for RA Healthcare and Nexus II. The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky, Ph.D. and Rajeev Shah are the managing members. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky, Ph.D., and Rajeev Shah may be deemed to have voting and investment power over the shares held of record by RA Healthcare and Nexus II. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky, Ph.D., and Rajeev Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of the entities listed above is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(4) Consists of 1,465,201 shares of common stock held by Bayer HealthCare LLC (BHC). Each of BHC, Bayer US Holding LP (BUSH LP), Bayer World Investments B.V. (BWI), and Bayer Aktiengesellschaft (Bayer AG) share voting and dispositive power over the shares of common stock held by BHC. BHC is controlled by BUSH LP. BWI is the general partner of BUSH LP. BWI is an indirect, wholly owned subsidiary of Bayer AG. Accordingly, Bayer AG may be deemed to be an indirect beneficial owner of the shares of common stock beneficially owned directly by BHC. The business address for BHC and BUSH LP is 100 Bayer Boulevard, Whippany, New Jersey 07981. The business address for BWI is Siriusdreef 36, 2132 WT Hoofddorp, The Netherlands 2132WT. The business address for Bayer AG is Bayerwerk, Gebaeude W11, Kaiser-Wilhelm-Allee 1, Leverkusen, Germany 51373.

(5) Consists of 1,178,069 shares of common stock held by Nextech VI Oncology SCSp (Nextech VI LP). Nextech VI GP S.à r.l. (Nextech VI GP) serves as the sole general partner of Nextech VI LP and has sole voting and investment control over the shares owned by Nextech VI LP and may be deemed to own beneficially the shares held by Nextech VI LP. Nextech VI GP owns no securities of the Company directly. Rocco Sgobbo, Costas Constantinides, and Ian Charoub are members of the board of managers of Nextech VI GP and share voting and dispositive power over the shares held by Nextech VI LP, and may be deemed to own beneficially the shares held by Nextech VI LP. The members of the board of managers own no securities of the Company directly. Each of the individuals and entities listed above expressly disclaims beneficial interest of the shares listed above except to the extent of any pecuniary interest therein. The principal business address of Nextech VI LP is: 8 rue Lou Hemmer, L-1748 Senningerberg, Grand-Duché de Luxembourg.

(6) Consists of 942,455 shares of common stock held by Vertex Global HC Fund II Pte. Ltd. (Vertex). Vertex is managed by Vertex Venture Management Pte. Ltd. (VVM) which is a private company limited by shares. VVM is deemed to have voting and dispositive power over the shares held by Vertex pursuant to a management agreement between Vertex and VVM whereby the divestment and voting decisions require the unanimous approval of the members of an investment committee established by VVM. The members of the investment committee are Ming Kian Teo, Kheng Nam Lee, and Kee Lock Chua. The address of Vertex is 250 North Bridge Road, #11-01 Raffles City Tower, Singapore 179101.

(7) Consists of 256,410 shares of common stock held directly and 413,385 shares of common stock underlying options held by Mr. Hornby that are exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date.

(8) Consists of 79,229 shares of common stock underlying options held by Dr. Wagner that are exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date.

(9) Consists of (i) 25,641 shares of common stock held directly and (ii) 114,228 shares of common stock underlying options held by Dr. Hassig that are exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date.

(10) Consists of (i) 102,564 shares of common stock held directly, (ii) 550,915 shares of common stock held by City Hill, LLC and (iii) 15,868 shares of common stock underlying options held by Dr. Lim that are exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date.

(11) Consists of 28,461 shares of common stock underlying options held by Dr. Christensen that are exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date.

(12) Consists of 21,423 shares of common stock underlying options held by Ms. Lew that are exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date.

(13) Dr. Loven resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(14) Dr. Pucci resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(15) Consists of 28,461 shares of common stock underlying options held by Dr. Whiting that are exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date.

(16) Includes the shares described in footnotes 7 through 15 above and an additional 834,297 shares of common stock underlying options exercisable as of February 15, 2024 or that will become exercisable within 60 days after such date held by our other executive officers.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of this offering, our investors' rights agreement and of the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and our investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

Following the closing of this offering, our authorized capital stock will consist of 700,000,000 shares of common stock, $0.0001 par value per share, and 70,000,000 shares of preferred stock, $0.0001 par value per share.

Common Stock

As of December 31, 2023, there were 15,989,333 shares of our common stock outstanding and held of record by 104 stockholders, including 1,481 shares of restricted common stock, which are subject to our right of repurchase, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 14,740,840 shares of common stock, which will automatically occur immediately prior to the closing of this offering. Based on the number of shares of common stock outstanding as of December 31, 2023, and further assuming the issuance by us of 6,250,000 shares of common stock in this offering, there will be 22,239,333 shares of common stock outstanding upon the closing of this offering. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation. See the subsection titled"—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws-Amendment of Charter Provisions" below.

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. The rights, preferences, and privileges of holders of common stock are subject to and

may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Upon the closing of this offering, all of our previously outstanding shares of convertible preferred stock will have been converted into common stock, there will be no authorized shares of our previously outstanding convertible preferred stock, and we will have no shares of preferred stock outstanding. Under the terms of our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, our board of directors has the authority, without further action by our stockholders, to issue up to 70,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences. and privileges of the shares of each wholly unissued series and any qualifications, limitations, or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deterring, or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Options

As of December 31, 2023, options to purchase 2,813,937 shares of our common stock were outstanding, of which 932,923 were vested and 1,007,739 were exercisable as of that date. For additional information regarding the terms of our 2018 Plan, see the section titled “Executive and Director Compensation— Equity Incentive Plans—2018 Equity Incentive Plan.”

