
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

TO
Commission File Number 001-41955

BRIDGEBIO ONCOLOGY THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
256 E. Grand Avenue, Suite 104
South San Francisco, CA
(Address of principal executive offices)

39-3690783
(I.R.S. Employer
Identification No.)

94080
(Zip Code)

Registrant's telephone number, including area code: (650) 405-4770

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	BBOT	The Nasdaq Global Market

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Global Market on August 13, 2025 was approximately \$465,152,172. Shares of the Registrant's Common Stock held by each executive officer and director and by each other person who may be deemed an affiliate of the Registrant have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 2, 2026 was 80,032,823.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant’s definitive Proxy Statement to be issued in conjunction with the Registrant’s 2026 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the Registrant’s fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K. Except as expressly incorporated by reference, the Registrant’s Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

BridgeBio Oncology Therapeutics, Inc.
2025 Form 10-K Annual Report
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EXPLANATORY NOTE

On August 11, 2025 (the “Closing Date”), Helix Acquisition Corp. II (“Helix”), a Cayman Islands exempted company which domesticated as a Delaware corporation in August 2025, consummated a series of transactions that resulted in the combination of Helix II Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Helix (“Merger Sub”), and TheRas, Inc. (d/b/a BridgeBio Oncology Therapeutics), a Delaware corporation (“Legacy BBOT”), pursuant to a Business Combination Agreement, dated February 28, 2025, as amended on June 17, 2025 (the “Business Combination Agreement”), by and among Helix, Merger Sub and Legacy BBOT, as described further below.

Pursuant to the terms of the Business Combination Agreement, a business combination between Helix and Legacy BBOT was effected through the merger of Merger Sub with and into Legacy BBOT, with Legacy BBOT surviving the merger as a wholly-owned subsidiary of Helix (the “Business Combination”), following the approval by shareholders of Helix at the extraordinary general meeting of the shareholders of Helix held on August 4, 2025 (the “Special Meeting”). Following the consummation of the Business Combination, Helix was renamed “BridgeBio Oncology Therapeutics, Inc.”

In this Annual Report on Form 10-K (“Form 10-K”), the terms “we,” “us,” “our,” and the “Company” generally refer to Helix Acquisition Corp. II prior to the Business Combination and BridgeBio Oncology Therapeutics, Inc. following the Business Combination, unless the context specifically indicates otherwise. References to “BBOT” include Legacy BBOT prior to the Business Combination and BridgeBio Oncology Therapeutics, Inc. following the Business Combination. Some of the information contained in this section or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements in this Form 10-K, other than statements of historical fact, including, without limitation, statements regarding our strategy, future operations, future operating expenses, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives may be forward-looking statements. The words “anticipates,” “approximately,” “believes,” “could,” “designed,” “estimates,” “expects,” “goal,” “intends,” “may,” “objective,” “plans,” “potential,” “predicts,” “projects,” “pursuing,” “seeks,” “should,” “will,” “would” and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this report include, but are not limited to, statements about:

- expectations related to the success, cost and timing of product development activities, including timing of initiation, completion and data readouts for clinical trials and the potential approval of our product candidates, including the progress and results of the ONKORAS-101, BREAKER-101 and KONQUER-101 clinical trials;
- the clinical and therapeutic potential of BBO-8520, BBO-10203 and BBO-11818;
- the size and growth potential of the markets for our product candidates;
- the therapeutic and curative potential of our product candidates;
- projected financial information, anticipated growth rate and market opportunities;
- our ability to maintain the listing of our Common Stock on Nasdaq;
- potential liquidity and trading volatility of our Common Stock;
- our ability to raise financing in the future;
- success in retaining or recruiting, or changes required in, officers, key employees or directors;
- our ability to obtain and maintain regulatory approval of current and potential future product candidates;
- our ability to obtain and maintain intellectual property protection for our technologies and our product candidates;
- the rate and degree of market acceptance of current and any potential future product candidates;
- regulatory developments in the United States and international jurisdictions;
- potential liability lawsuits and penalties related to our technologies, product candidates and current and future relationships with third parties;
- our ability to attract and retain key scientific and management personnel;

- our ability to effectively manage the growth of operations;
- our ability to compete effectively with existing competitors and new market entrants;
- our ability to implement and maintain effective internal controls;
- the impact of supply chain disruptions;
- unfavorable global economic conditions, including inflationary pressures, market volatility, acts of war and civil and political unrest; and
- other factors detailed under the section entitled “Risk Factors” in this Form 10-K.

Any forward-looking statements in this Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other 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 these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and elsewhere in this Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

RISK FACTOR SUMMARY

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

- We have a limited operating history, have not completed any clinical trials, have no products approved for commercial sale, have never commercialized a product, and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates. If we are unable to advance our product candidates through development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.
- We may require additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs, future commercialization efforts, product development or other operations.
- Our preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.
- Any delays in the commencement or completion, or any termination or suspension, of our current, planned or future clinical trials could result in increased costs, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials; interim, preliminary and topline data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data; and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

- The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable.
- Our product candidates may cause significant adverse events, toxicities or other undesirable adverse events when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- We currently rely on third parties to supply and manufacture preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product, which increases the risk that we will not have sufficient quantities of these product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We face substantial competition which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.
- Our business entails a significant risk of product liability.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in others, and even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.
- We may seek certain designations for our product candidates, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.
- We are or may become subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security.
- Our success is highly dependent on our ability to attract, hire and retain highly skilled executive officers and employees.
- If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to our.
- Patent terms may not protect our competitive position for an adequate amount of time.
- We may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.
- We rely on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.
- There may not be an active trading market for our Common Stock, which may make it difficult to sell shares of our Common Stock.
- Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for our securities to decline.
- We have identified a material weakness in our internal controls over financial reporting in the past.
- We have increased costs as a result of operating as a public company, and our management devotes substantial time to related compliance initiatives.
- We are currently in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by a new U.S. presidential administration and accompanying regulatory activities and economic policies and events related thereto, ongoing military conflicts and geopolitical instability and inflation and interest rates.

PART I

Item 1. Business.

Overview

BBOT is a clinical-stage biotechnology company with the mission of transforming the lives of patients with cancers driven by RAS and PI3K α , the two most frequently mutated oncogenes. Aberrant RAS signaling drives uncontrolled tumor growth in some of the deadliest cancers, including lung, breast, pancreas and colon cancer. This can come from mutations in RAS itself, which underlie approximately 30% of all human cancers, or from RAS-mediated overactivation of PI3K α . Our goal is to provide meaningful benefit to patients by designing and developing new therapies to achieve high levels of target inhibition against these oncogenic drivers while maintaining a favorable tolerability profile.

Our pipeline consists of three orally bioavailable small molecule inhibitors that were designed and optimized within BBOT with the goal to provide patients with significant benefit over standard of care. Additionally, we believe BBOT has the opportunity to provide further benefit to patients with KRAS mutant tumors through combination of our inhibitors. We believe our pipeline has the opportunity to address a large number of patients afflicted with metastatic cancer.

BBOT's pipeline is poised to close key activity gaps in the RAS-focused therapeutic space

			~250K annual incident patients in the US
Program/Target	Mechanism of Action	Status	Clinical Readouts
BBO-8520 KRAS ^{G12C} (ON / OFF)	- First direct inhibitor of KRAS^{G12C} (ON) - Inhibits both KRAS^{G12C} GTP (active) and GDP (inactive) states - Differentiates from KRAS^{G12C} GDP (inactive)-only inhibitors	Phase 1 monotherapy and PD-1 combination	KRAS ^{G12C} NSCLC
BBO-11818 Pan-KRAS (ON / OFF)	- Direct inhibitor of KRAS^{G12V} (ON/OFF) - Potent pan-KRAS inhibitor - Directly binds mutant KRAS	Phase 1	KRAS ^{G12V} NSCLC KRAS ^{G12V} PDAC KRAS ^{G12V} CRC
BBO-10203 RAS/PI3K α Breaker	- Blocks specific interaction between RAS and PI3Kα - RAS driver agnostic (KRAS, HRAS and NRAS) - Selectively blocks PI3K / AKT effector signaling in the tumor - Decreased risk for hyperglycemia / hyperinsulinemia	Phase 1	PIK3CA ^{WT} BC HER2 ^{WT} BC KRAS ^{G12C} NSCLC KRAS ^{G12C} PDAC KRAS ^{G12C} CRC

Note: Projections are subject to inherent limitations and ongoing development results. Actual results may differ from expectations. The timing of regulatory submissions is subject to additional discussions with regulators.
BC = breast cancer; NSCLC = non-small cell lung cancer; CRC = colorectal cancer; PDAC = pancreatic ductal adenocarcinoma



BBO-8520 (direct KRAS^{G12C} ON/OFF) and BBO-11818 (direct panKRAS ON/OFF) programs target KRAS — the most mutated oncogene. KRAS is a small GTPase protein that acts like a molecular switch, toggling between the GTP-bound active “ON” state, and the GDP-bound inactive “OFF” state. Oncogenic mutations in KRAS disrupt the normal equilibrium of the two states, resulting in a dramatic increase in the proportion of the “ON” state, and ultimately activating pathways that result in uncontrolled cell growth and cancer progression.

The majority of KRAS mutations occur in codon 12. In NSCLC, KRAS G12C mutation are present in approximately 15% of patients. In 2021, the FDA approved the first therapeutic that specifically targets KRAS G12C. However, this first-generation drug and others like it exclusively target the “OFF” state, which renders them susceptible to adaptive resistance, which may limit their efficacy and durability. In addition, patients treated with “OFF” state inhibitors experience significant toxicities which is worse when combined with immune checkpoint inhibitors (ICI). In contrast, BBO-8520, our orally bioavailable dual KRAS G12C “ON/OFF” inhibitor, directly engages both states of the mutant protein. We believe BBO-8520’s next-gen mechanism of action and degree of potency can provide significant benefit to patients with KRAS G12C-driven NSCLC — both as monotherapy and in combination with other therapies.

ONKORAS-101 is an ongoing Phase 1 study evaluating BBO-8520 alone and in combination with pembrolizumab in subjects with locally advanced and unresectable or metastatic NSCLC with a KRAS G12C mutation. We disclosed BBO-8520 clinical data in January 2026, where BBO-8520 showed differentiated efficacy, safety and pharmacokinetics with best-in-class potential. We expect to share additional clinical data from ONKORAS-101 in the second half of 2026.

BBO-11818, is an orally bioavailable pan KRAS “ON/OFF” inhibitor designed to bind directly to the target. It is able to bind to KRAS G12D, G12V, G12C and WT KRAS with picomolar affinity. In KRAS mutant cells, BBO-11818 has shown low nanomolar potency with greater than 500-fold selectivity for KRAS over H- and NRAS. Like BBO-8520, BBO-11818 was designed to inhibit

KRAS in both its “ON” and “OFF” states. We believe these properties will enable BBO-11818 to achieve optimal target inhibition to provide significant benefit to patients with tumors driven by these oncogenes while maintaining a favorable tolerability profile. The KONQUER-101 trial is a currently ongoing phase 1 study evaluating the safety and preliminary antitumor activity of BBO-11818 in heavily pretreated subjects with locally advanced unresectable or metastatic *KRAS* mutant solid tumors. Preliminary BBO-11818 monotherapy data is encouraging as we have observed anti-tumor activity with a favorable and differentiated safety profile. We expect to share additional clinical data from KONQUER-101 in the second half of 2026.

PI3K α is involved in many aspects of cell physiology, including growth, differentiation, survival and migration. It also plays an important role in glucose homeostasis through direct activation of its catalytic subunit, p110 α , by insulin and IGF-1. In addition to its role in physiologic processes, an oncogenic form of PI3K α (encoded by the *PIK3CA* gene) as well as activating mutations in *PIK3CA* were identified over 20 years ago. As such, oncology drug discovery and development have explored inhibition of the kinase activity of the p110 α catalytic subunit to block PI3K α signaling. Unfortunately, all of these initial efforts have been hampered to varying degrees by undesired hyperglycemia and hyperinsulinemia side effects as they cannot adequately block oncogenic signaling without effects on glucose homeostasis. More recently, direct binding and activation of PI3K α by RAS proteins has been described in tumorigenesis. Additionally, several studies in mice have shown that selective blocking of RAS activation of PI3K α can slow tumor growth without interfering with glucose homeostasis. We set out to discover a small molecule that can block RAS activation of PI3K α with the goal of inhibiting oncogenic signaling while avoiding hyperglycemia and hyperinsulinemia. If successful, we may be able to achieve high levels of target inhibition in patients while maintaining a favorable tolerability profile.

BBO-10203, our RAS:PI3K α Breaker, is an oral drug candidate that targets the RAS-binding domain of PI3K α , preventing its activation by HRAS, NRAS, and KRAS in tumors. BBO-10203’s mechanism of action can inhibit PI3K α signaling in tumors and avoid hyperglycemia and hyperinsulinemia in preclinical models. This stems from the simple fact that insulin signaling does not rely on RAS proteins to mediate glucose uptake. Thus far, we have observed activity in preclinical models and settings where RAS or PI3K α is known to play a role in tumorigenesis, such as tumors with oncogenic mutations in KRAS or *PIK3CA*. However, an important additional feature of BBO-10203 is that it is agnostic to the mutational status of RAS and *PIK3CA*, i.e. BBO-10203 can work in settings where either or both are wild-type. For example, we have observed activity in preclinical models with amplified or overexpressing HER2. In non-clinical testing, BBO-10203 has elicited significant tumor growth inhibition in multiple tumor types as monotherapy, and shown promising activity in combination with HER2 inhibitors, mutant KRAS inhibitors, ER antagonists, CDK4/6 inhibitors, and chemotherapy. BREAKER-101 is an ongoing Phase 1 study evaluating the safety, tolerability, pharmacokinetics (PK), and preliminary antitumor activity of BBO-10203 as monotherapy and in combination with trastuzumab, fulvestrant $\pm$ ribociclib, or FOLFOX + bevacizumab in patients with locally advanced or metastatic HER2+ breast cancer (BC), HR+/HER2- BC and KRAS mutant colorectal cancer (CRC). We disclosed the preliminary clinical data from BREAKER-101 study in January 2026. BBO-10203 showed differentiated safety profile as compared to other PI3K α -targeting agents with no hyperglycemia observed. We expect to share additional data from the trial in the second half of 2026. In addition, we plan to initiate internal combinations with BBO-8520 and BBO-11818 this year.

BBOT is developing three precision oncology assets to serve patients with tumors driven by the two most prevalent oncogenes. We believe each has the potential to deliver meaningful benefit by achieving high levels of target inhibition while maintaining a favorable safety profile. In addition, BBOT is well positioned to develop combination therapies from within our own pipeline to inhibit both the MAPK and PI3K α -AKT pathways simultaneously in patients with KRAS mutant tumors. While this has been a major goal in the field for over 20 years, the inability of other inhibitors to distinguish between tumor and wild-type cells has historically resulted in unacceptable toxicity. We aim to succeed where others have failed, due to BBO-10203’s unique mechanism of action that takes advantage of RAS’ distinct role in tumors. By inhibiting any RAS-driven activation of PI3K α , BBO-10203 blocks oncogenic signaling while avoiding hyperglycemia. The fact that BBO-10203 has the potential to provide benefit and avoid hyperglycemia in WT *PIK3CA* setting is key to our combination approaches, as RAS and *PIK3CA* are very rarely co-mutated in human cancer. Hence, we will evaluate the combination of BBO-10203 and BBO-8520, and the combination of BBO-10203 and BBO-11818.

Strategy

At BBOT, we are accelerating scientific and medical breakthroughs with the goal of delivering well-tolerated, safe medicines with greater efficacy to people facing the deadliest cancers. We focus on patients with RAS- and PI3K α -driven malignancies, including lung, breast, colorectal and pancreatic cancers. With deep expertise in small molecule targeted oncology, our team understands that maximizing target inhibition is critical to providing significant benefit to patients with oncogene-addicted tumors, requiring novel mechanisms of action and precise inhibitor design. Using state-of-the-art structure-based drug design, BBOT is advancing two approaches to achieve this goal.

First, we have designed KRAS inhibitors that bind the protein directly with high affinity, resulting in inhibition of both the ON and OFF states. By coupling ON-state inhibition — the form of KRAS that drives tumorigenesis — with high affinity, we believe we can achieve maximal suppression of oncogenic signaling in KRAS-driven tumors.

Second, we have designed highly selective PI3K α inhibitors that exclusively block RAS-dependent signaling. This approach enables inhibition of RAS-driven PI3K α tumorigenesis while preserving PI3K α signaling directly activated by growth factor receptors. With this selective mechanism, we believe our RAS:PI3K α breakers may achieve high levels of inhibition of RAS-dependent PI3K α signaling while minimizing side effects associated with PI3K α kinase inhibitors, such as hyperglycemia. Developing these inhibitors both as monotherapy and in combination has the potential to provide meaningful benefit to patients by safely delivering high-level inhibition of oncogenic signaling.

Overview of BBO-8520 Program

Preclinical

BBO-8520 is a direct and covalent dual inhibitor of GTP-bound (ON) and GDP-bound (OFF) KRAS G12C. KRAS G12C is an oncogenic mutation that leads to insensitivity to GTPase activating protein (GAP)-mediated hydrolysis, which significantly increases the proportion of KRAS G12C in the ON state and promotes tumor cell growth. Currently approved inhibitors of KRAS G12C bind and inhibit the OFF-form only. The mechanism of action of these inhibitors is through sequestering the OFF-form and preventing it from cycling to the ON-form. Tumor cells can adapt to this mechanism of action rather easily by activating receptor protein tyrosine kinases (RTKs) upstream of KRAS and by increasing de novo protein production through mutant allele amplification. Activation of RTKs activates SOS pushing KRAS into its ON-form where OFF-only inhibitors cannot bind. Amplification of the mutant allele also leads to increased ON-form protein as there is ten times more GTP than GDP in the cells. To prevent fast adaptation through the above-mentioned mechanisms and to achieve optimal target coverage of the KRAS G12C driver oncogene, new generation inhibitors must inhibit the ON-form of KRAS G12C. To address this critical gap in target coverage by approved OFF-only inhibitors, we have designed BBO-8520 to be a direct, covalent dual inhibitor of both OFF- and ON-forms of KRAS G12C.

Biochemical studies using MALDI-TOF show that while the OFF-only inhibitors effectively modify GDP-bound KRAS G12C, they are unable to modify the GTP-bound form. In contrast, MALDI-TOF demonstrates that BBO-8520 modifies KRAS G12C whether it is bound to GDP or GTP. The ability to modify GTP-bound KRAS G12C provides BBO-8520 with a differentiating mechanism of action that functions by blocking effector binding instead of just trapping the OFF-form. Effector binding blockade is only possible with inhibitors that target the ON-form as this is the only form of KRAS G12C that binds effector.