Registration Rights

As of December 31, 2023, upon the closing of this offering holders of 14,740,840 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion convertible preferred stock immediately prior to the closing of this offering, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an investors’ rights agreement by and among us and certain investors. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights

Form S-1. If at any time beginning six months following the effective date of the registration statement of which this prospectus forms a part, the holders of at least 60% of the registrable securities then-held by major investors (as defined therein) request in writing that we effect a registration with respect to at least 40% of the registrable securities then outstanding, we may be required to provide notice of such request to all holders of registrable securities and offer them the opportunity to participate in such registration, and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, among other things, we have already effected two registrations for the holders of registrable securities in response to these demand registration rights.

Form S-3. If at any time we become entitled under the Securities Act to register our shares on Form S-3, and the holders of at least 60% of the registrable securities then-held by major investors request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the anticipated aggregate offering price, net of expenses, is at least $15.0 million, we may be required to provide notice of such request to all holders of registrable securities and offer them the opportunity to participate in such registration, and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, among other things, within the preceding 12 months, we have already effected two registrations on Form S-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwritten offering, the underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares in accordance with the cut-back provisions of the investors' rights agreements.

Piggyback Registration Rights

If at any time following the closing of this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwritten offering, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares in accordance with the cut-back provisions of the investors' rights agreement.

Indemnification

Our investors' rights agreement contains customary cross indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in a registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expenses

Other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders, blue sky fees and expenses, and the expenses of any special audits incident to the registration.

Termination of Registration Rights

The registration rights terminate upon the earlier of (i) four years after the closing of this offering or (ii) with respect to a particular holder, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all shares by such holder without limitation during a three-month period without registration.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 70,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board of Directors

Our amended and restated bylaws provide that our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, with one class being elected each year by our stockholders. For more information on the classified board of directors, see the section titled “Management—Board Composition and Election of Directors.” This system of electing directors may tend to discourage a third party from attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware (the Court of Chancery) (or, in the event the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty by any of our directors, officers, or stockholders to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law. The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. 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. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of

our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board of directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar's address is 150 Royall Street, Canton, MA 02021.

The Nasdaq Global Select Market Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "BOLD."

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see the section titled "Executive and Director Compensation—Limitations of Liability and Indemnification Matters."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although our common stock has been approved for listing on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of December 31, 2023, and assuming (i) the issuance of 6,250,000 shares in this offering, (ii) the automatic conversion of all of our outstanding shares of convertible preferred stock into 14,740,840 shares of common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity upon the closing of this offering, (iii) no exercise of the underwriters' option to purchase additional shares of common stock and (iv) no exercise of outstanding options, we will have outstanding an aggregate of 22,239,333 shares of common stock following the closing of this offering.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 15,989,333 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

Lock-Up Agreements

We, our officers, directors, and substantially all of our securityholders, have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, among other things and subject to certain exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to sell, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock, or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock, or publicly declare an intention to do any of the foregoing. Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See the subsection titled "—Registration Rights" below and the section titled "Description of Capital Stock—Registration Rights."

Goldman Sachs & Co. LLC, Leerink Partners LLC, Piper Sandler & Co., and Guggenheim Securities, LLC may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, in certain cases without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 10b5-1 Trading Plans

Following the closing of this offering, certain of our officers, directors, and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director, or stockholder when entering into the plan, without further direction from such officer, director, or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director, or stockholder in connection with this offering.

Rule 144

Affiliate Resales of Restricted Securities

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, and who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 222,393 shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume in our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

An "affiliate" is a person that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with an issuer. Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and Nasdaq concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701 as currently in effect, any of an issuer's employees, directors, officers, consultants, or advisors who purchase shares from the issuer in connection with a compensatory stock

or option plan or other written agreement before the effective date of a registration statement under the Securities Act are entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements. However, substantially all Rule 701 shares are subject to lock-up agreements as described above and will become eligible for sale in compliance with Rule 144 only upon the expiration of the restrictions set forth in those agreements.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity incentive plans and employee stock purchase plan. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Registration Rights

Upon the closing of this offering, holders of 14,740,840 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering, will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the closing of this offering. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by our affiliates. See the section titled “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreements described above.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the Code), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the IRS), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax provisions of the Code. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying cash dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described in the subsection titled "—Sale or Other Taxable Disposition" below.

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). If a Non-U.S. Holder holds the stock through a financial institution or other intermediary, the Non-U.S. Holder will be required to provide appropriate documentation to the intermediary, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below of backup withholding and withholding under FATCA (defined below), a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (USRPI) by reason of our status as a U.S. real property holding corporation (USRPHC) for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and

constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will be subject to backup withholding or information reporting unless the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections are commonly referred to as the Foreign Account Tax Compliance Act (FATCA)) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers (including applicable withholding agents) generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. There can be no assurance that final Treasury Regulations would provide an exemption from FATCA withholding for gross proceeds.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Leerink Partners LLC, Piper Sandler & Co., and Guggenheim Securities, LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	2,500,000
Leerink Partners LLC	1,781,250
Piper Sandler & Co.	1,218,750
Guggenheim Securities, LLC	750,000
Total	6,250,000

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 937,500 shares of our common stock from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 937,500 shares of common stock from us.