BBO-8520 binds to the same switch II pocket and takes advantage of the same cysteine 12 mutant residue as OFF-only inhibitors. Head-to-head in vitro comparisons of potency, measured as k_{inact}/K_i , show that BBO-8520 is almost three times more active than the most active OFF-only inhibitor, divarasilb, and adds strong affinity against the ON-form of the protein which is completely absent in the OFF-only inhibitors. Notably, we were able to demonstrate activity in these studies against the ON-form while maintaining the selectivity of the molecule. Global cysteine proteomics shows that BBO-8520 is very specific for KRAS G12C with no significant binding to other cysteine containing proteins.

BBO-8520 is designed with a differentiated MoA, binding directly to the ON and OFF states of KRAS^{G12C} with a high degree of potency and selectivity

BBO-8520 has the unique ability to modify GTP-bound KRAS^{G12C}...

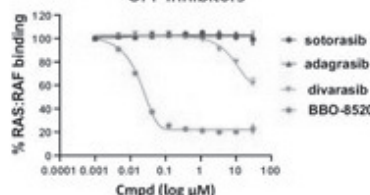
MALDI-TOF % Modified		BBO-8520	Sotorasib	Adagrasib	Divarasilb
GDP	15'	95	80	73	77
	60'	100	82	84	84
GTP	15'	84	0	0	0
	60'	97	0	0	0
GDP k_{inact}/K_i (M ⁻¹ s ⁻¹)		2,743,000	11,000	180,000	1,300,000
GTP k_{inact}/K_i (M ⁻¹ s ⁻¹)		20,000	0	0	0
Effector Binding IC_{50} (nM)		25	>100,000	20,000	4,200

BBO-8520 has high degree of selectivity for KRAS^{G12C} in global cysteine proteomics

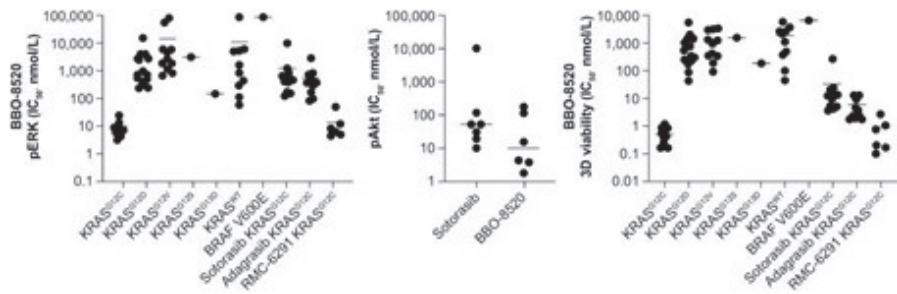


Note: MoA Mechanism of Action
Source: Data in table created based on data from Hwang et al., Cancer Discovery 2020; Internal BBOF data

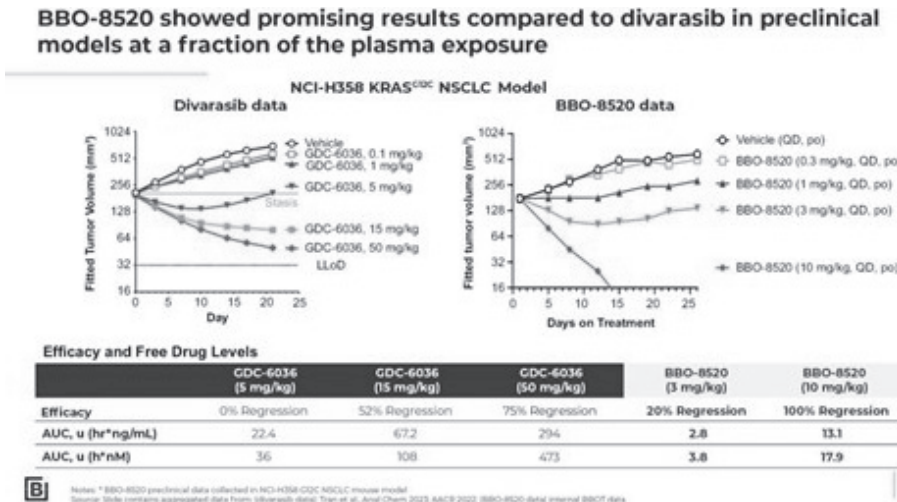
... and has been shown in preclinical models to inhibit effector binding without sacrificing selectivity or safety, in contrast to OFF inhibitors



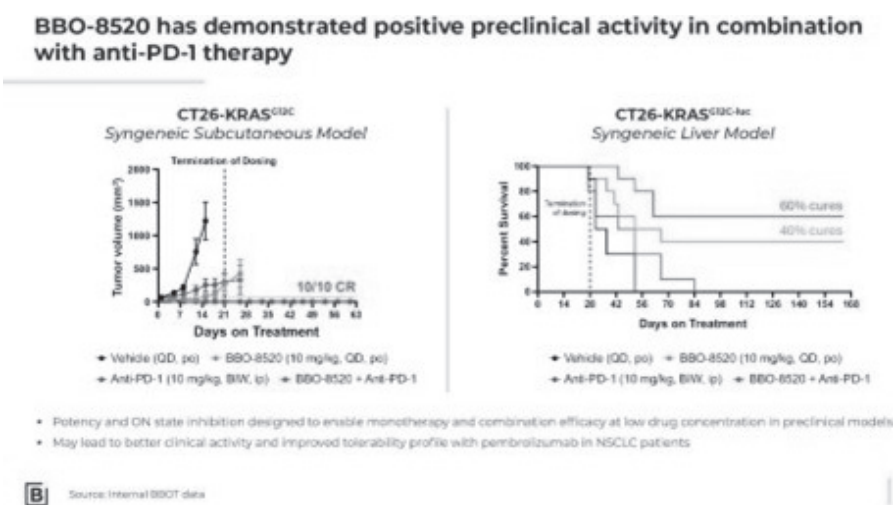
BBO-8520 has shown rapid (within 30 minutes) engagement of Cys-12 in the KRAS G12C mutant MIA PaCa-2 and SW1463 cell lines, leading to KRAS G12C covalent modification and strong pERK signal suppression, consistent with its dual (ON/OFF) mechanism of action. This early effect appears to only be achievable by engaging KRAS G12C (ON) as we have not observed it with sotorasib and adagrasib even at 5× higher concentrations (100 nmol/L). Peak downregulation of the MAPK signaling pathway was observed within the first 2 hours and lasted for at least 24 hours in both cell lines. A time course of pERK inhibition using HTRF, as a complementary method, in both MIA PaCa-2 and SW1463 cells confirmed the rapid and sustained inhibition of ERK phosphorylation by BBO-8520. To better understand the potency and selectivity of BBO-8520 in malignant cells, we have profiled BBO-8520 in a panel of approximately 50 cancer cell lines harboring either wild-type or mutant KRAS (G12C, G12D, G12S, G12V, and G13D) or a BRAFV600E mutation. BBO -8520 compared favorably against sotorasib and adagrasib in both the ERK phosphorylation inhibition and 3D viability assays, displaying better than 10 -fold gain in potency, in its results of head-to-head testing. Comparison with RMC-6291, a tricomplex KRAS G12C ON inhibitor, in six KRAS G12C cell lines showed a similar degree of inhibition for both compounds. BBO-8520 demonstrated selectivity for KRAS G12C over other KRAS codon 12 mutations approximately 50 to 500-fold selectivity and approximately 500 to 30,000-fold for 3D viability, and wild-type KRAS (>1,600-fold for pERK and >450-fold for 3D viability) and has no demonstrable activity in the BRAFV600E mutant cell line A375 (>10,000 -nmol/L IC50 for pERK and 3D viability). BBO-8520 also demonstrated inhibition of pAKT signaling in some KRASG12C cell lines with IC50 below 10 nmol/L.



In vivo activity was also studied in the NSCLC heterozygous KRAS G12C model NCI-H358. Orally administered BBO-8520, once daily for 28 days at 0.3, 1, 3, or 10 mg/kg resulted in tumor growth inhibition of 20% (0.3 mg/kg) and 71% (1 mg/kg), and mean tumor regressions of 19% (3 mg/kg) and 100% (10 mg/kg), in mice. The ED50 was 0.6 mg/kg, and ED90 was 1.6 mg/kg. Tumors from 1/10 and 10/10 mice in the 3- and 10-mg/kg BBO-8520 groups, respectively, had complete regressions. When the activity of BBO-8520 at the 3 mg/kg dose was compared to divarasis's 5 mg/kg dose, which is equivalent to the clinically determined recommended phase 2 dose of 400 mg, we observed that BBO-8520 was able to achieve better or similar activity with about a tenth of the free drug exposure. We believe BBO-8520 is able to achieve similar effects at a much lower free drug concentration because of its ability to inhibit all KRAS G12C (ON/OFF). Inhibition of the ON-form may allow BBO-8520 to decouple PK from PD, meaning that drug does not have to be present all the time to capture the cycling of KRAS G12C as required by OFF-only inhibitors. We believe the ability to provide optimal target coverage at lower free drug concentration could significantly reduce the toxicities observed in patients as both monotherapy and in combination with anti-PD-1 antibodies. If BBO-8520 is able to achieve better tolerability in combination with anti-PD-1 antibodies, the combination could provide first line metastatic NSCLC patients a better option than OFF inhibitors where liver toxicity has been observed and is a concern.

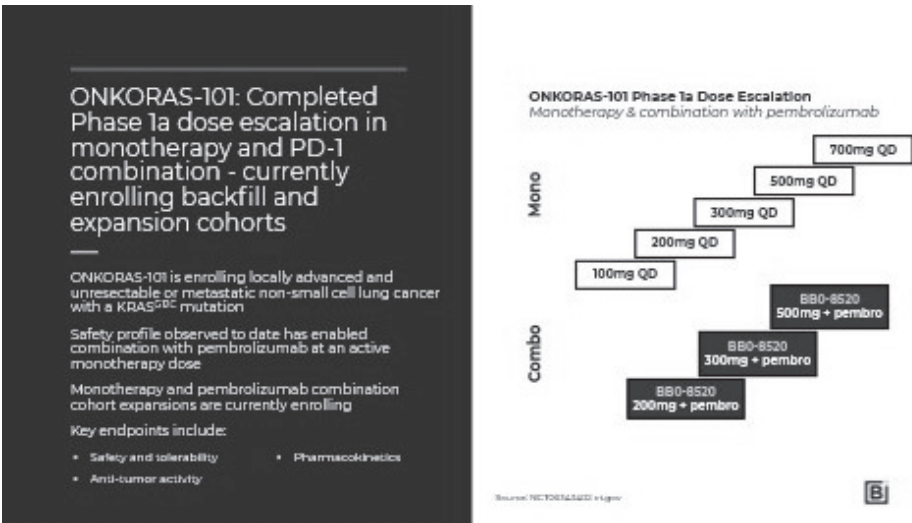


To assess BBO-8520’s ability to combine with anti-PD-1 antibodies, we have generated preclinical data in two syngeneic mouse models with limited sensitivity to anti-PD-1 reagents. Using both a subcutaneous model and a liver metastasis model, the combination of BBO-8520 and anti-PD-1 antibodies produced strong anti-tumor activity with favorable durability.



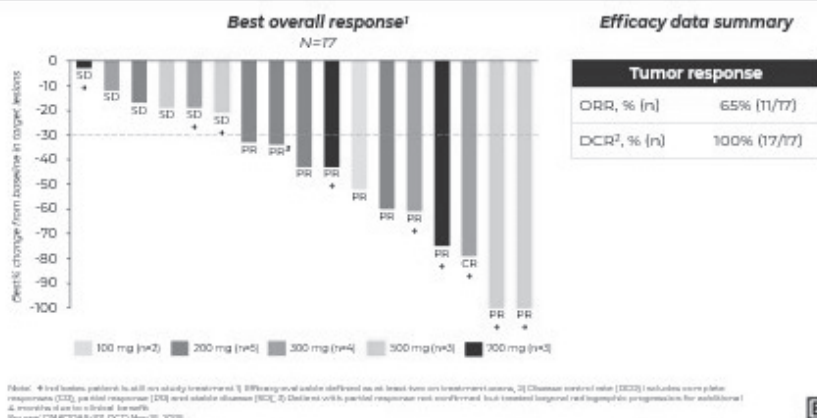
Clinical

The ONKORAS-101 Phase 1 study is currently enrolling patients with non-small cell lung cancer (NSCLC) carrying KRAS G12C mutation as monotherapy and in combination with pembrolizumab (NCT06343402).



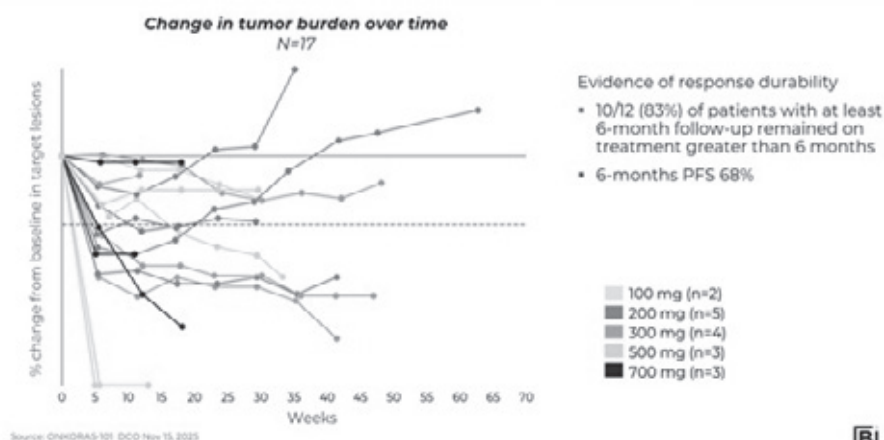
We disclosed encouraging updated clinical data in January 2026. As of November 15, 2025, a 65% (11/17) objective response rate (ORR) was observed in NSCLC patients with a KRAS G12C mutation across all dose levels, including 10 PRs and one complete response (CR).

Robust monotherapy activity across escalation dose levels in previously treated KRAS^{G12C} NSCLC with no prior G12C inhibitor experience



Responses appear durable with a 6-month progression-free survival (PFS) of 68% and 83% of patients with at least 6-month follow-up remaining on treatment greater than 6 months.

Responses appear durable with 83% of patients eligible for 6-month follow up remaining on treatment for at least 6 months



In this interim readout, BBO-8520 has shown a generally tolerable, manageable and potentially differentiated safety profile with no dose-limiting toxicities, no grade 3 or higher liver toxicity, and only low frequency and low grade, transient, and clinically asymptomatic liver enzyme elevations. There were no grade ≥ 4 treatment-related adverse events (TRAEs); and no treatment-related serious adverse events (TRSAEs). Nausea, vomiting, and diarrhea were the most common TRAEs.

BBO-8520 has shown a generally differentiated safety profile with no Grade 3 or higher liver toxicity

TRAEs reported in >15% patients and TRAEs of interest
N=37

AE term	All Grades	Grade ≥3
Any TRAE	31 (84%)	6 (16%)
NAUSEA	23 (62%)	1 (3%)
DIARRHEA	19 (51%)	3 (8%)
VOMITING	13 (35%)	0
FATIGUE	13 (35%)	1 (3%)
ANOREXIA	6 (16%)	0
AE of Interest		
AST INCREASED	3 (8%)	0
ALT INCREASED	2 (5%)	0

Source: ONKORAS-101 DCCD Nov 18, 2020

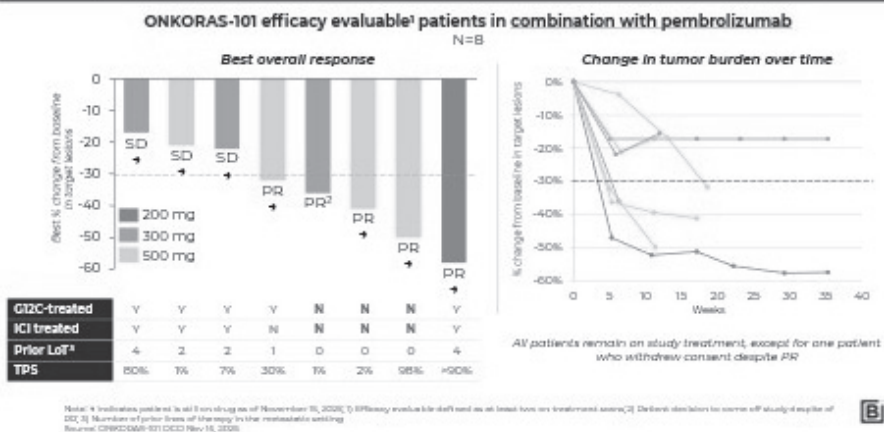
Monotherapy safety profile summary

- BBO-8520 safety profile as monotherapy appears generally tolerable and manageable, with a potentially differentiated liver toxicity profile
- No DLTs; no Grade ≥4 AEs; no treatment-related SAEs
- Nausea, vomiting, and diarrhea were the most common treatment-related AEs
 - Instances of G3 diarrhea were mostly associated with suboptimal management based on investigator assessment
- AST/ALT elevations occurred at low frequency and were low grade, transient, and clinically asymptomatic



BBO-8520 in combination with pembrolizumab showed promising efficacy in both first line and previously treated patients with NSCLC KRAS G12C. Each efficacy evaluable patient (n=8) experienced a tumor reduction regardless of PD-L1 status, and 3 out of 3 front-line patients and 2 out of 5 patients previously treated with KRAS^{G12C} inhibitor(s) achieved a PR.

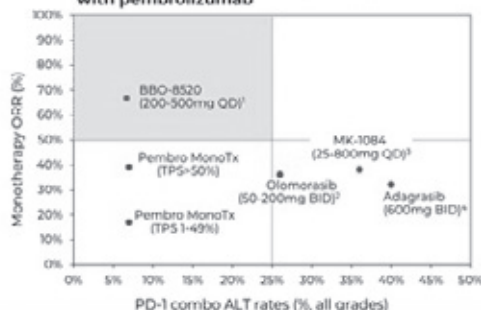
Promising data in combination with pembrolizumab in patient population largely pretreated with both ICI and G12Ci



BBO-8520 was generally well tolerated from 200 mg to 500 mg in combination with pembrolizumab. Potentially, the safety profile is best-in-class with a differentiated liver toxicity profile. In 15 patients, only one instance of AST/ALT elevation was observed which was considered by the principal investigator to mainly be due to co-medications. This favorable combination safety profile was achieved using active BBO-8520 dose levels.