	No Exercise	Full Exercise
Per Share	$ 1.12	$ 1.12
Total	$ 7,000,000	$ 8,050,000

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $0.672 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our capital stock and securities convertible into or exchangeable for our common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC, Leerink Partners LLC, Piper Sandler & Co., and Guggenheim Securities, LLC. This agreement does not apply to any existing employee benefit plans. See the section titled "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares of our common stock. The initial public offering price has been negotiated among the Company and the representatives. Among

the factors considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, were the company's historical performance, estimates of the business potential and earnings prospects of the Company, an assessment of our management, and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "BOLD."

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions, and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the closing of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain, or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $4.7 million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $40,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage, and other financial and non-financial activities and services. Certain of the underwriters and

their respective affiliates may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors, and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps, and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities, and/or instruments of ours (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities, and instruments.

Affiliates of Piper Sandler & Co. purchased 8,839,914 shares of our Series C convertible preferred stock in our May 2023 Series C convertible preferred stock financing. Those shares of Series C convertible preferred stock will automatically convert into 453,328 shares of our common stock immediately prior to and in connection with the closing of this offering. All such shares are subject to the 180-day lock-up restrictions pursuant to FINRA Rule 5110(g).

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant Member), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant Member prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member or, where appropriate, approved in another Relevant Member and notified to the competent authority in that Relevant Member, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant Member at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant Member means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by

the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression. "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (Companies (Winding Up and Miscellaneous Provisions) Ordinance) or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (Securities and Futures Ordinance), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each

case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the SFA)) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore (Regulation 32).

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement, or other disclosure document under the Corporations Act 2001 (the Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement, or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation, or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives, and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This offering document is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document. you should consult an authorized financial advisor.

Switzerland

This offering document is not intended to constitute an offer or solicitation to purchase or invest in the shares of our common stock. The shares of common stock may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act (FinSA), and no application has or will be made to admit the shares of common stock to trading on any trading venue (exchange or multilateral trading facility) in Switzerland. Neither this offering document nor any other offering or marketing material relating to the shares of common stock constitutes a prospectus pursuant to the FinSA, and neither this offering document nor any other offering or marketing material relating to the shares of common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this offering document nor any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this offering document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority, or the FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP, San Diego, California. The underwriters are being represented by Cooley LLP, San Diego, California.

EXPERTS

The financial statements of Boundless Bio, Inc. as of December 31, 2022 and 2023, and for each of the years in the two-year period ended December 31, 2023, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We are not currently subject to the information and periodic and current reporting requirements of the Exchange Act. Upon the closing of this offering, we will become subject to the information and periodic and current reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements, and other information with the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy statements, and other information regarding companies that file electronically with it. Our periodic and current reports, proxy statements and other information will be available at www.sec.gov.

We also maintain a website at www.boundlessbio.com. Upon the closing of this offering, you may access our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

BOUNDLESS BIO, INC.
INDEX TO FINANCIAL STATEMENTS

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, 2022 and 2023, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for 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, 2022 and 2023, and the results of its operations and its cash flows for 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. 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 2018.

San Diego, California
March 6, 2024, except for the third paragraph of Note 14, as to which the date is March 21, 2024.

Boundless Bio, Inc.

Balance Sheets
(in thousands, except par value, share data, and liquidation value)

	December 31, 2022	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 10,951	$ 23,706
Short-term investments	55,766	97,046
Prepaid expenses and other current assets	1,320	3,452
Total current assets	68,037	124,204
Property and equipment, net	2,922	2,573
Right-of-use asset, net	4,804	2,002
Restricted cash	533	560
Other assets	533	555
Total assets	$ 76,829	$ 129,894
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,838	$ 4,266
Accrued compensation	2,459	2,898
Lease liabilities, current portion	2,338	2,195
Unvested common stock	93	—
Total current liabilities	7,728	9,359
Lease liabilities, non-current	2,845	—
Unvested common stock, non-current	6	—
Total liabilities	10,579	9,359
Commitments and contingencies (Note 8)		
Convertible preferred stock, $0.0001 par value; 144,589,706 shares authorized, issued and outstanding as of December 31, 2022; 287,446,844 shares authorized, issued and outstanding as of December 31, 2023; liquidation preference of $152.1 million and $252.1 million as of December 31, 2022 and 2023, respectively	147,946	247,617
Stockholders' deficit:		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 1,199,769 shares issued, and 1,167,240 shares outstanding as of December 31, 2022; 402,600,000 shares authorized, 1,248,493 shares issued, and 1,247,012 shares outstanding as of December 31, 2023	—	—
Additional paid-in capital	5,377	8,987
Accumulated other comprehensive loss	(398)	40
Accumulated deficit	(86,675)	(136,109)
Total stockholders' deficit	(81,696)	(127,082)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 76,829	$ 129,894

See accompanying notes to financial statements.

Boundless Bio, Inc.

Statements of Operations and Comprehensive Loss
(in thousands)

	Year Ended December 31, 2022	Year Ended December 31, 2023
Operating expenses:		
Research and development	$ 37,159	$ 42,637
General and administrative	9,310	12,159
Total operating expenses	46,469	54,796
Loss from operations	(46,469)	(54,796)
Other income (expense), net:		
Interest income	668	5,282
Other income (expense)	(100)	80
Total other income (expense), net	568	5,362
Net loss	$ (45,901)	$ (49,434)
Net loss per common share, basic and diluted	$ (41.80)	$ (40.65)
Weighted-average shares used in net loss per common share calculation	1,098	1,216
Comprehensive loss:		
Net loss	$ (45,901)	$ (49,434)
Unrealized gain (loss) on investments	(223)	438
Comprehensive loss	$ (46,124)	$ (48,996)

See accompanying notes to financial statements.