... which may enable its combination with pembrolizumab at active dose levels to differentiate in earlier settings

Monotherapy activity vs. ALT elevations in combination with pembrolizumab



OFF inhibitor / pembrolizumab combinations

- All OFF inhibitors have had to **significantly reduce their dose to sub-optimal levels** when combined with pembrolizumab **due to liver toxicity**
 - This suggests that monotherapy efficacy for their combination dose level **may be lower than the benchmarks shown**
- Even at the sub-optimal dose levels, patients **experienced grade 3 toxicities** ranging from 30% to 70%

BBO-8520's superior safety profile positions it well to potentially achieve best-in-class status, by serving as the decisive factor for patient enrollment and physician adoption

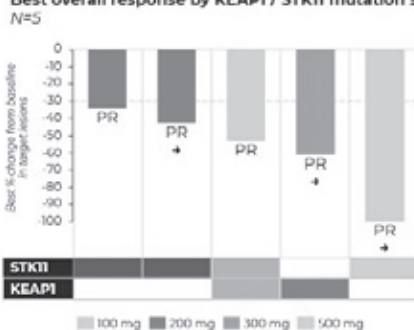
Note: 1) BBO-8520 dose levels tested in combination with pembrolizumab as of November 18, 2023. 2) Dose ranges listed for monotherapy efficacy data, safety data is derived from 50-100mg BID. 3) Dose ranges listed for monotherapy efficacy data, safety data is derived from 25-400mg QD. 4) 600mg BID tested for monotherapy efficacy data, safety data derived from 400mg BID. Source: De Castro et al. 2022 JCO; Procedure No. EMEA/H/C/003802/05/2022 Burns et al. 2024 ASCO; Johnson et al. 2025 WCLC; Sachter et al. 2025 ASCO; Cobb et al. 2024 ESMO; Asp, Negro et al. 2025 WCLC; Barlesi et al., Lancet 2025; Jinna et al., ASCO 2025; ONKORAS-101 ECO Nov 16, 2025



Encouraging early efficacy signals were seen in patients with *KRAS*^{G12C} and *STK11* and/or *KEAP1* co-mutants, where all five initial patients achieved a PR. This is a highly resistant patient population for which there is currently no effective therapy.

Early responses in STK11 / KEAP1 mutants – a key underserved portion of NSCLC patients

Best overall response by KEAP1 / STK11 mutation status



- Early efficacy signals seen in resistant **STK11/KEAP1 co-mutants**; all five initial patients showing a response
- STK11 / KEAP1 mutations** are highly prevalent in *KRAS*^{G12C} NSCLC, occurring in **25-33% of patients**
- Patients with STK11 / KEAP1 co-mutations show intrinsic resistance to ICI, leading to inferior clinical outcomes across TPS scores and regimens
- KRAS*^{G12C} OFF inhibitors perform poorly in these patients with divarasil showing ORR of 25-33% compared to ~60% in WT patients

Source: Mehrotra et al. 2024 JCO; Clinical Advances in Hematology & Oncology; Carlesimo et al. 2023, JCO Clin Res 2023; Sachter et al., NLM 2023; ONKORAS-101 ECO Nov 16, 2025



Opportunities

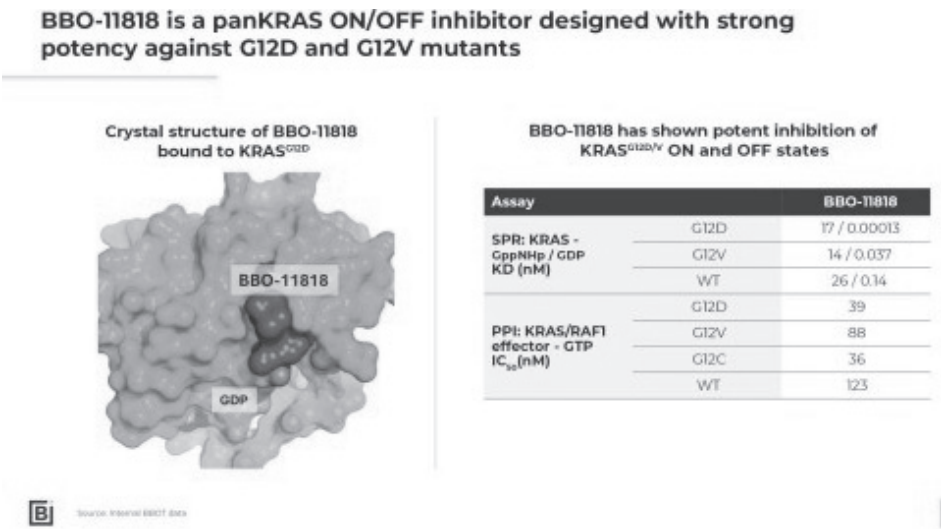
Lung cancer is among the most common cancers in the United States, with an annual estimated incidence of approximately 235,000 in 2024. Non-small cell lung cancer (NSCLC) accounts for approximately 87% of diagnosed lung cancer cases and approximately 10% of these patients have *KRAS*^{G12C} mutations. Current FDA-approved therapies targeting *KRAS*^{G12C} mutations in NSCLC include Sotorasib, which received accelerated approval in 2021, and Adagrasib, which received accelerated approval in 2022. Both of these therapies are indicated for second-line monotherapy treatment in the metastatic setting and target the OFF state of the *KRAS* protein. Additionally, both therapies have modest efficacy compared to other precision oncology medicines, with an ORR of approximately 40% and a median PFS of approximately 6 months based on phase 3 trials and have suffered from grade 3+ toxicities in some patients. By targeting both the ON and OFF states of *KRAS*^{G12C} with strong affinity, we believe BBO-8520 has the potential to improve clinical outcomes for patients with *KRAS*^{G12C} NSCLC. BBOT aims to offer BBO-8520 to NSCLC patients who carry *KRAS*^{G12C} mutation across settings of the disease either as monotherapy or in combination with other agents such as immunotherapy and other candidates in BBOT's internal pipeline.

Overview of BBO-11818 Program

Preclinical

KRAS is one of the most commonly mutated oncogenes in human cancers, with mutations found in approximately 11% to 15% of all cancers. It is particularly prevalent in lung, colorectal, and pancreatic cancers, where mutations occur in about 30%, 40%, and 90% of cases, respectively. The most common KRAS mutations occur at codon 12, accounting for 81% of all KRAS mutations. The most frequent mutations are KRASG12D (glycine to aspartate), which accounts for 33%, and KRASG12V (glycine to valine), which accounts for 23%. Every year, over 90,000 patients in the United States are diagnosed with cancers harboring KRASG12D or KRASG12V mutations. These mutations result in a significantly increased abundance of the active GTP-bound state of KRAS, disrupting the normal GAP-mediated cycling of GTP to GDP. This persistent activation leads to continuous downstream signaling, driving tumor cell growth and contributing to oncogenesis.

BBO-11818 is a selective, orally bioavailable non-covalent dual ON/OFF panKRAS inhibitor. Its discovery was facilitated by the structure-based drug design from our KRAS G12C inhibitor program that produced BBO-8520. It is designed to target KRAS G12D and G12V mutations, two of the three most common KRAS mutations in human cancers. BBO-11818 effectively binds both the inactive GDP-bound (OFF) and active GTP-bound (ON) forms of KRAS, exhibiting high affinity and specificity for KRAS over other RAS isoforms like HRAS and NRAS. In SPR assays, the KD value for the (OFF)-form of KRAS G12D is in the sub nanomolar range. In contrast, KD values for HRAS and NRAS are significantly higher, demonstrating the compound’s specificity for KRAS. BBO-11818 has also been shown to disrupt the interaction between KRAS and its effector RAF1, demonstrating strong affinity for the GTP-bound (ON) form of KRAS, which we believe is a key attribute to achieve optimal target coverage.



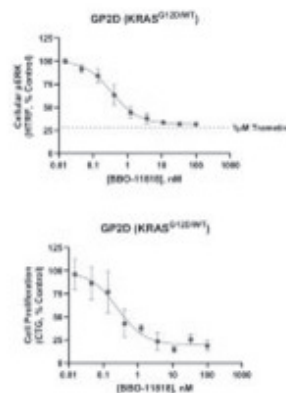
In cellular assays, BBO-11818 exhibited inhibition of pERK and cell viability in a range of cancer cell lines harboring KRAS mutations. The EC50 values for pERK inhibition in a series of KRAS G12D and G12V-mutant cell lines ranged from sub nanomolar to low double digit nanomolar potency. Importantly, BBO -11818 demonstrated similar activity in reducing cell viability in KRASG12D, KRASG12V, and KRASG12C -mutant cell lines, with EC50 values as low as 0.244 nM. The potency of BBO-11818 in the short-term signaling assay was consistent with what was observed in the long-term 3D-viability assay, a characteristic seen as important in translating the activity of mutant KRAS inhibitors to in vivo tumor models and clinical studies. Cell-based data using NRAS and BRAF mutant cell lines showed insensitivity to BBO-11818, reinforcing the compound’s high selectivity for KRAS mutations.

BBO-11818 has shown potent inhibition of MAPK signaling and viability in KRAS^{mut} cells...

Genotype	Cell Line	Histotype	BBO-11818 EC ₅₀ (nM)	
			pERK	3D Viability
G12D	GP2D	CRC	0.352	0.244
	SW1990	Panc	114	0.878
	AsPC-1	Panc	4.07	1.48
	HPAC	Panc	3.43	4.19
	KP4	Panc	0.916	0.778
G12V	Capan-2	Panc	6.41	2.88
	SW620	CRC	2.21	3.96
	RKN	LMS	4.27	0.559
G12C	H461	NSCLC	9.81	8.55
G12C	H358	NSCLC	2.00	2.26
WT	MKN1	Stomach	3.73	11.2
NRAS	HT-1080	Fibrosarcoma	>10 μ M	3.66 μ M
BRAF	A375	Melanoma	>10 μ M	7.27 μ M

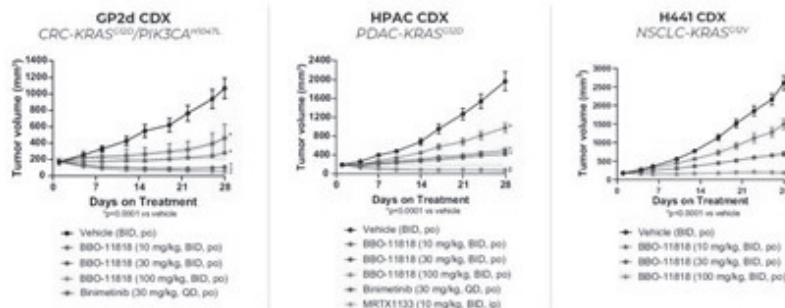


Source: Chart and table compiled from Internal BBO71 data



The high affinity, potency and selectivity of BBO-11818 for KRAS mutant cell lines have translated well into in vivo efficacy in animal models of human cancers. BBO-11818 exhibited robust in vivo antitumor activity in KRAS^{G12D}- and KRAS^{G12V}-driven CDX models of CRC, PDAC, and NSCLC. BBO-11818 showed a clear dose response in all three models with significant tumor regressions shown at the 100 mg/kg BID dose level in the KRAS G12D setting and stasis in the KRAS G12V setting. In the HPAC CDX model of KRAS G12D PDAC, BBO-11818 achieved ED₅₀ of 9.0 mg/kg BID and an ED₉₀ of 30.1 mg/kg BID.

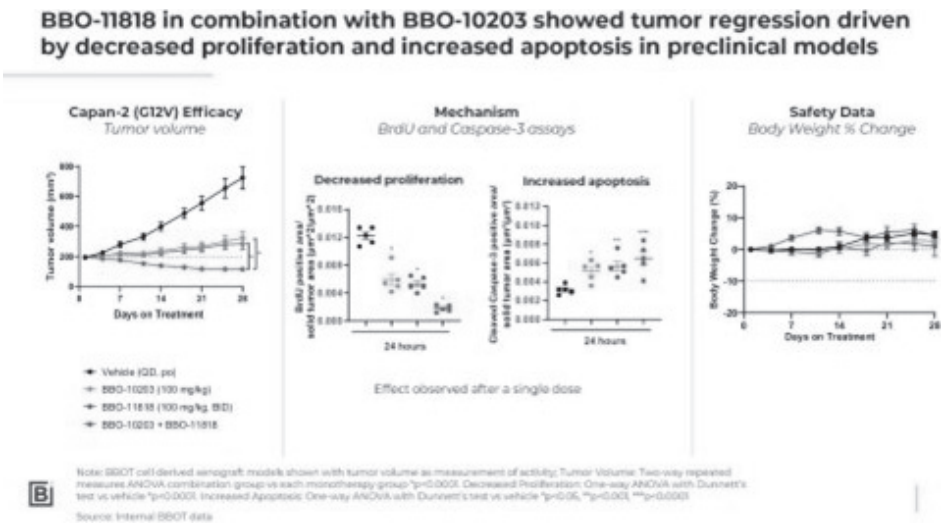
... and has shown anti-tumor activity across multiple KRAS^{G12D/V} CDX preclinical models



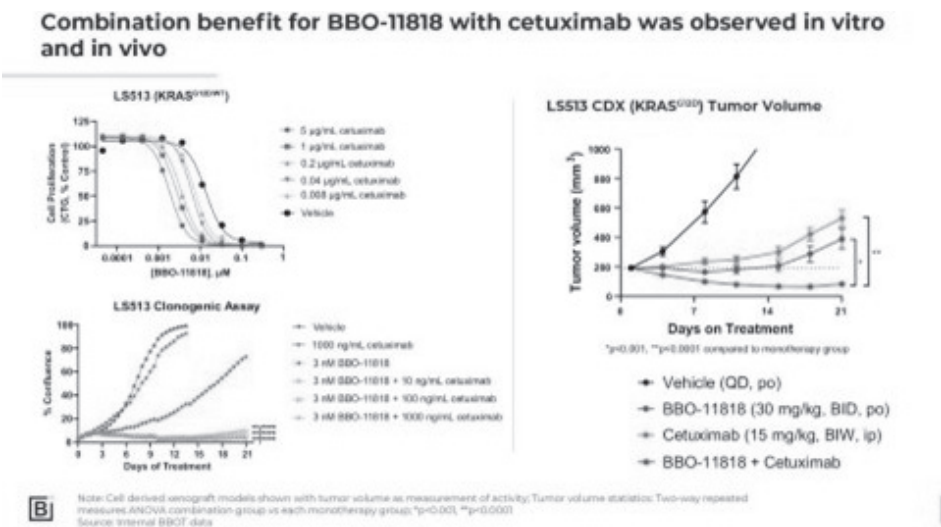
Note: BBO71 cell-derived xenograft models shown with tumor volume as measurement of activity. Two-way repeated measures ANOVA with Dunnett's multiple comparison test performed for statistical analysis (day 4 to 28). Source: Internal BBO71 data

A significant focus in the development of BBO-11818 is combinations with other targeted therapies to overcome resistance mechanisms and potentially enhance clinical activity. We believe BBOT is uniquely positioned to deliver the combination of co-inhibition of the MAPK and PI3K/Akt pathways with a therapeutic index. Consistent with our data showing the strong interaction between our KRAS G12C inhibitor with our BBO-10203 RAS:PI3K α inhibitor, the combination of BBO-11818 with BBO-10203 in the PDAC Capan-2 CDX model (KRAS G12V) showed significant tumor volume regressions in the combination treatment. Notably, MOA studies demonstrated that BBO-11818 had tumor intrinsic effects on decreasing cell proliferation and increasing apoptosis, and

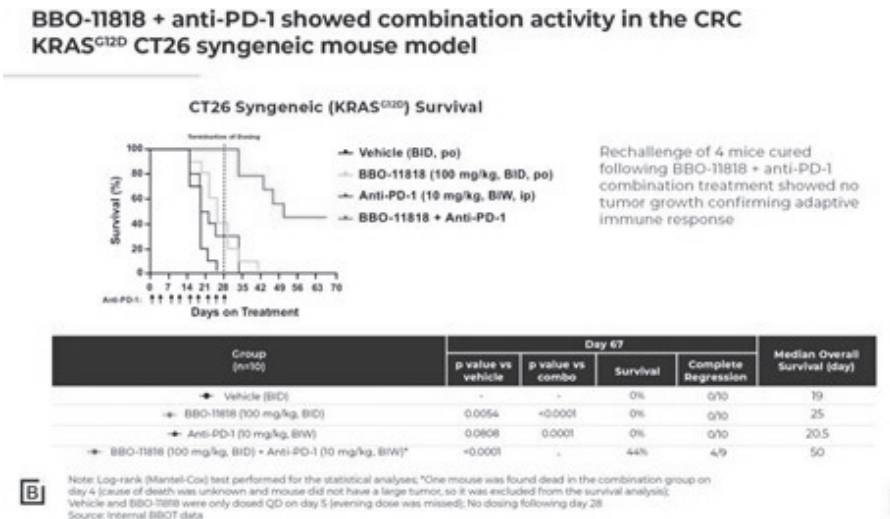
that the combination of BBO-11818 and BBO-10203 led to an antitumor benefit likely due to further reduction tumor cell proliferation and increase in apoptosis in this model.



Combining BBO-11818 with cetuximab, an anti-EGFR monoclonal antibody, in the LS513 model of KRAS G12D-driven CRC, led to synergy in a 2D cellular viability assay, suppression of the long-term growth of cells in a clonogenic assay, and robust 57% mean tumor regression in an efficacy study, which surpassed the antitumor effects of either compound alone. We believe this combination may be particularly beneficial for CRC patients with KRAS G12D or KRAS G12V mutations, as it targets the feedback activation of EGFR signaling, which can mediate resistance to KRAS inhibition.



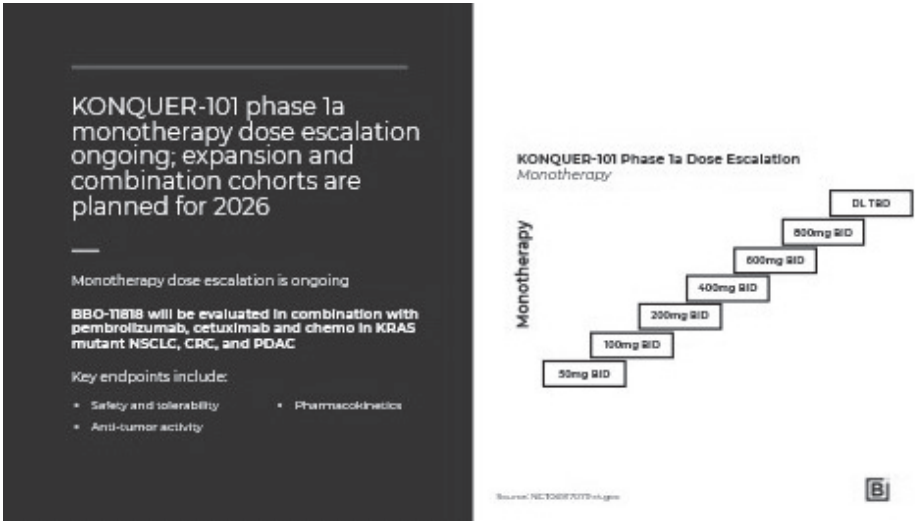
The immunosuppressive nature of KRAS-mutant tumors prompted exploration of combining KRAS inhibitors with ICIs. In the CT26 syngeneic mouse model of KRAS G12D CRC, the combination of BBO-11818 and anti- PD-1 significantly prolonged survival compared to both monotherapy treatments alone and led to 44% of the mice having complete tumor regressions.



These preclinical findings provide support to the evaluation of BBO-11818 as both monotherapy and in combination particularly with EGFR inhibitors, ICIs, or PI3Ka inhibitors. We believe these combination approaches have the potential to overcome resistance mechanisms and offer superior therapeutic outcomes for patients with KRAS G12D and KRAS G12V mutations, paving the way for further clinical benefit.

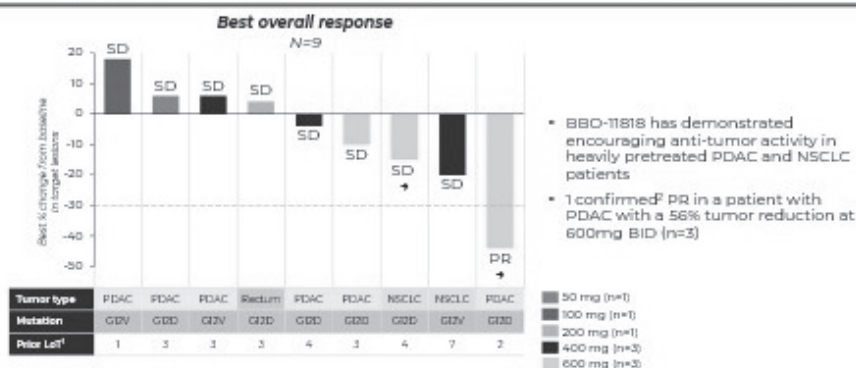
Clinical

KONQUER-101 (NCT06917079) is an open- label, multi-center, Phase 1 study designed to evaluate the safety, tolerability, pharmacokinetics, and efficacy of BBO-11818 alone and in combination with pembrolizumab, pembrolizumab cis/carboplatin and pemetrexed, or cetuximab in subjects with locally advanced unresectable or metastatic KRAS mutant solid tumors. We anticipate that additional clinical data from this study will be available in the second half of 2026.



As of December 10, 2025, BBO-11818 demonstrated encouraging early anti-tumor activity across dose levels and tumor types, including a PR in a patient with pancreatic ductal adenocarcinoma (PDAC) with a 56% tumor reduction, as well as tumor reductions at higher dose levels. The response was unconfirmed at the time of data cutoff but was subsequently confirmed.

Initial cohorts demonstrate anti-tumor activity at predicted efficacious dose levels across tumor types



Notes: ¹ Indication prior to start of study as of December 10, 2018; ² Number of prior lines of therapy in the metastatic setting; ³ SD was a reconfirmed at the time of data cutoff but was subsequently resolved.

Source: HCP/QUAD-18 DCC Dec 10, 2018



BBO-11818 monotherapy treatment (n=13) appeared generally tolerable with no DLTs. TRAEs were largely gastrointestinal-related.

BBO-11818 appears generally tolerable and manageable

TRAEs reported in >1 patient N=13

AE term	All Grades	Grade 1/2	Grade 3
Nausea	6	7	1
Diarrhea	6	5	1
Vomiting	3	5	-
Dry Mouth	3	3	-
Fatigue	3	3	-
Anorexia	3	3	-
Hypomagnesemia	2	2	-
Dysgeusia	2	2	-

Source: HCP/QUAD-18 DCC Dec 10, 2018

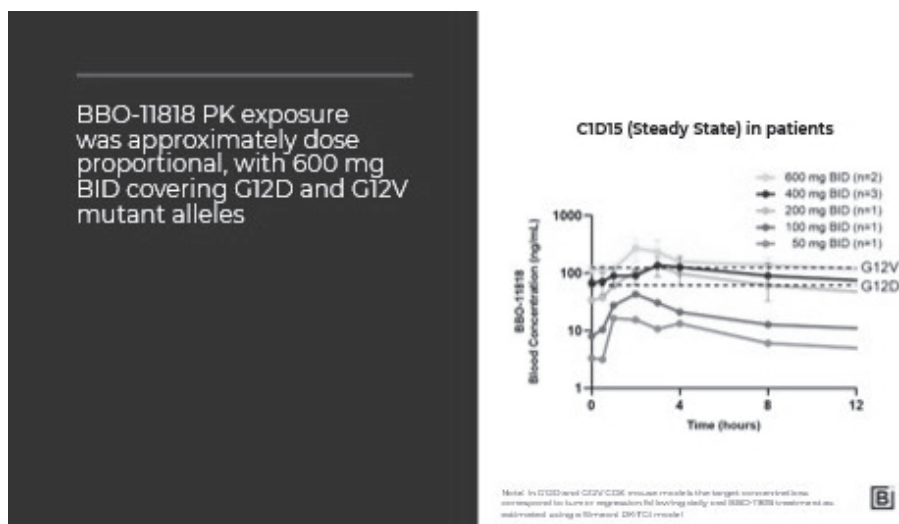
Monotherapy safety data

BBO-11818 monotherapy (N=13) appears generally tolerable and manageable

- No DLTs
- TRAEs mainly GI related
- 2 Gr 3 GI events (diarrhea and nausea) in patients with pre-existing GI conditions



BBO-11818 demonstrated approximately dose-proportional exposure with 600 mg BID covering G12D and G12V mutant alleles.



Opportunities

We intend to develop BBO-11818 primarily in KRAS^{G12D} and KRAS^{G12V} mutant NSCLC, CRC, and PDAC. Lung cancer had an annual estimated incidence in the U.S. of approximately 235,000 in 2024. Non-small cell lung cancer (NSCLC) accounts for approximately 87% of diagnosed lung cancer cases and approximately 8% of patients have KRAS^{G12D} and KRAS^{G12V} mutations. As of 2024, there were an estimated 153,000 patients with colorectal cancer in the U.S. Approximately 15% of patients have KRAS^{G12D} mutations and approximately 10% of patients have KRAS^{G12V} mutations. As of 2024, there were an estimated 66,000 incident pancreatic cancer patients in the U.S., with approximately 90% of these patients presenting with pancreatic ductal adenocarcinoma. Of these patients, approximately 40% have KRAS^{G12D} mutations and 29% have KRAS^{G12V} mutations.

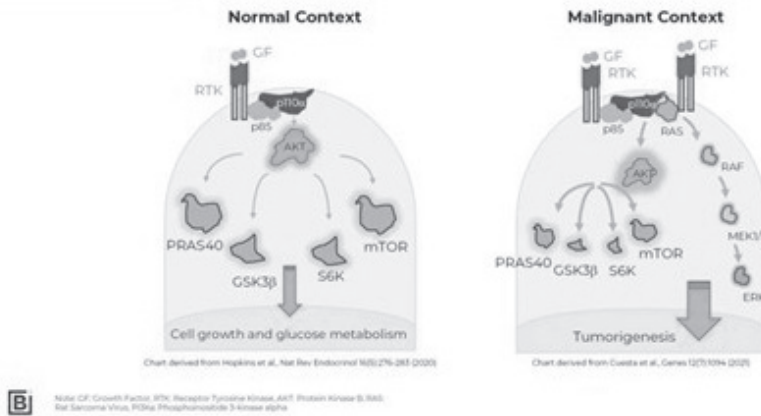
There are currently no targeted therapies approved for KRAS^{G12D} and KRAS^{G12V} mutations. If approved, we believe BBO-11818 may offer an improved product profile over current standard of care. In NSCLC, commercial opportunities include combination with immune-oncology agents such as pembrolizumab with and without platinum-based chemotherapy regimens in the first line, as well as monotherapy potential and combination with our RAS:PI3Ka Breaker BBO-10203 in 2L+ metastatic populations. CRC commercial opportunities include combination with chemotherapy and bevacizumab in 1L populations, as well as monotherapy potential and combination with BBO-10203 or EGFR antibodies. The commercial opportunity in PDAC includes combinations with chemotherapy regimens as well as monotherapy potential and combination with BBO-10203.

Overview of BBO-10203 Program

Preclinical

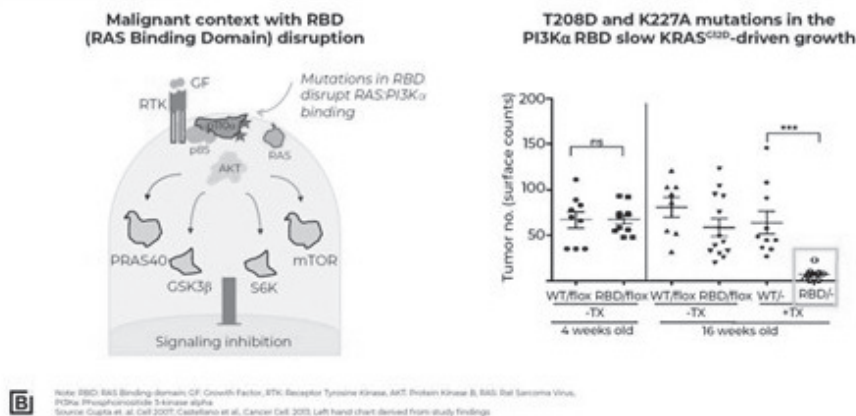
Phosphoinositide 3-kinases function in many aspects of cell physiology, including growth, differentiation, survival, and migration. PI3Ka is regulated by receptor tyrosine kinases and contributes to insulin homeostasis. The catalytic subunit of PI3K α , p110 α (encoded by the PIK3CA gene), is recruited to activated receptors through its direct interaction with the PI3K α regulatory subunit p85, or in the case of insulin and insulin-like growth factor 1 (IGF-1), through p85 binding to insulin receptor substrate (IRS) proteins. Deletion of p110 α causes embryonic lethality, whereas mice heterozygous for p110 α survive but are glucose intolerant and suffer from hyperinsulinemia and hyperphagia, among other phenotypes associated with defective insulin signaling. An oncogenic form of PI 3-kinase α (PIK3CA) was discovered in an avian retrovirus, and activating mutations in PIK3CA were later identified in human tumors. These mutations occur in 24-46% of endometrial cancers, 20-32% of breast cancers, 20-27% of bladder cancers, and at notable frequencies in most other cancer types. Canonical RAS proteins bind directly to PI3-kinases but with lower affinity than to RAF kinases. Oncogenic RAS proteins activate PI3Ka when over-expressed. The ability to bind and activate PI3Ka gives mutant RAS the ability to co-activate both the MAPK and PI3K/AKT pathways leading to its strong tumorigenic activity.

The interaction between RAS and PI3K α plays a critical role in malignant cells but not in normal human physiology



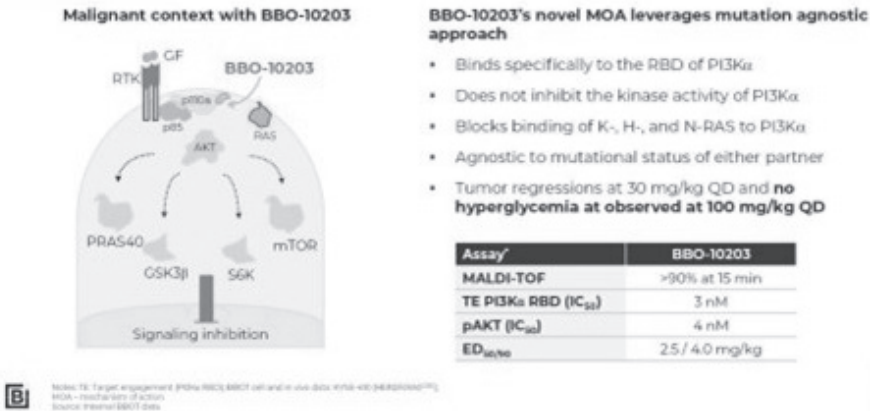
Disrupting RAS-PI3K α interaction through mutations T208D and K227A in the PI3K α RAS-binding domain (RBD) severely impairs tumor formation driven by KRAS-G12D. Systemic disruption of RAS-PI3K α interaction in mice is well tolerated and does not provoke hyperglycemia. Tumors driven by oncogenic mutants of EGFR regress after genetic disruption of RAS-PI3K α binding, and neo-angiogenesis is impaired. These findings indicate that RAS binding to PI3K α is not essential in normal cells, or for insulin homeostasis, but is vital for tumor formation and maintenance.

Genetic disruption of the RAS:PI3K α interaction has been shown to inhibit KRAS^{G12D}-driven tumor growth with no observed hyperglycemia



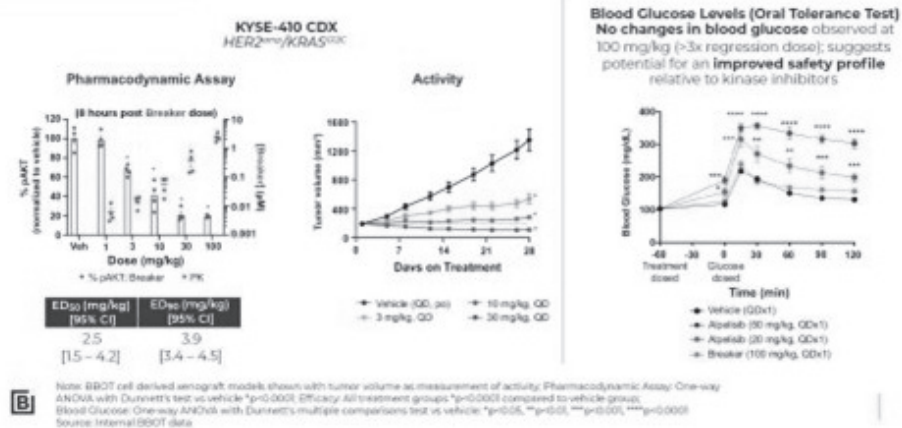
The hypothesis for the BBO-10203 program is that if we could mimic the effect of these two point mutations in the RBD domain of PI3K α with a small molecule, we could recapitulate the benefits on the efficacy without the limitations of potential safety signals. BBO-10203 is a covalent small molecule that binds to the RBD of PI3K α . It is specific for PI3K α , does not inhibit the kinase activity of PI3K α , blocks K-, H-, & NRAS from binding to PI3K α , and it is agnostic to the mutational status of either RAS or PI3K α . This mutation agnostic feature is important because more than 90% of human mutant RAS tumors are PI3K α wild-type. Therefore, recently developed selective inhibitors of mutant PI3K α cannot be combined with mutant KRAS inhibitors. BBO-10203 has single digit nanomolar affinity for the PI3K α RBD and has shown the ability to potently inhibit signaling.

BBO-10203 utilizes a novel MOA that is designed to inhibit the physical interaction between RAS and PI3K α , disrupting RAS-driven PI3K α /AKT signaling



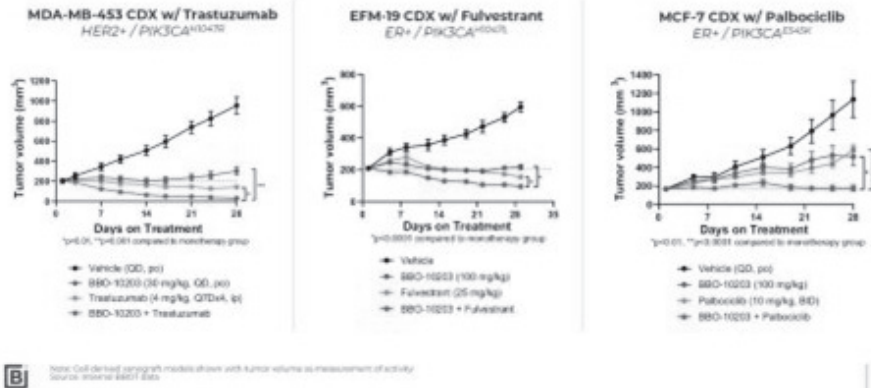
Pharmacology experiments using mouse models with BBO-10203 showed that significant inhibition of pAKT could be achieved by disrupting the interaction between PI3K α and RAS. In a pharmacodynamic model, increasing doses of BBO-10203 were inversely correlated with pAKT levels, reaching maximal inhibition of approximately 81%. Importantly, this inhibition of pAKT resulted in 44% tumor regression as monotherapy when BBO-10203 was dosed daily, orally, for 28 days. As predicted by the genetic experiments, BBO-10203 treatment did not result in hyperglycemia. In a glucose tolerance test in male mice, BBO-10203, at three times the dose required to elicit tumor regressions, did not induce hyperglycemia when compared to the PI3K α kinase inhibitor, alpelisib. This trait has the potential to differentiate BBO-10203 from all PI3K α /Akt pathway inhibitors.

BBO-10203 showed strong activity while avoiding the hyperglycemic effects associated with approved kinase inhibitors in preclinical models



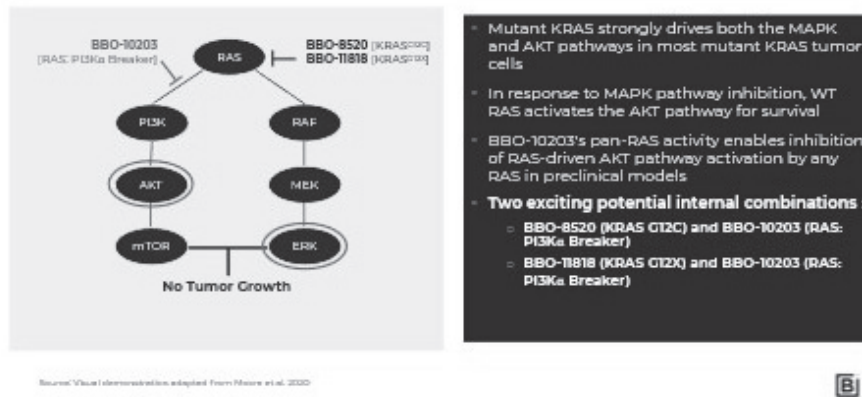
In the context of human tumors, PI3K α mutations are mostly found within breast cancers. BBO-10203 as monotherapy, or in combination with standard of care, showed significant tumor growth inhibition in three PI3K α mutant preclinical breast cancer models. In these models, which include both HER2 overexpressing and ER+ models, BBO-10203 showed tumor growth inhibition consistent with its GI arrest mechanism of action. Interestingly, when combined with standard of care inhibitors like trastuzumab, fulvestrant and palbociclib, BBO-10203 showed significantly better preclinical activity than these single agents alone.