Boundless Bio, Inc.

Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	144,589,706	$ 147,946	1,007,534	$ —	$ 2,760	$ (175)	$ (40,774)	$ (38,189
Vesting of founder shares and restricted stock awards	—		65,595	—	—	—	—	—
Vesting of early exercised stock options	—	—	69,639	—	206	—	—	206
Exercise of stock options	—	—	24,472	—	121	—	—	121
Stock-based compensation	—	—	—	—	2,290	—	—	2,290
Unrealized loss on short-term investments	—	—	—	—	—	(223)	—	(223
Net loss	—	—	—	—	—	—	(45,901)	(45,901
Balance as of December 31, 2022	144,589,706	$ 147,946	1,167,240	$ —	$ 5,377	$ (398)	$ (86,675)	$ (81,696
Issuance of Series C convertible preferred stock, net of issuance costs of $329	142,857,138	99,671	—	—	—	—	—	—
Vesting of early exercised stock options	—	—	31,048	—	92	—	—	92
Exercise of stock options	—	—	48,724	—	182	—	—	182
Stock-based compensation	—	—	—	—	3,336	—	—	3,336
Unrealized gain on short-term investments	—	—	—	—	—	438	—	438
Net loss	—	—	—	—	—	—	(49,434)	(49,434
Balance as of December 31, 2023	287,446,844	$ 247,617	1,247,012	$ —	$ 8,987	$ 40	$ (136,109)	$ (127,082

See accompanying notes to financial statements.

Boundless Bio, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2022	2023
Cash flows from operating activities		
Net loss	$ (45,901)	$ (49,434)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	2,290	3,336
Depreciation	942	957
Amortization (accretion) of investments, net	503	(3,300)
Non-cash lease expense	1,607	2,360
Other	97	25
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	217	85
Accounts payable and accrued liabilities	1,911	1,663
Operating lease liabilities	(1,262)	(2,547)
Net cash used in operating activities	(39,596)	(46,855)
Cash flows from investing activities		
Purchases of investments	(42,598)	(160,123)
Maturities of investments	59,796	122,496
Purchases of property and equipment	(1,066)	(633)
Net cash provided by (used in) investing activities	16,132	(38,260)
Cash flows from financing activities		
Proceeds from issuance of Series C preferred stock, net of issuance costs	—	99,671
Payment of deferred offering costs	—	(1,956)
Proceeds from the exercise of stock options	126	182
Net cash provided by financing activities	126	97,897
Net increase (decrease) in cash and cash equivalents	(23,338)	12,782
Cash, cash equivalents, and restricted cash at beginning of year	34,822	11,484
Cash, cash equivalents, and restricted cash at end of year	$ 11,484	$ 24,266
Components of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 10,951	$ 23,706
Restricted cash	533	560
Cash, cash equivalents, and restricted cash at end of year	$ 11,484	$ 24,266
Non-cash investing and financing activities		
Deferred offering costs in accounts payable and accrued expenses	$ —	$ 197
Addition to ROU assets	$ 5,506	$ 282
Increase (decrease) to ROU assets due to remeasurement of lease obligation	$ 562	$ (723)
Vesting of early exercised stock options	$ 206	$ 92
Unpaid property and equipment purchases	$ 102	$ —

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

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, 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.

As of December 31, 2023, the Company had an accumulated deficit of $136.1 million and cash, cash equivalents, and short-term investments of $120.8 million. The Company has incurred significant operating losses and negative cash flows from its operations and expects that it will continue to do so into the foreseeable future as it continues its development of, seeks regulatory approval for, and potentially commercializes any of its ecDTx and seeks to discover, and develop additional ecDTx, utilizes third parties to manufacture its ecDTx and related raw materials, hires additional personnel, and expands and protects its intellectual property. If the Company obtains regulatory approval for any of its ecDTx, it expects to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. As such, the Company will need to continue to raise a substantial amount of funds until it is able to generate revenues to fund its development activities and operations. Since its inception, the Company has funded its operations from the gross proceeds from the sale and issuance of its convertible preferred stock.

The Company does not have any products approved for sale and has not generated any revenue to date. The Company does not expect to generate any revenue from product sales until it successfully completes development and obtains regulatory approval for one or more of its ecDTx, which the Company expects will take a number of years and may never occur. The Company will need substantial additional funding to support its continuing operations and pursue its long-term business plan, including to complete the development and commercialization of its ecDTx, if approved. Accordingly, until such time as the Company can generate significant revenue from sales of its ecDTx, if ever, the Company expects to finance its future cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company's failure to raise capital or enter into such other arrangements when needed would have a negative impact on its financial condition and could force it to delay, limit, reduce, or terminate its research and development programs or other operations, or grant rights to develop and market ecDTx that the Company would otherwise prefer to develop and market itself. Although there can be no assurance that the Company will be successful in acquiring additional funding, that projections of future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years, the Company believes that its existing cash, and cash equivalents and investments securities will be sufficient to fund operations for the next 12 months from the date these financial statements are available to be issued.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. 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 and common stock, and accrued research and development costs. These estimates are based on historical data and experience, as well as various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company's estimates relating to the valuation of stock options require the selection of appropriate valuation methodologies and models, and significant judgment in evaluating ranges of assumptions and financial inputs.