BBO-10203 showed strong activity with SoC in HER2+ and ER+ PIK3CA^{mut} breast cancer preclinical models across both helical and kinase mutants



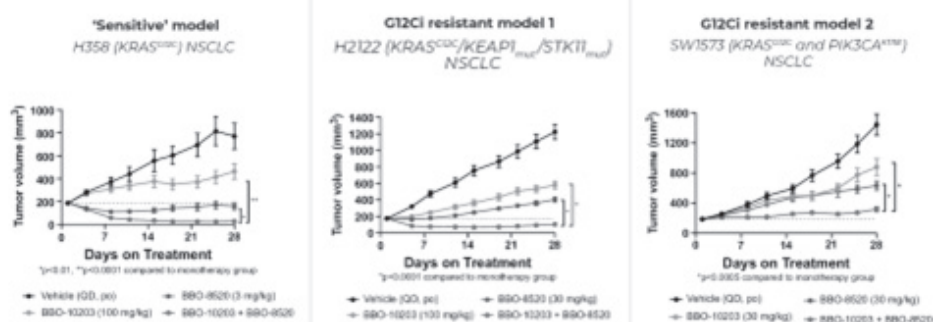
In combination with mutant KRAS inhibitors, BBO-10203 presents a unique opportunity to co-inhibit both the MAPK and PI3Kα signaling pathways. As previously mentioned, a key attribute of mutant RAS is that it can co-activate the MAPK and PI3Kα/AKT pathways. Tumors driven by mutant KRAS can be targeted with new generation KRAS inhibitors (such as BBO-8520 and BBO-11818) resulting in strong MAPK pathway inhibition. This effect drives reactivation of the PI3Kα/AKT pathway for cell survival and resistance. In the presence of a mutant KRAS inhibitor, reactivation of PI3Kα/AKT is driven by WT RAS (K-, H-, or N-). As BBO-10203 is agnostic to the RAS isoform and/or mutation status, we believe it is the ideal therapeutic candidate to inhibit PI3Kα/AKT pathway reactivation in KRAS mutant tumors.

Our encouraging data positions us well to simultaneously inhibit two major oncogenic pathways; we believe we are the only company positioned to achieve this



The combination of BBO-10203 with our KRAS G12C inhibitor BBO-8520 has shown that strong preclinical activity is achievable by inhibiting both pathways. In three different xenograft models with KRAS G12C mutations, the combination of both agents was significantly better than either alone. This is true whether the model is inherently sensitive or resistant to BBO-8520 monotherapy. In the clinically relevant H2122 xenograft model, which displays a KEAP1 mutation, the combination of BBO-8520 and BBO-10203 resulted in significantly better effects than either agent alone. Importantly, this combination led to significant decrease in cell proliferation and to increase in cellular apoptosis and was well tolerated in tumor bearing mice with no differences in body weight versus the vehicle group.

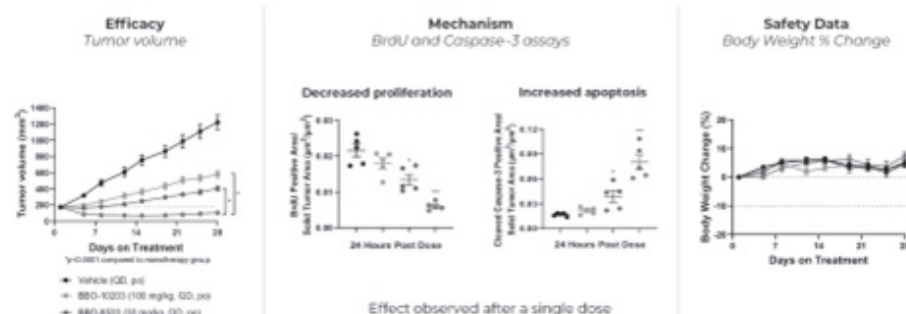
BBO-10203 combined with BBO-8520 showed superior activity relative to monotherapy in RAS-driven cancers in multiple preclinical models



B

Note: BBO7 cell derived xenograft models shown with tumor volume as measurement of activity. *B06610203. Source: Internal BBO7 data.

In the H2122 model, the combination of BBO-8520 and BBO-10203 reduced proliferation and increased apoptosis with generally favorable tolerability



B

Note: BBO7 cell derived xenograft models shown with tumor volume as measurement of activity. Tumor Volume: Two-way repeated measures ANOVA combination groups vs each monotherapy group. *p<0.0001. Decreased Proliferation: One-way ANOVA with Dunnett's test vs vehicle. **p<0.0001. Increased Apoptosis: One-way ANOVA with Dunnett's test vs vehicle. *p<0.05, **p<0.0001. Source: Internal BBO7 data.

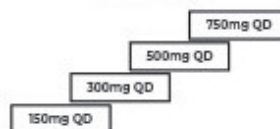
Clinical

BREAKER-101 is a multicenter, open-label, Phase 1 study evaluating the safety, tolerability, pharmacokinetics (PK), and preliminary antitumor activity of BBO-10203 as monotherapy and in combination with trastuzumab, fulvestrant ± ribociclib, or FOLFOX + bevacizumab in patients with locally advanced or metastatic HER2+ breast cancer (BC), HR+/HER2- BC and KRAS mutant colorectal cancer (CRC). BREAKER-101 has completed Phase 1a monotherapy dose escalation enrollment. Combination cohorts with fulvestrant in HR+ HER2- PIK3CA mutant BC, with trastuzumab in HER2+ BC and with FOLFOX + bevacizumab in KRAS mutant CRC are enrolling. Additional data from the study are expected to be available in the second half of 2026. BBO-10203 in combination with BBO-8520 and BBO-11818 in KRAS mutant tumors are planned this year.

- Monotherapy dose escalation is complete
- Key endpoints include:
 - Safety and tolerability
 - Pharmacokinetics
 - Anti-tumor activity
- Combination cohorts with fulvestrant + ribociclib in HR+ HER2- PIK3CA mutant BrCa and with both BBO-8520 and BBO-1818 in KRAS mutant tumors are planned

500mg QD has been selected as RDE and 3 combination cohorts have been initiated

Monotherapy



Open combination cohorts

BrCa HER2+	BB0-10203 + trastuzumab
BrCa HR+ / HER2- PIK3CA ^{mut}	BB0-10203 + fulvestrant
CRC KRAS ^{mut}	BB0-10203 + POLFOX + bevacizumab

See also: **McTigue, D. J.** and **others**



BBO-10203 demonstrated a potentially differentiated safety profile in heavily pretreated patients

N=32

	Nonotherapy		Trastuzumab Combination		FOLFIRI/Bev Combination	
	N=24		N=4		N=4	
AE term	All Grades	Grade ≥3	All Grades	Grade ≥3	All Grades	Grade ≥3
Any TRAE	17 (71%)	0	4	0	3	0
Diarrhea	7 (29%)	0	1 (25%)	0	0	0
Fatigue	6 (25%)	0	1 (25%)	0	0	0
Nausea	6 (25%)	0	1 (25%)	0	2 (50%)	0
Decreased Appetite/Anorexia	5 (21%)	0	0	0	0	0
Vomiting	3 (13%)	0	1 (25%)	0	1 (25%)	0
Rash/ Dermatitis	3 (13%)	0	0	0	0	0

Notes: 1) Clinical trial code [CCT] includes complete response [CR], partial response [PR] and stable disease [SD] in efficacy evaluable patients defined as at least one scan interval scan.
Source: SWOG/S13-001, CCT Dec 01, 2008

Monotherapy and combination safety profile has potential to be a **key differentiator** compared to other PI3K α -targeting agents

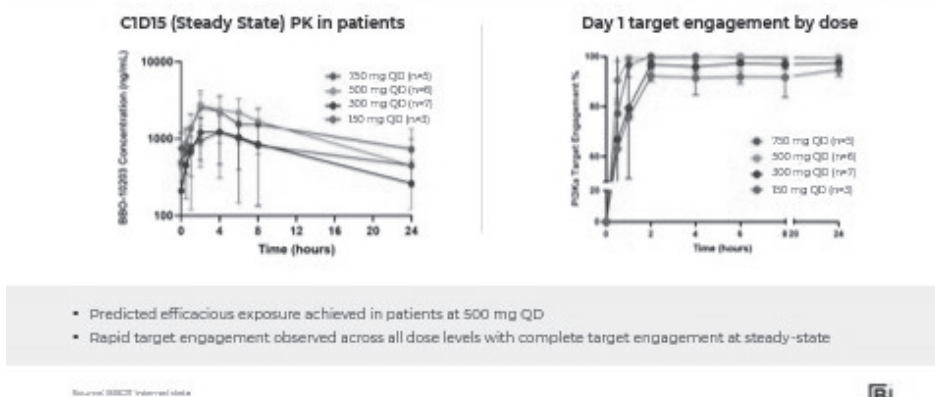
- **No** DLIs and treatment-related SAEs
- **No** hyperglycemia
- **No** Grade ≥3 TRAEs except for 1 incidence of asymptomatic hypokalemia (lab abnormality)
- **No** dose reductions
- Early combination data with trastuzumab and POLLOCK/Bev appears generally tolerable with **no** grade 3+ TRAE

Efficacy data

- Clinical benefit was observed in patients with CRC (≥50% 3L*) and HR+ BC who were previously heavily treated and tumor reductions observed in some patients.
- Monotherapy DCR: 62% (13/21)

20

BBO-10203 exposure achieved predicted efficacious levels with complete target engagement across all dose levels at steady-state



Opportunities

BBO-10203 is being developed in hormone receptor-positive PIK3CA mutant breast cancer in combination with HR-directed therapies and CDK4/6 inhibitors, HER2-positive breast cancer in combination with HER2-directed biologics, and KRAS^{G12X} non-small cell lung cancer (NSCLC), colorectal cancer (CRC), and pancreatic ductal adenocarcinoma (PDAC) in combination with KRAS inhibitors.

Breast cancer is among the most common cancers in the U.S. with an annual estimated incidence of approximately 314,000 in 2024. Approximately 14% of patients have HER2+ breast cancer while 70% of patients have HR+/HER2- breast cancer with 40% of HR+/HER2- breast cancer patients presenting with PIK3CA mutations.

Lung cancer is among the most common cancers with an annual estimated incidence in the U.S. of approximately 235,000 in 2024. Non-small cell lung cancer (NSCLC) accounts for approximately 87% of diagnosed lung cancer cases and approximately 15% of these patients have KRAS^{G12C} mutations and approximately 8% of patients have KRAS^{G12D} and KRAS^{G12V} mutations. As of 2024, there were an estimated 153,000 patients with colorectal cancer in the U.S. Approximately 15% of patients have KRAS^{G12D} mutations and approximately 10% of patients have KRAS^{G12V} mutations. As of 2024, there were an estimated 66,000 pancreatic cancer patients in the U.S., with approximately 90% of these patients presenting with pancreatic ductal adenocarcinoma. Of these patients, approximately 40% have KRAS^{G12D} mutations and 29% have KRAS^{G12V} mutations.

Intellectual Property

We pursue a layered intellectual property strategy, including by securing and/or filing for patents, trademarks, and trade secret rights, to protect our drug candidates.

Our commercial success depends in large part on our ability to protect our intellectual property rights, including our ability to obtain and maintain patent protection in the U.S. and other countries for our drug candidates, to operate without infringing valid and enforceable patents and proprietary rights of others, and to defend and enforce our intellectual property rights, in particular our patent rights. We seek to protect our proprietary position by filing, in the U.S. and certain other countries, patent applications that cover the composition of matter of our drug candidates, their methods of use and related discoveries, technologies, inventions and improvements that may be commercially important to our business. We may also rely on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We also intend to take advantage of regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

We have three drug candidates in our KRAS and PI3K programs. Given the early stage of development of our drug candidates, we cannot be certain that any of our intellectual property rights will provide protection for any drug candidate that may ultimately be commercialized. Our patent portfolio consists of patent applications co-owned with Lawrence Livermore National Security, LLC and Frederick National Laboratory for Cancer Research, operated by Leidos Biomedical Research, Inc., and Company-owned patent applications. As of December 31, 2025, our patent portfolio consists of patent applications filed in the United States and in foreign jurisdictions such as Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Peru, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand, Ukraine, and Vietnam, directed to, for example, compositions of matter and methods of use related to our drug candidates. Of these, BBOT has 11 patent families directed to KRAS inhibitor compounds and 1 patent family each directed to methods of

treatment with BBO-8520 or BBO-11818. Of these, BBOT has 4 patent families directed to compounds disrupting RAS-PI3K α interaction and 5 patent families directed to methods of treatment with BBO-10203 alone or in combination with other therapeutic agents. The term of any patents that issue from our U.S. and foreign patent applications will vary in accordance with the laws of each jurisdiction but is typically 20 years from the earliest non-provisional filing date. In the United States, the patent term may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a U.S. patent may be lengthened by patent term adjustment if there are administrative delays by the USPTO in examining and granting a patent. Any patents that may issue in the future from our pending patent applications are projected to expire between 2042 and 2046, unless extended or otherwise adjusted.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our investigational products and enforce the patent rights that we own and could affect the value of such intellectual property and the business. With respect to our intellectual property, we cannot guarantee that the patent applications we are currently pursuing or may file in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Our competitors may independently develop similar investigational products or technologies that are outside the scope of the rights granted under any patents that may issue. We cannot be sure that any patents granted to us will be commercially useful in protecting our products or their methods of use or manufacture. Moreover, even issued patents do not guarantee us the right to commercialize our products. For example, third parties may have blocking patents that could be used to prevent us from commercializing or manufacturing our investigational products.

In addition, the coverage claimed in a patent application may be significantly reduced before a patent is granted, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our products will be protected or remain protectable by enforceable patents. Moreover, any patents that we license or may own in the future may be challenged, circumvented, or invalidated by third parties. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before our product candidate can be commercialized successfully, any related patents may expire or remain in force for only a short period following commercial launch, thereby limiting the protection such patent would afford the applicable product and any competitive advantage such patent may provide.

Because of the extensive time required for development, testing and regulatory review of an investigational product, it is possible that, before a product can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. In the U.S., the term of a patent covering an FDA-approved product may, in certain cases, be eligible for a patent term extension (“PTE”) under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended and the amount of available extension to any PTE-eligible patent depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. Similar extensions may be available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved product. While we intend to seek patent term extensions in any jurisdictions where they are available to us, there is no guarantee that the applicable authorities, including the FDA or the USPTO, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

We cannot be sure that any patents will issue from any pending or future patent applications. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law or governmental agency, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. For example:

- we might not have been the first to file patent applications for the inventions covered by our pending patent applications and any patents that issue therefrom;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- some or all of our pending patent applications may not result in issued patents or the claims that issue may be narrow in scope and not provide us with a competitive advantage;
- any patents that issue from any of our pending patent applications may be challenged by a third party and invalidated;
- any patents that issue from our pending patent applications may be subject to post-grant proceedings, oppositions or other administrative or court proceedings that may result in a reduction in their scope or their loss altogether;
- we may not develop proprietary technologies or investigational products that are patentable; and
- the patents of others may prevent us from discovering, developing or commercializing our investigational products.

The defense and prosecution of intellectual property infringement suits, post-grant proceedings, oppositions and related legal and administrative proceedings are costly, time-consuming to pursue and divert resources. The outcome of these types of proceedings is uncertain and could significantly harm our business.

The development of our investigational products and the commercialization of any resulting drugs may be impacted by patents of other companies or by companies engaged in the development of competitive programs or those with significantly greater resources. This could result in the expenditure of significant legal fees and management resources.

We also rely on trade secrets to protect our technology and product candidates, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are often difficult to protect, especially outside of the U.S. While we believe that we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, partners and other advisors may unintentionally or willfully disclose our trade secrets to others, including competitors. Enforcing a claim that a third party illegally disclosed, obtained or is using our trade secrets would be expensive and time-consuming, and the outcome would be unpredictable. Even if we are able to maintain our trade secrets as confidential, our competitors may independently develop information that is equivalent or similar to our trade secrets.

KRAS Portfolio

The KRAS patent portfolio consists of eleven patent families, including G12C and G12D KRAS inhibitors and pan-KRAS inhibitors. The G12C portfolio includes patent applications directed to BBO-8520 composition of matter, pharmaceutical compositions thereof, and methods of use in treating diseases mediated by KRAS. Patent applications covering BBO-8520 are pending in the United States and foreign jurisdictions including Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Peru, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand, Ukraine, and Vietnam. One patent covering BBO-8520 is granted in the United States. Any patents issuing from these patent applications, if granted, are expected to expire mid-2042, without taking potential patent term adjustments or extensions into account. The pan-KRAS portfolio includes patent applications directed to BBO-11818 composition of matter, pharmaceutical compositions thereof, and methods of use in treating diseases mediated by KRAS. Patent applications covering BBO-11818 are pending in the United States and foreign jurisdictions including Argentina, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Republic of Korea, Mexico, New Zealand, South Africa, and Taiwan. Any patents issuing from these patent applications, if granted, are expected to expire mid-2043, not including patent term adjustments and extensions. Other filings in the KRAS portfolio, if granted, are expected to expire between 2042 and 2046, not including patent term adjustments and extensions.

PI3K Breaker Portfolio

Our PI3K breaker portfolio consists of nine patent families, including patent applications directed to BBO-10203 composition of matter, pharmaceutical compositions thereof, and methods of use in treating diseases associated with interruption of the interaction between a PI3K protein and a RAS protein. Patent applications covering BBO-10203 are pending in the United States and foreign jurisdictions including Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Peru, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand, Ukraine, and Vietnam. Any patents issuing from the patent applications, if granted, are expected to expire in February 2043, not including patent term adjustments and extensions. Other filings in the PI3K breaker portfolio, if granted, are expected to expire between 2044 and 2046, not including patent term adjustments and extensions.

Combination of a KRAS Inhibitor and a PI3K Breaker

We have one patent family directed to the use of a KRAS inhibitor compound in combination with a PI3K breaker compound. Any patents issuing from the patent applications, if granted, are expected to expire in October 2045, not including patent term adjustments and extensions.