Cash, Cash Equivalents, and Restricted Cash

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

The balance reflected in these financial statements as restricted cash represents a deposit account pledged as collateral to secure a standby letter of credit required as a security deposit on one of the Company's leased facilities. The Company has classified the restricted cash as a noncurrent asset on its balance sheets as of December 31, 2022 and 2023.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to the concentration of credit risk, consist primarily of cash, cash equivalents, and investments. The Company maintains deposits in federally insured financial institutions which exceeded federally insured limits by $1.6 million. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company's investment policy includes guidelines for the quality of the related institutions and financial instruments and defines allowable investments that the Company may invest in, which the Company believes minimizes its exposure to concentration of credit risk.

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

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

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

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

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

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2022 and 2023, there were $0 and $2.2 million of deferred offering costs, respectively.

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 ranges 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

The Company leases real estate facilities under non-cancellable operating leases with various expiration dates through fiscal year 2034. At the inception of an arrangement, the Company determines whether the arrangement is or contains a 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.

Prior to January 1, 2021, the Company accounted for its leases under *ASC 840, Leases* (ASC 840). The Company adopted ASU 2016-02, *Leases* (Topic 842) on January 1, 2021. The Company elected the package of practical expedients for transition under which the Company did not reassess its prior conclusions about lease identification, lease classification, and initial direct costs. Additionally, the Company elected the "hindsight" and "land easement" practical expedients for transition under which conclusions around lease term, impairment, and land easements will not be reassessed. The Company did not apply the portfolio approach to its lease agreements.

Operating leases are included in operating lease assets and in operating lease liabilities in the accompanying balance sheets. Operating lease 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. 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 the more readily determinable of (i) the rate implicit in the lease or (ii) the Company's incremental borrowing rate (which is the estimated rate the Company would be required to pay for a collateralized borrowing equal to the total lease payments over the term of the lease). 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 lease commencement date for borrowings with a similar term.

The Company's operating lease 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. The Company does not assume renewals or early terminations unless it is reasonably certain to exercise these options at commencement. The Company elected the practical expedient, which allows the Company to not 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 the practical expedient such that it does not recognize lease assets or lease liabilities for leases with a term of 12 months or less of all asset classes. Operating lease expense is recognized on a straight-line basis over the lease term.

Segments

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

Convertible Preferred Stock

The Company's convertible preferred stock is classified as temporary equity in the accompanying balance sheets and excluded from stockholders' deficit as the potential redemption of such stock is outside the Company's control and would require the redemption of the then-outstanding convertible preferred stock. The convertible preferred stock is not redeemable except for in the event of a liquidation, dissolution, or winding up of the Company. Costs incurred in connection with the issuance of convertible preferred stock are recorded as a reduction of gross proceeds from issuance. The Company does not accrete the carrying values of the preferred stock to the redemption values since the occurrence of these events was not considered probable as of December 31, 2022 and 2023. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that these events will occur.

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, benefits, and stock-based compensation, 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, 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 expenses stock-based compensation over the requisite service period (usually the vesting period) on a straight-line basis, net of actual forfeitures during the period, based on the estimated grant-date fair value of the awards. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including the:

- *Fair value of common stock*. Due to the absence of an active market for the Company's common stock, the Company utilized methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation* to estimate the fair value of its common stock. In determining the fair value of the restricted stock awards, the Company has considered the fair value of the common stock as of the grant date. The fair value of the common stock has been 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.
- *Expected volatility*. Given that the Company's common stock is privately held, there is no active trading market for its common stock. The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.
- *Risk-free interest rate*. The Company bases the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.
- *Expected term.* The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have significant historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.
- *Expected dividend yield*. The Company used an expected dividend yield of zero, as it has never paid dividends on its common stock and has no present intention of doing so in the foreseeable future.

For restricted stock awards, the fair value of the award is the estimated fair value of the Company's common stock on the grant date, as determined by the Company's Board of Directors.

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

Common Stock Valuation

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid (*Valuation of Privately Held Company Equity Securities Issued as Compensation*) to estimate the fair value of its common stock. In

determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights, preferences, and privileges of the convertible preferred stockholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

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.

Net Loss Per Share

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

Comprehensive Loss

Comprehensive loss consists of net loss and unrealized gains and losses on the Company's available-for-sale investments. The Company reports all components of comprehensive income (loss) in the statements of operations and comprehensive loss in the period in which they are recognized.

Emerging Growth Company Status

The Company is 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. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company FASB standards' effective dates.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments- Credit Losses: Measurement of Credit Losses on Financial Instruments (Topic 326*) (CECL). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. This ASU does not change the core principle of the guidance in ASU 2016-13, instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses guidance. The FASB also subsequently issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Derivatives and Hedging (Topic 815)*, and *Financial Instruments (Topic 825*), which did not change the core principle of the guidance in ASU 2016-13 but clarified that expected recoveries of amounts previously written off and expected to be written off should be included in the valuation account and should not exceed amounts previously written off and expected to be written off. In March 2020, the FASB issued ASU No. 2020-3, *Codification Improvements to Financial Instruments* which makes narrow-scope improvements to various financial instruments topics, including the new credit losses standard and clarifies the following areas (i) the contractual term of a net investment in a lease should be the contractual term used to measure expected credit losses; (ii) when an entity regains control of financial assets sold, an allowance for credit losses should be recorded. The new standard is effective for annual reporting periods beginning after December 15, 2022, including interim reporting periods within each annual reporting period for smaller reporting companies. The Company adopted ASU 2016-13 on a modified retrospective basis on January 1, 2023, and noted no material impact to the Company's financial statements for the year ended December 31, 2023.

In August 2020, the FASB issued ASU 2020-06, *Debt: Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)* (ASU 2020-06), which simplifies the accounting for convertible instruments and contracts in an entity's own equity. This guidance is effective for the Company in its annual reporting period beginning after December 15, 2023, including interim periods within that reporting period, with early adoption permitted only as of annual reporting periods beginning after December 15, 2020. The Company adopted ASU 2020-06 on a modified retrospective basis on January 1, 2023, and the adoption had no impact on its financial statements and related disclosures.

As of December 31, 2023, several new accounting pronouncements had been issued by the Financial Accounting Standards Board with future adoption dates. All applicable accounting pronouncements will be adopted by the Company by the date required. Management is reviewing the impact of adoption of all pending accounting pronouncements but is not yet in a position to determine the impact on the Company's financial statements and the notes thereto.

3. Fair Value Measurements

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

		Fair Value Measurements Using		
December 31, 2022 (in thousands)	**Amount**	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds (1)	$ 9,078	$ 9,078	$ —	$ —
U.S. government obligations (2)	34,898	—	34,898	—
Corporate debt securities (2)	17,279	—	17,279	—
Commercial paper (2)	3,484	—	3,484	—
Asset backed securities (2)	105	—	105	—
Total fair value of assets	$ 64,844	$ 9,078	$ 55,766	$ —

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

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

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

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

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

4. Investments

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

	December 31, 2022			
	Acquisition Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 9,078	$ —	$ —	$ 9,078
U.S. government obligations	35,209	—	(311)	34,898
Corporate debt securities	17,366	—	(87)	17,279
Commercial paper	3,484	—	—	3,484
Asset-backed securities	105	—	—	105
Total available-for-sale securities	$ 65,242	$ —	$ (398)	$ 64,844
Classified as:				
Cash equivalents				$ 9,078
Short-term investments				55,766
Total cash equivalents and investments				$ 64,844

	December 31, 2023			
	Acquisition Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 21,737	$ —	$ —	$ 21,737
U.S. government obligations	92,106	58	(21)	92,143
Corporate debt securities	4,900	5	(2)	4,903
Total available-for-sale securities	$ 118,743	$ 63	$ (23)	$ 118,783
Classified as:				
Cash equivalents				$ 21,737
Short-term investments				97,046
Total cash equivalents and investments				$ 118,783

On December 31, 2022 and 2023, the remaining contractual maturities of all the Company's available-for-sale investments were less than 24 months. As of December 31, 2022 and 2023, the Company has not established an allowance for credit losses for any of its available-for-sale securities.

As of December 31, 2022, there were 18 available-for-sale securities with an estimated fair value of $50.3 million in gross unrealized loss positions. As of December 31, 2023, there were 24 available-for-sale securities with an estimated fair value of $40.3 million in gross unrealized loss positions. Based on its review of these investments, the Company believes that the unrealized losses reflected the impact of the rising interest rate environment and were not other-than-temporary in nature.

5. Property and Equipment, Net

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

	December 31,	
	2022	2023
Lab equipment	$ 3,861	$ 4,264
Computers and software	622	833
Leasehold improvements	46	46
Furniture and fixtures	204	157
Total property and equipment	4,733	5,300
Less accumulated depreciation and amortization	1,811	2,727
Property and equipment, net	$ 2,922	$ 2,573

Depreciation and amortization expense related to property and equipment was $0.9 million and $1.0 million for the years ended December 31, 2022 and 2023, respectively.

6. Accounts Payable and Accrued Liabilities

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

	December 31,	
	2022	2023
Accounts payable	$ 1,402	$ 2,222
Accrued research and development costs	967	1,575
Other accrued liabilities	469	469
Total accounts payable and accrued liabilities	$ 2,838	$ 4,266

7. Lease Agreements

2022 Lease

In March 2021, as amended in November 2021, the Company entered into a non-cancelable operating lease for a facility in San Diego, California (the 2022 Lease). The 2022 Lease had an initial term that ended in May 2024, although this was subsequently amended such that this lease now ends on that date occurring 14 days after the lease commencement date for the 2024 Lease (see below). The 2022 Lease provides for the rental of lab and office space, contains rent escalation provisions, and obligates the Company to pay a portion of the operating costs related to the underlying multitenant facility. Rental payments under the 2022 Lease commenced in mid-January 2022. Based on information obtained from its landlord, the Company has recorded an ROU asset and an associated lease obligation for the lab and office space leased under the 2022 Lease. The net ROU asset ($2.0 million) and associated lease obligation ($2.2 million) which are reflected in the Company's balance sheet as of December 31, 2023, are estimates that will change should there be a change in the anticipated occupancy date of the property and associated campus underlying the 2024 Lease. The Company's estimated incremental borrowing rate of approximately 8.0% was used in its present value calculation as the 2022 Lease does not have a stated rate and the implicit rate was not readily determinable.

As of December 31, 2023, future minimum lease payments under the 2022 Lease are expected to total $2.3 million, including imputed interest of approximately $0.1 million. All future payments under the 2022 Lease are expected to occur in 2024.

2024 Lease

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

As of December 31, 2023, although construction of the property underlying the 2024 Lease is underway, the commencement date of the 2024 lease has not yet been determined. At completion of construction, the Company will occupy the facility for a 120-month term, with payments under the lease commencing after a six-month rent abatement period and continuing through the conclusion of the term. As of December 31, 2023, the landlord has advised the Company that this property will be available for occupancy in October 2024. This date is an estimate which is subject to change based on the delivery of the property and its associated campus. The 2024 Lease includes base lease payments aggregating $71.9 million, as well as additional charges for common area maintenance and property taxes. The Company has the right to extend the term of the 2024 Lease for an additional 60 months.