License and Cooperative Research and Development Agreements

LLNS Cooperative Research and Development Agreement

On May 22, 2018, BBOT entered into a cooperative research and development agreement with Lawrence Livermore National Security, LLC (“LLNS”), as amended by that certain Amendment No. 1 to the cooperative research and development agreement, dated as of December 2, 2019, as further amended by that certain Amendment No. 2 to the cooperative research and development agreement, dated as of May 21, 2021, as further amended by that certain Amendment No. 3 to the cooperative research and development agreement, dated as of June 22, 2022, as further amended by that certain Amendment No. 4 to the cooperative research and development agreement, dated as of December 21, 2023, as extended by that certain No Cost Time Extension Letter, dated as of December 2, 2024, and as further amended by that certain Amendment No. 5 to the cooperative research and development agreement,

dated as of May 20, 2025 (collectively, the “**Livermore CRADA**”). Pursuant to the Livermore CRADA, BBOT and LLNS granted each other a royalty-free, nonexclusive, nontransferable, worldwide license to practice (a) such party’s background intellectual property and (b) the inventions of LLNS or BBOT made during the performance of work under the Livermore CRADA (the “**Subject Inventions**”), in each case to the extent needed by the non-granting party to perform its obligations or practice its rights under the Livermore CRADA. BBOT has the exclusive option for a specified period of time to negotiate an exclusive license to LLNS’s Subject Inventions in the field of small molecule KRAS inhibitors. The United States government retains a nonexclusive, nontransferable, irrevocable, paid-up, worldwide license to practice the Subject Inventions.

As of December 31, 2025, BBOT has contributed a total value of \$28.6 million for the Livermore CRADA, of which \$6.5 million was contributed funds-in and \$22.1 million was contributed in-kind.

The Livermore CRADA will expire in June 2027 unless the parties mutually agree to extend the term. Either party has a right to terminate the CRADA for any reason by providing advanced written notice. The parties’ rights in the Subject Inventions and data survive the expiration of the Livermore CRADA in accordance with the terms therein.

PI3Kα Breakers Patent License Agreement

On July 7, 2022, BBOT entered into a patent license agreement with LLNS, as amended by that certain Amendment One to limited exclusive patent license agreement, dated as of November 18, 2025 (collectively, the “**PI3Kα Breakers Patent License Agreement**”) pursuant to which BBOT received a worldwide, exclusive, royalty-bearing, sublicensable (through no more than two tiers) license under certain patent rights relating to the PI3Kα breakers compounds to make, have made, use, import/export, develop, sell, offer to sell, and have sold licensed products and licensed services, and to practice and have practiced licensed methods for all fields of use, subject to certain retained rights by LLNS. Under certain circumstances and subject to restrictions, the United States government reserves the right to a nonexclusive, royalty-free, irrevocable, nontransferable license under the licensed patent rights.

BBOT has certain typical diligence obligations under the PI3Kα Breakers Patent License Agreement, including the obligation to use commercially reasonable efforts to develop, manufacture, and sell any licensed method, licensed product or licensed service and file and obtain relevant regulatory applications for the manufacturing, marketing, and sale of licensed products. In addition, BBOT is obligated to use commercially reasonable efforts to meet specific development, regulatory and commercial performance obligations.

BBOT made a one-time, non-creditable, non-refundable upfront payment of \$0.1 million to LLNS after BBOT entered into the PI3Kα Breakers Patent License Agreement. Additionally, BBOT is obligated to pay LLNS (i) an annual license maintenance fee of a specified amount until the first commercial sale or other exploitation of a licensed method, licensed product or licensed service, (ii) a creditable, tiered, minimum annual royalty in a low-to-mid hundred thousand dollar range after the first commercial sale or other exploitation of a licensed method, licensed product or licensed service, (iii) a low single-digit tiered royalty on sales of licensed products or licensed services, (iv) up to a total of \$7.0 million in regulatory and commercialization milestones based upon indication, (v) a mid double-digit percentage in the range of 45% to 55% of certain non-royalty consideration received under a sublicense to a third party, subject to a specified cap, and (vi) an assignment fee of a specified amount.

As of December 31, 2025, BBOT has paid an aggregate of \$0.4 million to LLNS under the PI3Kα Breakers Patent License Agreement.

The term of the PI3Kα Breakers Patent License Agreement will extend until the expiration of the last to expire of the patents and patent applications included within the licensed patent rights, unless earlier terminated. The licensed patent applications, if issued, are expected to expire in 2043. LLNS may terminate the PI3Kα Breakers Patent License Agreement or convert the exclusive license granted to a nonexclusive license upon the occurrence of certain events, including if BBOT materially breaches the PI3Kα Breakers Patent License Agreement or becomes insolvent. LLNS may immediately terminate the PI3Kα Breakers Patent License Agreement or convert the exclusive license granted to a nonexclusive license if BBOT directly or indirectly challenges the validity of any of the licensed patent rights. BBOT may terminate the PI3Kα Breakers Patent License Agreement for any reason by giving written notice to LLNS.

KRAS G12C Inhibitors Patent License Agreement

On July 7, 2022, BBOT entered into a patent license agreement with LLNS, as amended by that certain Amendment One to limited exclusive patent license agreement, dated as of November 18, 2025 (the “**KRAS G12C Inhibitors Patent License Agreement**”) pursuant to which BBOT received a worldwide, exclusive, royalty-bearing, sublicensable (through no more than two tiers) license under certain patent rights relating to the KRAS G12C inhibitor compounds to make, have made, use, import/export, develop, sell, offer to sell, and have sold licensed products and licensed services, and to practice and have practiced licensed methods for all fields of use, subject to certain retained rights by LLNS. Under certain circumstances and subject to restrictions, the United

States government reserves the right to a nonexclusive, royalty-free, irrevocable, nontransferable license under the licensed patent rights.

BBOT has certain typical diligence obligations under the KRAS G12C Inhibitors Patent License Agreement, including the obligation to use commercially reasonable efforts to develop, manufacture, and sell any licensed method, licensed product or licensed service and file and obtain relevant regulatory applications for the manufacturing, marketing, and sale of licensed products. In addition, BBOT is obligated to use commercially reasonable efforts to meet specific development, regulatory and commercial performance obligations.

BBOT made a one-time, non-creditable, non-refundable upfront payment of less than \$0.1 million to LLNS after BBOT entered into the KRAS G12C Inhibitors Patent License Agreement. Additionally, BBOT is obligated to pay LLNS (i) an annual license maintenance fee of a specified amount until the first commercial sale or other exploitation of a licensed method, licensed product or licensed service, (ii) a creditable, tiered, minimum annual royalty in a low-to-mid hundred thousand dollar range after the first commercial sale or other exploitation of a licensed method, licensed product or licensed service, (iii) a low single-digit tiered royalty on sales of licensed products or licensed services, (iv) up to a total of \$7.0 million in regulatory and commercialization milestones based upon indication, (v) a mid double-digit percentage in the range of 45% to 55% of certain non-royalty consideration received under a sublicense to a third party, subject to a specified cap, and (vi) an assignment fee of a specified amount.

As of December 31, 2025, BBOT has paid \$0.4 million to LLNS under the KRAS G12C Inhibitors Patent License Agreement.

The term of the KRAS G12C Inhibitors Patent License Agreement will extend until the expiration of the last to expire of the patents and patent applications included within the licensed patent rights, unless earlier terminated. The licensed patent applications, if issued, are expected to expire between 2042-2043. LLNS may terminate the KRAS G12C Inhibitors Patent License Agreement or convert the exclusive license granted to a nonexclusive license upon the occurrence of certain events, including if BBOT materially breaches the KRAS G12C Inhibitors Patent License Agreement or becomes insolvent. LLNS may immediately terminate the KRAS G12C Inhibitors Patent License Agreement or convert the exclusive license granted to a nonexclusive license if BBOT directly or indirectly challenges the validity of any of the licensed patent rights. BBOT may terminate the KRAS G12C Inhibitors Patent License Agreement for any reason by giving written notice to LLNS.

Pan-KRAS Inhibitors Agreement

On December 20, 2024, BBOT entered into a patent license agreement with LLNS, as amended by that certain Amendment One to limited exclusive patent license agreement, dated as of November 18, 2025 (the “**Pan-KRAS Inhibitors Agreement**”) pursuant to which BBOT received a worldwide, exclusive, royalty-bearing, sublicensable (through no more than two tiers) license, under certain patent rights relating to the Pan-KRAS inhibitor compounds to make, have made, use, import/export, develop, sell, offer to sell, and have sold licensed products and licensed services, and to practice and have practiced licensed methods, limited to the oncology indications, subject to certain retained rights by LLNS. Under certain circumstances and subject to restrictions, the United States government reserves the right to a nonexclusive, royalty-free, irrevocable, nontransferable license under the licensed patent rights.

BBOT has certain typical diligence obligations under the Pan-KRAS Inhibitors Agreement, including the obligation to use commercially reasonable efforts to develop, manufacture, and sell any licensed method, licensed product or licensed service and file and obtain relevant regulatory applications for the manufacturing, marketing, and sale of licensed products. In addition, BBOT is obligated to use commercially reasonable efforts to meet specific development, regulatory and commercial performance obligations.

BBOT will make a one-time, non-creditable, non-refundable upfront payment of \$100,000 to LLNS after BBOT entered into the Pan-KRAS Inhibitors Agreement. Additionally, BBOT is obligated to pay LLNS (i) an annual license maintenance fee of a specified amount until the first commercial sale or other exploitation of a licensed method, licensed product or licensed service, (ii) a creditable, tiered, minimum annual royalty in a low-to-mid hundred thousand dollar range after the first commercial sale or other exploitation of a licensed method, licensed product or licensed service, (iii) a low single-digit tiered royalty on sales of licensed products or licensed services, (iv) up to a total of \$7.8 million in regulatory and commercialization milestones based upon indication, (v) a mid double-digit percentage in the range of 45% to 55% of certain non-royalty consideration received under a sublicense to a third party, subject to a specified cap, and (vi) an assignment fee of a specified amount.

As of December 31, 2025, BBOT has paid an aggregate of \$0.3 million to LLNS under the Pan-KRAS Inhibitors Agreement.

The term of the Pan-KRAS Inhibitors Agreement will extend until the expiration of the last to expire of the patents and patent applications included within the licensed patent rights, unless earlier terminated. The licensed patent applications, if issued, are expected to expire between 2042-2044. LLNS may terminate the Pan-KRAS Inhibitors Agreement or convert the exclusive license granted to a nonexclusive license upon the occurrence of certain events, including if BBOT materially breaches the Pan-KRAS Inhibitors Agreement or becomes insolvent. LLNS may immediately terminate the Pan-KRAS Inhibitors Agreement or convert the

exclusive license granted to a nonexclusive license if BBOT directly or indirectly challenges the validity of any of the licensed patent rights. BBOT may terminate the Pan-KRAS Inhibitors Agreement for any reason by giving written notice to LLNS.

Leidos Cooperative Research and Development Agreement

On March 3, 2017, BBOT entered into a cooperative research and development agreement with The Frederick National Laboratory for Cancer Research, operated by Leidos Biomedical Research, Inc. (“**Leidos**”), as amended by that certain Amendment No. 1 to the cooperative research and development agreement dated as of January 19, 2018, as further amended by that certain Amendment No. 2 to the cooperative research and development agreement dated as of January 2, 2019, as further amended by that certain Amendment No. 3 to the cooperative research and development agreement dated as of November 14, 2019, as further amended by that certain Amendment No. 4 to the cooperative research and development agreement dated as of January 13, 2020, as further amended by that certain Amendment No. 5 to the cooperative research and development agreement dated as of September 22, 2021, as further amended by that certain Amendment No. 6 to the cooperative research and development agreement dated as of March 27, 2023, as further amended by that certain Amendment No. 7 to the cooperative research and development agreement dated as of August 20, 2024, as further amended by that certain Amendment No. 8 to the cooperative research and development agreement dated as of September 2, 2025, as further amended by that certain Amendment No. 9 to the cooperative research and development agreement dated as of December 3, 2025, (collectively, the “**Leidos CRADA**”). Pursuant to the Leidos CRADA, Leidos retains the right (a) to utilize any invention of either or both parties conceived or first actually reduced to practice in the performance of work under the Leidos CRADA (“**CRADA Subject Invention**”) that constitutes an improvement to a tangible material not first produced in the performance of the Leidos CRADA that is owned or controlled by BBOT and used in the performance of work under the Leidos CRADA, solely as a research tool for internal, non-profit, pre-clinical research purposes and (b) to any CRADA Subject Invention included within the scope of the retained rights under the exclusive license agreement entered into between BBOT and The Regents of the University of California, San Francisco (“**UCSF**”) dated as of September 28, 2016 (the “**UCSF License Agreement**”). Leidos granted BBOT an exclusive option for a specified period of time to negotiate an exclusive or nonexclusive commercialization license to CRADA Subject Inventions made solely or jointly by Leidos for a field of use that does not exceed the scope of the work committed to under the Leidos CRADA. To the extent required by applicable law, BBOT granted the United States government a nonexclusive, nontransferable, irrevocable, paid -up, worldwide license to practice and have practiced the CRADA Subject Inventions for research and government purposes.

As of December 31, 2025, BBOT has paid an aggregate of \$15.9 million to Leidos under the Leidos CRADA.

The Leidos CRADA expires on September 3, 2026. Either Party has a right to terminate the CRADA upon at least 60 days’ prior written notice.

Leidos PLA I

On August 5, 2022, BBOT entered into a patent license agreement (the “**Leidos PLA I**”) with Leidos, pursuant to which BBOT received a worldwide, exclusive, royalty-bearing, sublicensable (through multiple tiers) license under certain patent rights relating to the PI3K α breaker compounds to (i) make and have made, to use and have used, to sell and have sold, to offer to sell, to develop, and to import licensed products and (ii) practice and have practiced any licensed processes, in each case (i) and (ii), for prophylactic, therapeutic, and diagnostic use in humans and animals. The licensed patent rights result from an ongoing research collaboration between BBOT and Leidos, and BBOT may opt to negotiate an exclusive license to any additional inventions resulting from such research collaboration. Under certain circumstances and subject to restrictions, Leidos and the United States government reserve the right to a nonexclusive, royalty-free, irrevocable, nontransferable license under the licensed patent rights.

BBOT has certain typical diligence obligations under the Leidos PLA I, including the obligation to use reasonable commercial efforts to bring the licensed products and licensed processes to practical application, and upon the initial transfer of a licensed product or initial practice of a licensed process in exchange for compensation, the obligation to use reasonable commercial efforts to make the licensed products and licensed processes reasonably accessible to the United States public. In addition, BBOT has specific development and regulatory performance milestones to meet.

BBOT made a one-time, non-creditable, non-refundable upfront payment of \$0.5 million to Leidos after BBOT entered into the Leidos PLA I. Additionally, BBOT is obligated to pay Leidos (i) a non-refundable minimum annual royalty of \$150,000 until the initial transfer of a licensed product or initial practice of a licensed process in exchange for compensation, (ii) a low, single-digit royalty on sales of licensed products, (iii) up to a total of (A) \$6.75 million in development milestones for the first indication for the first licensed product and (B) \$1.875 million in development milestones for the second indication for each licensed product, (iv) a low double-digit percentage in the range of 5% to 15% of certain non-royalty consideration received under a sublicense to a third party, and (v) reimburse Leidos for patenting expenses for the licensed patent rights, if any. In December 2025, the parties amended the Leidos PLA I to include an additional \$0.5 million payment for the first indication, triggered by the achievement of a specific development milestone after the amendment date.

As of December 31, 2025, BBOT has paid an aggregate of \$1.5 million to Leidos under the Leidos PLA I.

The term of the Leidos PLA I will extend to the expiration of the last to expire of the licensed patent rights, unless earlier terminated. The licensed patent applications, if issued, are expected to expire in 2034. BBOT has the unilateral right to terminate the Leidos PLA I at any time upon prior written notice to Leidos. Additionally, the Leidos PLA I will terminate if BBOT files a claim that asserts any portion of the licensed patent rights are invalid or unenforceable, unless BBOT withdraws or cause the withdrawal of such claim within a specified period of time. Leidos may terminate the Leidos PLA I in its entirety for BBOT's material breach that is not remediated within a specified period of time, or upon the occurrence of certain events of BBOT's insolvency. Further, Leidos has the right to terminate or modify the Leidos PLA I if Leidos determines that BBOT (i) is not using commercially reasonable efforts to develop and commercialize the licensed patent rights, (ii) has not achieved the milestone benchmarks set forth in the Leidos PLA I, or (iii) has willfully made a false statement of, or willfully omitted a material fact in the license application or any report required by the Leidos PLA I.

Leidos PLA II

On August 5, 2022, BBOT entered into a patent license agreement (the "**Leidos PLA II**") with Leidos, pursuant to which BBOT received a worldwide, exclusive, royalty-bearing, sublicensable (through multiple tiers) license under patent rights relating to the KRAS G12C inhibitor compounds to (i) make and have made, to use and have used, to sell and have sold, to offer to sell, to develop, and to import licensed products and (ii) practice and have practiced any licensed processes, in each case (i) and (ii), for prophylactic, therapeutic, and diagnostic use in humans and animals. The licensed patent rights result from an ongoing research collaboration between BBOT and Leidos, and BBOT may opt to negotiate an exclusive license to any additional inventions resulting from such research collaboration. Under certain circumstances and subject to restrictions, Leidos and the United States government reserve the right to a nonexclusive, royalty-free, irrevocable, nontransferable license under the licensed patent rights.

BBOT has certain typical diligence obligations under the Leidos PLA II, including the obligation to use reasonable commercial efforts to bring the licensed products and licensed processes to practical application, and upon the initial transfer of a licensed product or initial practice of a licensed process in exchange for compensation, the obligation to use reasonable commercial efforts to make the licensed products and licensed processes reasonably accessible to the United States public. In addition, BBOT has specific development and regulatory performance milestones to meet.

BBOT made a one-time, non-creditable, non-refundable upfront payment of \$0.5 million to Leidos after BBOT entered into the Leidos PLA II. Additionally, BBOT is obligated to pay Leidos (i) a non-refundable minimum annual royalty of \$0.15 million until the initial transfer of a licensed product or initial practice of a licensed process in exchange for compensation, (ii) a low, single-digit royalty on sales of licensed products, (iii) up to a total of (A) \$6.75 million in development milestones for the first indication for the first licensed product and (B) \$1.875 million in development milestones for the second indication for each licensed product, (iv) a low double-digit percentage in the range of 5% to 15% of certain non-royalty consideration received under a sublicense to a third party, and (v) reimburse Leidos for patenting expenses for the licensed patent rights, if any. In December 2025, the parties amended the Leidos PLA II to include an additional \$0.5 million payment for the first indication, triggered by the achievement of a specific development milestone after the amendment date.

As of December 31, 2025, BBOT has paid an aggregate of \$1.5 million to Leidos under the Leidos PLA II.