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

Operating Leases

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

For the year ended December 31, 2022, payments associated with the Company's lease arrangements totaled $1.7 million, which included operating lease costs of $1.4 million, variable lease costs of $0.2 million and short-term lease costs of $0.1 million. Cash paid for operating lease liabilities during the year ended December 31, 2022 totaled $1.4 million.

For the year ended December 31, 2023, payments associated with the Company's lease arrangements totaled $2.8 million, which included operating lease costs of $2.8 million, and variable lease costs of $21,000. Cash paid for operating lease liabilities during the year ended December 31, 2023 totaled $2.6 million.

8. Commitments and Contingencies

Contracts

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

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of its Board of Directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs because of these indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2022 and 2023.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding for which any liabilities have been accrued. The Company was not a defendant in any lawsuit for the years ended December 31, 2022 and 2023.

9. Convertible Preferred Stock

Series A, B, and C Convertible Preferred Stock

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

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

Rights, Preferences, and Privileges of Convertible Preferred Stock

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

Voting Rights

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

Dividends

The Company cannot declare and pay any common stock dividends without first declaring and paying dividends, as defined in the terms of the Company's amended and restated certificate of incorporation, to the convertible preferred stockholders. The holders of Preferred Stock are entitled to receive, when, as and if declared by the Company's Board of Directors, noncumulative dividends at the rate of 6.0% of the applicable original issue price of such Preferred Stock (Original Issue Price), subject to appropriate adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization with respect to the Preferred Stock. No dividends have been declared as of December 31, 2022 or 2023, respectively.

Liquidation Rights

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

basis among the holders of the Preferred Stock in proportion to the respective amounts that would otherwise be payable in respect of such stock. After payments have been made in full to the holders of Preferred Stock, then, to the extent available, the remaining amounts would be distributed among the holders of the common stock, pro rata based on the number of shares held by each holder.

Conversion Rights

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

Redemption

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

10. Common Stock

Common Stock Rights

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

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following:

	December 31,	
	2022	2023
Conversion of outstanding convertible preferred stock	7,414,844	14,740,840
Common stock options issued and outstanding	1,340,555	2,813,937
Equity awards available for future issuance	244,437	861,155
Total	8,999,836	18,415,932

11. Stock Options and Stock-Based Compensation

Equity Incentive Plan

In December 2018, the Company adopted the 2018 Equity Incentive Plan (as amended, the Plan) to provide for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, and other stock awards to its employees, consultants, and directors. Recipients of option awards are eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Plan is ten years and, in general, the options

issued under the Plan vest over a four-year period from the vesting commencement date. Shares of unused common stock that cover awards that are expired, terminated, surrendered, or canceled under the Plan without having been fully exercised will be available for future awards. On April 5, 2023, the Company's Board of Directors increased the number of shares authorized for issuance under the Plan to 4,226,659. On December 31, 2023, 861,155 of these shares remain available for grant under the Plan.

The Plan allows for the early exercise of stock option awards, which are then subject to repurchase by the Company at the lower of (i) the fair market value at the repurchase date or (ii) the original exercise price. The exercise price of these shares is initially recorded as a repurchase liability, which is amortized to shareholder's equity as the shares vest. As of December 31, 2022 and 2023, 32,529 and 1,481 shares, respectively, remain unvested. The repurchase liability associated with these shares is included in unvested common stock on the balance sheets as of December 31, 2022.

Stock Options

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

	Number	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate-Intrinsic Value (1) (in 000's)
Balance as of December 31, 2022	1,340,550	$ 8.39	8.5 years	$ 2,150
Granted	1,537,723	$ 4.15		
Exercised	(48,724)	$ 3.71		
Forfeited and expired	(15,612)	$ 6.24		
Balance as of December 31, 2023	2,813,937	$ 4.13	8.6 years	$ 1,253
Vested and expected to vest as of December 31, 2023	932,923	$ 4.04	7.6 years	$ 559
Exercisable as of December 31, 2023	1,007,739	$ 4.14	7.8 years	$ 562

(1) 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, 2022 or 2023, and the exercise price of stock options that had exercise prices below that value.

The options exercised during the years ended December 31, 2022 and 2023 had an intrinsic value at exercise of $439,000 and $22,000, respectively.

Stock-Based Compensation Expense

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

	Year Ended December 31,	
	2022	2023
Research and development	$ 915	$ 1,420
General and administrative	1,375	1,916
Total stock-based compensation expense	$ 2,290	$ 3,336

On June 13, 2023, the Company's Board of Directors approved an option repricing to reprice certain underwater options to purchase the Company's shares of common stock held by its employees (including officers of the Company) and non-employee directors. Under the option repricing, options with an exercise price at or above $9.75 per share, representing an aggregate of 1,019,029 shares of common stock, were amended to reduce such exercise price to $4.10 per share. The repricing resulted in one-time stock-based compensation expense of approximately $263,000 related to vested options and incremental stock option expense of approximately $377,000 related to unvested options which will be amortized on a straight-line basis over the remaining vesting period of those options.

As of December 31, 2022 and 2023, unrecognized compensation cost related to outstanding time-based options was $6.0 million and $8.2 million, respectively, which is expected to be recognized over a weighted-average period of 2.0 years and 2.5 years, respectively.