The term of the Leidos PLA II will extend to the expiration of the last to expire of the licensed patent rights, unless earlier terminated. The licensed patent applications, if issued, are expected to expire between 2042-2043. BBOT has the unilateral right to terminate the Leidos PLA II at any time upon prior written notice to Leidos. Additionally, the Leidos PLA II will terminate if BBOT files a claim that asserts any portion of the licensed patent rights are invalid or unenforceable, unless BBOT withdraws or causes the withdrawal of such claim within a specified period of time. Leidos may terminate the Leidos PLA II in its entirety for BBOT's material breach that is not remediated within a specified period of time, or upon the occurrence of certain events of BBOT's insolvency. Further, Leidos has the right to terminate or modify the Leidos PLA II if Leidos determines that BBOT (i) is not using commercially reasonable efforts to develop and commercialize the licensed patent rights, (ii) has not achieved the milestone benchmarks set forth in the Leidos PLA II, or (iii) has willfully made a false statement of, or willfully omitted a material fact in the license application or any report required by the Leidos PLA II.

Leidos PLA III

On December 20, 2023, BBOT entered into a patent license agreement (the "**Leidos PLA III**") with Leidos, pursuant to which BBOT received a worldwide, exclusive, royalty-bearing, sublicensable (through multiple tiers) license under certain patent rights relating to the Pan -KRAS inhibitor compounds to (i) make and have made, to use and have used, to sell and have sold, to offer to sell, to develop, and to import licensed products and (ii) practice and have practiced any licensed processes, in each case (i) and (ii), for prophylactic, therapeutic, and diagnostic use in humans and animals. The licensed patent rights result from an ongoing research

collaboration between BBOT and Leidos, and BBOT may opt to negotiate an exclusive license to any additional inventions resulting from such research collaboration. Under certain circumstances and subject to restrictions, Leidos and the United States government reserve the right to a nonexclusive, royalty-free, irrevocable, nontransferable license under the licensed patent rights.

BBOT has certain typical diligence obligations under the Leidos PLA III, including the obligation to use reasonable commercial efforts to bring the licensed products and licensed processes to practical application, and upon the initial transfer of a licensed product or initial practice of a licensed process in exchange for compensation, the obligation to use reasonable commercial efforts to make the licensed products and licensed processes reasonably accessible to the United States public. In addition, BBOT has specific development and regulatory performance milestones to meet.

BBOT made a one-time, non-creditable, non-refundable upfront payment of \$0.75 million to Leidos after BBOT entered into the Leidos PLA III. Additionally, BBOT is obligated to pay Leidos (i) a non-refundable minimum annual royalty of \$0.2 million until the initial transfer of a licensed product or initial practice of a licensed process in exchange for compensation, (ii) a low, single-digit royalty on sales of licensed products, (iii) up to a total of (A) \$6.75 million in development milestones for the first indication for the first licensed product and (B) \$1.875 million in development milestones for the second indication for each licensed product, (iv) a low double-digit percentage in the range of 5% to 15% of certain non-royalty consideration received under a sublicense to a third party, and (v) reimburse Leidos for patenting expenses for the licensed patent rights, if any. In December 2025, the parties amended the Leidos PLA III to include an additional \$0.5 million payment for the first indication, triggered by the achievement of a specific development milestone after the amendment date.

As of December 31, 2025, BBOT has paid an aggregate of \$1.0 million to Leidos under the Leidos PLA III.

The term of the Leidos PLA III will extend to the expiration of the last to expire of the licensed patent rights, unless earlier terminated. The licensed patent applications, if issued, are expected to expire between 2042-2044. BBOT has the unilateral right to terminate the Leidos PLA III at any time upon prior written notice to Leidos. Additionally, the Leidos PLA III will terminate if BBOT files a claim that asserts any portion of the licensed patent rights are invalid or unenforceable, unless BBOT withdraws or causes the withdrawal of such claim within a specified period of time. Leidos may terminate the Leidos PLA III in its entirety for BBOT's material breach that is not remediated within a specified period of time, or upon the occurrence of certain events of BBOT's insolvency. Further, Leidos has the right to terminate or modify the Leidos PLA III if Leidos determines that BBOT (i) is not using commercially reasonable efforts to develop and commercialize the licensed patent rights, (ii) has not achieved the milestone benchmarks set forth in the Leidos PLA III, or (iii) has willfully made a false statement of, or willfully omitted a material fact in the license application or any report required by the Leidos PLA III.

Manufacturing and Supply

We currently contract with third parties to manufacture our product candidates and anticipate using third parties for all preclinical, clinical and commercial manufacturing if any of our investigational products obtain marketing approval. We do not own or operate facilities for product manufacturing, packaging, storage and distribution, or testing. We have internal personnel and utilize consultants with extensive technical, manufacturing, analytical, and quality experience to oversee contract manufacturing and testing activities. 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 development of our investigational products.

Commercialization

We intend to retain significant development and commercial rights to our investigational products and, if marketing approval is obtained, to commercialize our investigational products on our own, or potentially with a partner, in the U.S. and other regions. We intend to build the necessary infrastructure and sales, marketing and commercial product distribution capabilities for the U.S., and potentially other regions, following further advancement of our investigational products. Clinical data, the size of the addressable patient population and the size of the commercial infrastructure and manufacturing needs and economics related to the foregoing may all influence or alter our commercialization plans.

Competition

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

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop small molecules and drug conjugates as treatments for cancer patients. There are many other companies that have commercialized and/or are developing such treatments for cancer including large pharmaceutical and biotechnology companies, such as AstraZeneca plc, Bristol-Myers Squibb Company, Merck, Pfizer in partnership with Merck KGaA, Regeneron Pharmaceuticals, Inc. in partnership with Sanofi Genzyme and Roche.

We are currently developing BBO-8520 in KRAS^{G12C} NSCLC as a KRAS^{G12C} ON/OFF inhibitor. If approved, BBO-8520 would compete with approved KRAS^{G12C} inhibitors Sotorasib and Adagrasib, which target the OFF state of the KRAS^{G12C} protein. There are also a number of other KRAS^{G12C} OFF inhibitor product candidates in clinical development, including Divarasib, Glecirasib, Olomorasib, and Calderasib. In addition, BBO-8520 may compete with Elironrasib, a tricomplex inhibitor of KRAS^{G12C} ON that is currently in early clinical development and FMC -376, a direct inhibitor of KRAS^{G12C} ON/OFF that is currently in early clinical development. BBO-10203 is being developed in hormone receptor-positive PIK3CA mutant breast cancer in combination with HR-directed therapies and CDK4/6 inhibitors, HER2-positive breast cancer in combination with HER2-directed biologics, and we are combining BBO-10203 with chemotherapy and bevacizumab in CRC with KRAS. We are planning to combine with our internal KRASi agents, BBO-8520 and BBO-11818.

If approved in the HR+ PIK3CA^{mut} breast cancer setting, BBO-10203 will compete with approved non-mutant-selective PI3K α inhibitors, Alpelisib and Inavolisib. BBO-10203 may also compete with mutant-selective PI3K α inhibitors that are currently in clinical development such as STX-478, Zovegalisib, and OKI-219. BBO-10203 may also compete with downstream inhibitors of the PI3K α pathway such as AKT inhibitor Capivasertib and mTOR inhibitor Everolimus as well as PI3K/mTOR inhibitors such as Gedatolisib. In HER2+ breast cancer, if approved, BBO-10203 may compete with approved small molecule inhibitors of HER2 including Tucatinib, Neratinib, and Lapatinib as well as small molecules inhibitors of HER2 that are currently in clinical development such as ELVN-002, Pyrotinib, Epertinib, IAM-1363, DZD-1516.

BBO-11818 is planned to be developed in KRAS^{G12X} mutant solid tumors with a specific focus on KRAS^{G12D} and KRAS^{G12V} mutant tumors in NSCLC, CRC, and PDAC. If approved, BBO-11818 may compete with other pan-KRAS inhibitors currently in clinical or preclinical development such as QTX-3034, BI3706674, QLC1101, PF-07934040, YL-17231, JAB-23400, LY4066434, ABT-200, QTX-3544, BPI-585359, GFH547, ERAS-4001. BBO-11818 may also compete with KRAS^{G12D} inhibitors currently in clinical or preclinical development such as RMC-9805, ASP-3082, HRS-4642, INCB161734, GHF-375, TSN1611, ASP4396, QTX-3046, SHR1127, LY3962673, HBW-012D. BBO-11818 may compete with KRAS^{G12V} inhibitors currently in early clinical development such as RMC-5127. BBO-11818 may also compete with daraxonrasib, a pan-RAS inhibitor currently in clinical development and ERAS-0015, a pan-RAS inhibitor currently in early clinical development.

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

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our investigational products, if approved, are likely to be their degree of efficacy, tolerability profile, convenience and price, the effectiveness of companion diagnostics (if required), the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Government Regulation

Government authorities in the U.S. at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Food, Drug, and Cosmetic Act (“**FDCA**”). Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are considered small molecule drugs and must be approved by the FDA through the new drug application (“**NDA**”), process before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with the FDA’s Good Laboratory Practice (“**GLP**”);
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related protocols and regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA after completion of pivotal trial(s) and other required clinical studies;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with current good manufacturing practice (“**cGMP**”) requirements to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA filing;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, if applicable, prior to any commercial marketing or sale of the drug in the U.S.; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (“**REMS**”) and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any current and future product candidates will be granted on a timely basis, or at all.

Preclinical Studies and IND

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all clinical trial subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study is conducted in accordance with GCP, including review and approval by an independent ethics committee (IEC) and informed consent from subjects. The GCP requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. FDA must also be able to validate the data from the study through an on-site inspection if necessary. An NDA based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies have been performed by clinical investigators of recognized competence and (3) the FDA is able to validate the data through an onsite inspection or other appropriate means, if deemed necessary.

Clinical trials in the U.S. generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, which may overlap or be combined.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, are 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.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. The sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse reactions, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the clinical trial 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. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies often complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in

commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our product candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA Review Process

Following completion of the clinical trials, the results of preclinical studies and clinical trials are submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data, which is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. In short, the NDA is a request for approval to market the drug in the U.S. for one or more specified indications and must contain proof of safety and efficacy for a drug.

The application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity NDA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA designated for priority review. The FDA may make a decision earlier than the PDUFA goal date or, the review process may be extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements.

Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

After the FDA evaluates an NDA, it will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The complete response letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a complete response letter is issued, the applicant may resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request the opportunity for a hearing. Even if an applicant submits the requested data and information, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000

individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug 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 drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication. If one of our product candidates designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a number of programs intended to facilitate and expedite development and review of new drugs if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition.

The fast track program is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product 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.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate 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 ("IMM"), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product. The FDA may also place other conditions on approvals, including the requirement for REMS, to assure the safe use of the product. 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. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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 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 holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

FDA regulations require that approved products be manufactured in specific approved facilities and in accordance with cGMP regulations which require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products, and those supplying products, ingredients, and components of them, are required to register their establishments with the FDA and certain state agencies, and are subject to periodic announced and unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other regulatory requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications 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, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

Other U.S. Regulatory Matters

Pharmaceutical manufacturers are subject to various healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Our conduct, including those of our employees, as well as our business operations and relationships with third parties, including current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- *Anti-Kickback Statute.* The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward or in return for, either the referral of an individual for or the purchase, lease or order of a good, facility, item or service for which payment may be made under a federal healthcare program such as

Medicare and Medicaid. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

- *False Claims Laws.* The federal false claims and civil monetary penalties laws, including the federal civil False Claims Act (“FCA”), impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions against individuals or entities for, among other things, knowingly presenting or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties. Pharmaceutical companies can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims.
- *HIPAA.* HIPAA imposes criminal and civil liability for, among other things, executing a scheme or making materially false statements in connection with the delivery of or payment for health care benefits, items or services. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information.
- *Federal Trade Commission Act.* Even when HIPAA does not apply, according to the Federal Trade Commission (“FTC”), failing to take appropriate steps to keep consumers’ personal information secure could constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act (“FTCA”). The FTC’s current guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA security regulations, but this guidance may change in the future, resulting in increased complexity and the need to expend additional resources to ensure we are complying with the FTCA.
- *The U.S. Federal Physician Payments Sunshine Act.* The federal Physician Payments Sunshine Act 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 specific exceptions, to report annually to CMS information related to payments or transfers of value made to physicians, other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- *Price Reporting Laws.* Certain federal and state laws including U.S. federal government price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs.
- *Analogous State and Foreign Laws.* Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors and are generally broad and are enforced by many different federal and state agencies as well as through private actions.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Federal and state consumer protection laws are increasingly being applied by the FTC and states’ attorneys general to regulate the collection, use, storage and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content. The FTC has authority to initiate enforcement actions against entities that mislead customers about HIPAA compliance, make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5(a) of the FTCA, and has brought enforcement actions against companies in the healthcare space in recent years. As a result of regulatory enforcement proceedings, we may be subject to related litigation, settlements or enforcement actions that could include monetary penalties and/or compliance requirements.

Many states have laws that protect the privacy and security of sensitive and personal information, including health information, to which BBOT is subject. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, the California Consumer Privacy Act (the “CCPA”) and similar consumer privacy laws in a number of states establish privacy frameworks for covered businesses, including broad definitions of regulated personal information, data privacy rights for consumers residing in the relevant state, special rules on the collection of consumer data from minors, and an enforcement framework

for violations and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Many of the state laws differ from each other and cover personal information other than protected health information subject to HIPAA, thus complicating compliance efforts and potentially requiring BBOT to incur additional costs and expenses to comply.

Furthermore, certain consumer health privacy laws, such as Washington's My Health My Data Act, which became effective on March 31, 2024 and contains a private right of action, further increase compliance risks and costs. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, states such as Illinois and Texas have passed laws that regulate biometric data specifically, and enforcement and litigation surrounding such laws has resulted in significant penalties, settlements and awards.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including 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, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain 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 a 505(b)(2) NDA submitted by another company for a generic version of such drug 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. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b) (2) 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 conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA by another applicant. 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 or generate such data themselves.

European Union Drug Development

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

The EU Clinical Trials Directive has been repealed by the Clinical Trials Regulation (EU) No. 536/2014 ("***EU Clinical Trials Regulation***"), which became applicable on 31 January 2022. The EU Clinical Trials Regulation harmonizes the processes for assessment and supervision of clinical trials throughout the EU. The EU Clinical Trials Regulation enables sponsors to submit one online application via a single online platform known as the Clinical Trials Information System (CTIS) for approval to run a clinical trial in several EU Member States, making it more efficient to carry out such multinational trials and for EU Member States to evaluate and authorize such applications together, via the CTIS.

Other key benefits of the EU Clinical Trials Regulation include:

- improving information-sharing and collective decision-making on clinical trials;
- increasing transparency of information on clinical trials;
- ensuring high standards of safety for all participants in EU clinical trials.

For clinical trials conducted in the EU, sponsors must report suspected unexpected serious adverse reactions through the EudraVigilance system.

European Union Drug Review and Approval

In the European Economic Area (“EEA”), which comprises the Member States of the European Union and three European Free Trade Association States (Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a marketing authorization (“MA”). There are two types of MAs.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, of the EMA, and is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EU and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this national MA can be recognized in other EU Member States through the mutual recognition procedure. If the product has not received a national MA in any EU Member State at the time of application, it can be approved simultaneously in various EU Member States through the decentralized procedure.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EU make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and Marketing Exclusivity

In the EU, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan Designation

In the EU, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and that, without incentives, it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment in development. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EU, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity. During this market exclusivity period, the EMA or the EU Member State competent authorities, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication as the authorized orphan product. The period of market exclusivity may be extended by two years for orphan medicines that have also complied with an agreed pediatric investigational plan.

This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example because the product is sufficiently profitable not to justify market exclusivity. In very select cases a marketing authorization may be granted to a similar medicinal product for the same indication as an authorized orphan product during the market exclusivity period, such as where there is consent from the marketing authorization holder for the authorized orphan product, inability to supply sufficient quantities of the authorized orphan product, or demonstration of “clinical superiority” by a similar medicinal product to the authorized orphan product. Medicinal products designated as orphan products are eligible for incentives made available by the EU and its Member States to support research into, and the development and availability of, orphan products.

All of the aforementioned EU rules are generally applicable in the EEA.

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text has been agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted, and are not expected to become applicable before 2028.

Coverage and Reimbursement

Sales of our products, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS’s decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA -approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“**MMA**”), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

In addition, in case a drug product needs companion diagnostics, then 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.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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 substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The Affordable Care Act contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price ("AMP"), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. These changes included the U.S. Budget Control Act of 2011, which among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2031 unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, currently previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The Inflation Reduction Act of 2022 (the "IRA") also was signed into law in August 2022. The IRA, in part, creates a \$2,000 out-of-pocket cap for Medicare Part D beneficiaries, imposes new manufacturer financial liability on all drugs in Medicare Part D, allows the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requires companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delays the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet known. Overall, these new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

With respect to drug pricing reforms proposed by the Trump Administration, CMS released two proposed rules on December 19, 2025 that would introduce most-favored-nation ("MFN") pricing principles into Medicare drug reimbursement. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting certain spending and eligibility criteria established by CMS. The second proposal, the Guarding U.S.

Medicare Against Rising Drug Costs (“**GUARD**”) model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five-year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals are likely to face legal challenges that could delay or modify their implementation. Separately, in November 2025, CMS introduced the Generating Cost Reductions For U.S. Medicaid (“**GENEROUS**”) Model, a voluntary MFN-based framework for manufacturers participating in the Medicaid Drug Rebate Program. While participation is optional, the GENEROUS Model could nonetheless influence manufacturer pricing strategies and the broader drug pricing landscape.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 programs and reform government program reimbursement methodologies for drug products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient 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. It is possible that additional governmental action is taken, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Facilities

Our principal executive office is located in South San Francisco, California, where we lease approximately 11,000 square feet of combined office and lab space under a lease that terminates in April 2030. We believe that these existing facilities will be adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

Human Capital

As of December 31, 2025, we had 92 employees. 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.

We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset and we aim to create an environment that is equitable, inclusive and representative in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical-stage platform, business and operations, and also protect the long-term interests of our securityholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value agility, passion and teamwork, and are building a diverse environment where our employees can thrive and one that inspires exceptional contributions and professional and personal development in order to achieve our mission to significantly change the practice of oncology. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees.

We plan to continue to develop our efforts related to attracting, retaining and motivating our workforce as we grow and develop and hire more employees.