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

	Year Ended December 31,	
	2022	2023
Expected term (in years)	6.0	6.0
Expected volatility	94.0%	92.4%
Risk-free interest rate	2.5%	3.9%
Expected dividend yield	0.0%	0.0%

The weighted-average grant date per share fair value of the stock options granted during the years ended December 31, 2022 and 2023 was $7.61 and $3.32, respectively.

12. Income Taxes

The Company is subject to taxation in the United States and certain states therein, however, due to the net losses incurred in each of the years ended December 31, 2022 and 2023, the Company has not recorded a provision for income taxes for either year. A reconciliation of the federal statutory tax rate and the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2022	2023
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	6.7	6.6
Tax credits	4.8	7.0
Change in valuation allowance	(30.7)	(23.0)
Other permanent differences	0.1	—
Stock compensation	(0.7)	(0.7)
Uncertain tax position	(1.3)	(11.0)
Other	0.1	0.1
Effective income tax rate	—%	—%

The Company has established a full valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets that preclude it from determining that is more likely than not that such assets will be realized. The Company periodically evaluates the recoverability of the deferred tax assets. When it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. Management's assessment as of December 31, 2022 and 2023 considered the generation of pre-tax book losses, no ability to carryback its operating losses, the lack of feasible tax-planning strategies, the limited existing taxable temporary differences, and the subjective nature of forecasting future taxable income. During 2022 and 2023, total deferred tax assets increased by $14.2 million and $11.3 million, respectively. Due to its full valuation allowance position, the Company's valuation allowance increased by the same amount during those time periods.

Deferred Tax Assets and Liabilities

As of December 31, 2022 and 2023, the significant components of deferred income taxes are as follows (in thousands):

	December 31, 2022	December 31, 2023
Deferred tax assets:		
Net operating loss carryforward	$ 16,426	$ 18,327
Research tax credits	2,522	5,052
Lease liability	1,452	615
Capitalized R&D	6,969	13,396
Intangible assets	53	48
Other, net	1,083	1,567
Total deferred tax assets	28,505	39,005
Less valuation allowance	(27,063)	(38,323)
Net deferred tax assets	1,442	682
Deferred tax liabilities:		
Right-of-use asset	(1,346)	(561)
Property and equipment	(96)	(121)
Total deferred tax liabilities	(1,442)	(682)
Net deferred tax assets	$ —	$ —

As of December 31, 2022 and 2023, federal net operating loss (NOL) carryforwards totaled $51.0 million and $66.4 million, respectively, before consideration of limitations under Section 382 of the Internal Revenue Code of 1986, as amended (IRC). The Company also had state NOL carryforwards of $81.5 million and $127.0 million as of December 31, 2022 and 2023, respectively. Unused federal NOL's carry forward indefinitely, while unused state NOL carryforwards begin to expire in 2040. As of December 31, 2022 and 2023, federal research tax credit carryforwards totaled approximately $2.0 million and $4.5 million, respectively, and state research tax credit carryforwards totaled approximately $2.1 million and $3.4 million, respectively. Unused federal credits begin to expire in 2040, while the unused state credits carry forward indefinitely.

Pursuant to IRC Sections 382 and 383, the Company's ability to use its NOL and research tax credit carry forwards 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 NOL's and research tax credits could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize and amortize R&D expenditures over five years for domestic research and 15 years for foreign research pursuant to Section 174 of the IRC.

The Inflation Reduction Act of 2022 (IRA), which incorporates a Corporate Alternative Minimum Tax (CAMT), was signed on August 16, 2022. The changes will become effective for the tax years beginning after December 31, 2022. The CAMT will require companies to compute two separate calculations for federal income tax purposes and pay the greater of the new minimum tax or their regular tax liability. The IRA is not expected to have a material impact on the Company's income tax position.

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 in the Company's gross unrecognized tax benefits was as follows (in thousands):

	Year Ended December 31,	
	2022	2023
Balance at beginning of period	$ 526	$ 1,198
Increase related to current year positions	660	982
Increase related to prior year positions	12	5,868
Balance at the end of the year	$ 1,198	$ 8,048

Company policy is to recognize a tax benefit from uncertain tax positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Due to the existence of the full valuation allowance, future changes in unrecognized tax benefits will not impact the Company's effective tax rate. The Company does not foresee any material changes to its liability for uncertain tax benefits within the next 12 months.

13. Net Loss Per Common Share

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

	Year Ended December 31,	
	2022	2023
Net loss	$ (45,901)	$ (49,434)
Weighted-average shares used in calculation, basic and diluted	1,098	1,216
Net loss per common share, basic and diluted	$ (41.80)	$ (40.65)

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

	Year Ended December 31,	
	2022	2023
Conversion of outstanding convertible preferred stock	7,414,844	14,740,840
Options to purchase common stock	1,340,550	2,813,937
Options early exercised subject to future vesting	32,529	1,481
Total	8,787,923	17,556,258

14. Subsequent Events

The Company has evaluated subsequent events occurring between the end of the most recent fiscal year and through March 6, 2024 (the date the Company's financial statements were available to be issued) and has concluded that no subsequent events have occurred that require disclosure herein except as noted below.

In February 2024, the Company granted a total of 840,292 options to employees and members of its Board of Directors at an exercise price of $8.19 per share.

Reverse stock split

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

6,250,000 Shares

Boundless Bio, Inc.

Common Stock

Goldman Sachs & Co. LLC **Leerink Partners** **Piper Sandler** **Guggenheim Securities**