Corporate and Other Information

Our business was established in August 2016 by BridgeBio Pharma Inc. (“**BridgeBio Pharma**”) under the name, TheRas, Inc. (“**Legacy BBOT**”). We operated as part of BridgeBio Pharma through April 30, 2024. Legacy BBOT entered into a definitive business combination agreement (“**Business Combination Agreement**”) with Helix Acquisition Corp. II, a publicly traded special purpose acquisition company (“**Helix**”) listed on Nasdaq under the ticker symbol “HLXB.” On August 11, 2025 (the “**Closing**”), Helix II Merger Sub, Inc., a wholly owned subsidiary of Helix, merged with and into Legacy BBOT, with Legacy BBOT surviving the merger as a wholly-owned subsidiary of Helix (“**Merger**”). In connection with the Merger, Helix changed its name to BridgeBio Oncology Therapeutics, Inc., and the combined company became listed on Nasdaq under the new ticker symbol “BBOT” (“**de-SPAC Transaction**”). Our principal executive offices are located at 256 E. Grand Avenue, Suite 104, South San Francisco, CA 94080. Our telephone number is (650) 405-4770.

Our web page address is <https://bbotx.com>. Our investor relations website is located at <https://investors.bbotx.com>. We make available free of charge on our investor relations website under “SEC Filings” our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, our directors’ and officers’ Section 16 Reports and any amendments to those reports after filing or furnishing such materials to the SEC. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, as well as the other information in this Form 10-K, including our consolidated financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and in other documents we file with the SEC when evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations and future prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. The risks described below are not intended to be exhaustive and are not the only risks that we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risks Related to BBOT’s Financial Position and Need for Additional Capital

BBOT has a limited operating history, has not completed any clinical trials, has no products approved for commercial sale and has not generated any revenue, which may make it difficult for investors to evaluate BBOT’s current business and likelihood of success and viability.

BBOT is a biopharmaceutical company with a limited operating history upon which investors can evaluate its business and prospects. BBOT was incorporated in August 2016 and commenced significant operations as an independent entity starting in May 2024, has never completed a clinical trial, has no products approved for commercial sale and has never generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, BBOT has devoted substantially all of its resources to research and development activities, including with respect to BBO-8520, BBO-10203 and BBO-11818, and its discovery programs, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

BBOT has not yet demonstrated its ability to successfully complete clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for investors to evaluate BBOT’s likelihood of success and viability.

In addition, BBOT may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies at BBOT’s stage of development in rapidly evolving fields. BBOT also expects that, as BBOT advances its product candidates, BBOT will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. BBOT has not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If BBOT does not adequately address these risks and difficulties or successfully make such a transition, its business will suffer.

BBOT has incurred significant net losses in each period since its inception, and expects to continue to incur significant net losses for the foreseeable future.

BBOT incurred significant net losses in each reporting period since its inception, has not generated any revenue to date and has financed its operations principally through private placements of securities. BBOT’s net losses for the years ended December 31, 2025 and 2024 were \$134.0 million and \$74.3 million, respectively. As of December 31, 2025, BBOT had an accumulated deficit of \$356.6 million. BBOT has not yet completed any clinical trials. As a result, BBOT expects that it will be several years, if ever, before BBOT generates revenue from product sales. Even if BBOT succeeds in receiving marketing approval for and commercializing one or more product candidates, BBOT expects that it will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

BBOT expects to continue to incur significant and increasing expenses and increasing operating losses for the foreseeable future. The net losses BBOT incurs may fluctuate significantly from quarter to quarter such that a period-to-period comparison of BBOT’s results of operations may not be a good indication of future performance. The size of future net losses will depend, in part, on the pace of development activities and the rate of future growth of expenses and BBOT’s ability to generate revenue. BBOT’s prior losses and expected future losses have had and will continue to have an adverse effect on working capital, BBOT’s ability to fund the development of its product candidates and its ability to achieve and maintain profitability and the performance of its stock.

BBOT's ability to generate revenue and achieve profitability depends significantly on its ability to achieve its objectives relating to the discovery, development and commercialization of its product candidates.

BBOT relies on its team's expertise in chemistry, structure-based drug design, oncology drug development, business development and patient-driven approach to develop its product candidates. BBOT's business depends significantly on the success of its approach and the development and commercialization of the product candidates that BBOT discovers with this approach. BBOT has no products approved for commercial sale and does not anticipate generating any revenue from product sales for the next several years, if ever. BBOT's ability to generate revenue and achieve profitability depends significantly on its ability to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of BBO-8520, BBO-10203, BBO-11818 and any future product candidates from BBOT's discovery program
- maintaining current and establishing new relationships with contract research organizations ("CROs") and clinical sites for the clinical development of BBO-8520, BBO-10203, BBO-11818 and any future product candidates from BBOT's current or future discovery programs;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which BBOT successfully completes clinical development;
- developing an efficient and scalable manufacturing process for BBOT's product candidates, including the production of finished products that are appropriately packaged for sale if BBOT's product candidates obtain marketing approvals;
- maintaining current and establishing new commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for BBOT's product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- maintaining an acceptable safety profile following any marketing approval of BBOT's product candidates;
- commercial acceptance of BBOT's product candidates by patients, the medical community and third-party payors, including the willingness of physicians to use BBOT's product candidates, if approved, in lieu of (or in conjunction with) other approved therapies;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- defending against third-party interference or infringement claims, if any, with respect to BBOT's intellectual property rights;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize BBOT's product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for BBOT's product candidates, if approved;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

BBOT may never be successful in achieving its objectives and, even if it does, may never generate revenue that is significant or large enough to achieve profitability. If BBOT does achieve profitability, BBOT may not be able to sustain or increase profitability on a quarterly or annual basis. BBOT's failure to become and remain profitable would decrease the value of the company and could impair BBOT's ability to maintain or further its research and development efforts, raise additional necessary capital, grow its business and continue its operations.

BBOT may require additional capital to finance its operations. If BBOT is unable to raise such capital when needed, or on acceptable terms, BBOT may be forced to delay, reduce or eliminate one or more of its research and drug development programs, future commercialization efforts, product development or other operations.

Since inception, BBOT has used substantial amounts of cash to fund its operations, and its expenses will increase substantially in the foreseeable future in connection with its ongoing activities, particularly as BBOT continues the research and development of,

initiates additional clinical trials of, and seeks marketing approval for, its product candidates. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Even if one or more of BBOT's product candidates or any future product candidates that BBOT develops is approved for commercial sale, BBOT anticipates incurring significant costs associated with sales, marketing, manufacturing and distribution activities. BBOT's expenses could increase beyond expectations if BBOT is required by the FDA, the EMA or other regulatory authorities to perform clinical trials or preclinical studies in addition to those that BBOT currently anticipates. Other unanticipated costs may also arise. Because the design and outcome of BBOT's clinical trials, including its planned and anticipated clinical trials, are highly uncertain, BBOT cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of its product candidates or any future product candidates that it develops. BBOT is currently conducting Phase 1 clinical trials of BBO-8520, BBO-10203 and BBO-11818. BBOT is not permitted to market or promote any product candidate before it receives marketing approval from the FDA, EMA or any comparable foreign regulatory authorities. BBOT is also incurring additional costs associated with operating as a public company. Accordingly, BBOT may need to obtain additional funding in order to continue its operations.

BBOT estimates that its existing cash, cash equivalents and short-term marketable securities as of the date of this report will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into early 2028.

Advancing the development of BBO-8520, BBO-10203 and BBO-11818 and BBOT's discovery programs will require a significant amount of capital. BBOT's existing cash, cash equivalents and marketable securities will not be sufficient to fund all of BBOT's product candidates through regulatory approval, and BBOT may need to raise additional capital to complete the development and commercialization of its product candidates. BBOT's estimate as to how long it expects its existing cash, cash equivalents and marketable securities to fund its operations does not include potential product revenue and is based on assumptions that may prove to be wrong, and BBOT could use its available capital resources sooner than currently expected. Changing circumstances, some of which may be beyond BBOT's control, could cause BBOT to consume capital significantly faster than currently anticipated, and BBOT may need to seek additional funds.

BBOT may be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute BBOT's stockholders or restrict its operating activities. BBOT does not have any committed external source of funds. Adequate additional financing may not be available to BBOT on acceptable terms, or at all. BBOT's ability to raise additional funds may be adversely impacted by general economic conditions, both inside and outside the U.S., including disruptions to, and instability and volatility in, the credit and financial markets in the U.S. and worldwide, including heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession as well as concerns related to public health emergencies, natural disasters or geopolitical events, including civil or political unrest or military conflicts. In addition, market instability and volatility, high levels of inflation and interest rate fluctuations may increase BBOT's cost of financing or restrict BBOT's access to potential sources of future liquidity. To the extent that BBOT raises additional capital through the sale of equity or convertible debt securities, each investor's ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor's rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect BBOT's business. If BBOT raises additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, BBOT may have to relinquish valuable rights to its product candidates or grant licenses on terms that are not favorable to BBOT. In addition, BBOT may seek additional capital due to favorable market conditions or strategic considerations even if BBOT believes it has sufficient funds for its current or future operating plans.

BBOT's failure to raise capital as and when needed or on acceptable terms would have a negative impact on its financial condition and its ability to pursue its business strategy, and BBOT may have to delay, reduce the scope of, suspend or eliminate one or more of its research or drug development programs, clinical trials or future commercialization efforts.

Risks Related to BBOT's Product Development, Regulatory Approval and Commercialization

BBOT's future prospects are substantially dependent on the advancement of its product candidates. If BBOT is unable to advance its product candidates through development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, BBOT's business will be materially harmed.

BBOT is currently conducting Phase 1 clinical trials of BBO-8520, BBO-10203 and BBO-11818. BBOT's ability to generate product revenue, which BBOT does not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of one or more product candidates. BBOT is not permitted to market or promote any product candidate before BBOT receives marketing approval from the FDA, EMA or any comparable foreign regulatory authorities, and BBOT may never receive such marketing approvals.

The success of BBOT's product candidates will depend on several factors, including the following:

- successful and timely completion of preclinical studies;
- submission of INDs in the U.S. and CTAs and/or comparable applications outside the U.S. for regulatory authority review and agreement to proceed with BBOT's clinical trials;
- successful initiation and completion of clinical trials;
- successful and timely patient selection and enrollment in and completion of clinical trials;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of BBOT's product candidates both in the U.S. and internationally;
- maintaining and growing an organization of scientific, medical and other professionals who can develop and commercialize BBOT's product candidates;
- the frequency and severity of adverse events in clinical trials;
- obtaining positive data that support demonstration of efficacy, safety and tolerability profiles and durability of effect for BBOT's product candidates that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the timely identification, development and approval of companion diagnostic tests, if required;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of BBOT's product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- the protection of BBOT's rights in its intellectual property portfolio;
- establishing sales, marketing and distribution capabilities and the successful launch of commercial sales of BBOT's product candidates if and when approved for marketing, whether alone or in collaboration with others;
- maintaining an acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors, including the willingness of physicians to use BBOT's product candidates, if approved, in lieu of (or in conjunction with) other approved therapies;
- BBOT's ability to compete with other therapies; and
- BBOT's ability to address any potential delays resulting from factors related to public health emergencies, natural disasters or geopolitical events.

BBOT does not have complete control over many of these factors, including certain aspects of preclinical and clinical development and the regulatory submission process, potential threats to BBOT's intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If BBOT is not successful with respect to one or more of these factors in a timely manner or at all, BBOT could experience significant delays or an inability to successfully commercialize any product candidates from its lead programs, which would materially harm its business. If BBOT does not receive marketing approvals for such product candidates, BBOT may not be able to continue its operations.

BBOT's preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of any of its product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of BBOT's product candidates, BBOT must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that its product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and the ultimate outcome is uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, there is a high risk of failure, and BBOT may never succeed in developing marketable products.

BBOT may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or BBOT's ability to commercialize its product candidates, including:

- failure of BBOT's product candidates in preclinical studies or clinical trials to demonstrate safety and efficacy;
- receipt of feedback from regulatory authorities that requires BBOT to modify the design of its clinical trials;
- negative or inconclusive clinical trial results that may require BBOT to conduct additional clinical trials or abandon certain research, discovery and/or drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated, particularly if there are other trials enrolling the same or overlapping precisely targeted patient populations, or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to BBOT in a timely manner, or at all;
- the suspension or termination of BBOT's clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that BBOT's product candidates have undesirable adverse events or other unexpected characteristics or risks;
- the cost of clinical trials of BBOT's product candidates being greater than anticipated;
- the supply or quality of BBOT's product candidates or other materials necessary to conduct clinical trials of BBOT's product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving BBOT's product candidates.

If BBOT is required to conduct additional clinical trials or other testing of its product candidates beyond those that BBOT is currently contemplating, if BBOT is unable to successfully complete clinical trials of its product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, BBOT may incur unplanned costs, be delayed in seeking and obtaining marketing approval, if BBOT receives such approval at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

BBOT's discovery and development activities are focused on precision oncology to treat RAS-dependent cancers, which is a rapidly evolving area of science, and the approach BBOT is taking to discover and develop drugs may never lead to approved or marketable products.

The discovery and development of precision oncology therapeutics for patients with RAS-dependent cancers is an emerging field, and the scientific discoveries that form the basis for BBOT's efforts to discover and develop product candidates are evolving. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although BBOT believes, based on BBOT's preclinical work and clinical trials to date, that BBOT's product candidates can inhibit RAS, clinical results may not confirm this hypothesis or may only confirm it for certain tumor types. The patient populations for BBOT's product candidates are limited to those with KRAS and PI3Ka mutations and HER2 amplification and may not be completely defined but are substantially smaller than the general treated cancer population, and BBOT will need to screen and identify these targeted patients. Successful identification of patients is dependent on several factors, including evaluation of patient biopsies and blood samples, which may require the use of companion diagnostic tests. Furthermore, even if BBOT is successful in identifying patients, BBOT cannot be certain that the resulting patient populations for each mutation will be large enough to allow BBOT to successfully obtain approval for each mutation type and commercialize BBOT's product candidates and achieve profitability. BBOT does not know if its approach of focusing on treating patients with RAS-dependent cancers will be successful, and if its approach is unsuccessful, BBOT's business will suffer.

Any delays in the commencement or completion, or any termination or suspension, of BBOT's current, planned or future clinical trials could result in increased costs to BBOT, delay or limit BBOT's ability to generate revenue and adversely affect BBOT's commercial prospects.

Before BBOT can initiate clinical trials of any product candidate in any indication, BBOT must submit the results of preclinical studies to the FDA, EMA or other comparable foreign regulatory authorities along with other information, including information about the product candidate's chemistry, manufacturing and controls and its proposed clinical trial protocol, as part of an IND or similar regulatory submission under which BBOT must receive authorization to proceed with clinical development. The FDA, EMA or other comparable foreign regulatory authorities may require BBOT to conduct additional preclinical studies for any product candidate before they allow BBOT to initiate clinical trials under any IND, CTA or comparable application which may lead to additional delays and increase the costs of BBOT's preclinical development programs.

Before obtaining marketing approval from the FDA of BBO-8520, BBO-10203, BBO-11818 or of any other future product candidate in any indication, BBOT must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, BBOT expects to rely in part on preclinical, clinical and quality data generated by BBOT's CROs and other third parties for regulatory submissions for BBOT's product candidates. While BBOT has or will have agreements governing these third parties' services, BBOT has limited influence over their actual performance. If these third parties do not make data available to BBOT, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to BBOT's agreements with them, BBOT's development programs may be significantly delayed and BBOT may need to conduct additional studies or collect additional data independently. In either case, BBOT's development costs would increase. BBOT is currently conducting Phase 1 clinical trials of BBO-8520, BBO-10203 and BBO-11818. An IND submission must become effective prior to initiating any clinical trials in the U.S. for any of BBOT's future product candidates.

BBOT could also encounter delays if a clinical trial is suspended or terminated by BBOT, by the independent institutional review board ("IRB") or independent ethics committee ("IEC") of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or 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 regulatory requirements or BBOT's clinical protocols, inspection of the clinical trial operations or trial site by the FDA or foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, failure to demonstrate a benefit from using a pharmaceutical, 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 BBOT may need to amend clinical trial protocols to comply with these changes. Amendments may require BBOT to resubmit its clinical trial protocols to IRBs/IECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, if BBOT is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, BBOT's development plans may be impacted.

Certain of BBOT's current or future scientific advisors or consultants who receive compensation from BBOT may become investigators for BBOT's future clinical trials. Under certain circumstances, BBOT may be required to report some of these relationships to the FDA. Although BBOT expects any such relationships to be within the FDA's guidelines, the FDA may conclude that a financial relationship between BBOT and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA 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 BBOT's marketing applications by the FDA and may ultimately lead to the denial of marketing approval of BBOT's product candidates. If BBOT experiences delays in the completion of, or any termination or suspension of, any clinical trial of any product candidate, the commercial prospects of such product candidate will be harmed, and BBOT's ability to generate product revenue will be delayed. Moreover, any delays in completing BBOT's clinical trials will increase BBOT's costs, slow down BBOT's development and approval process and jeopardize BBOT's ability to commence product sales and generate revenue, which may harm BBOT's business, financial condition, results of operations and prospects significantly.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of BBOT's clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

BBOT will be required to demonstrate with substantial evidence through well-controlled clinical trials that BBOT's product candidates are safe and effective for use in the target population before BBOT can seek marketing approvals for their commercial sale. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes; there is a high risk of failure and BBOT may never succeed in developing marketable products.

The results of preclinical studies may not be predictive of the results of clinical trials of BBOT's product candidates, and the results of early clinical trials may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. Favorable results from certain animal studies may not accurately predict the results of other animal studies or of human trials, due to the inherent biologic differences in species, the differences between testing conditions in animal studies and human trials, and the particular goals, purposes, and designs of the relevant studies and trials. Similarly, certain of BBOT's hypotheses regarding the potential clinical and therapeutic benefits of its product candidates compared to other approved products and product candidates or molecules in development are based on observations from the preclinical studies and early clinical trials that BBOT has completed, and results from such preclinical studies and early clinical trials are not necessarily predictive of the results of later preclinical studies or clinical trials.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products. The development of BBOT's product candidates and its stock price may also be impacted by inferences, whether correct or not, that are drawn between the success or failure of preclinical studies or clinical trials of BBOT's competitors or other companies in the biopharmaceutical industry, in addition to BBOT's own preclinical studies and clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with BBOT's product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause adverse events that are unrelated to BBOT's product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, BBOT's clinical trial outcomes.

Any preclinical studies or clinical trials that BBOT conducts may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market BBOT's product candidates. If the results of BBOT's ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of BBOT's product candidates, if BBOT does not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with BBOT's product candidates, BBOT may be prevented or delayed in obtaining marketing approval for such product candidates.

BBOT does not know whether any clinical trials BBOT conducts will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of BBOT's product candidates.

In addition to BBO-8520, BBO-10203 and BBO-11818, BBOT's prospects depend in part upon discovering, developing and commercializing additional product candidates from BBOT's discovery programs, which may fail in development or suffer delays that adversely affect their commercial viability.

BBOT's future operating results are dependent on its ability to successfully discover, develop, obtain regulatory approval for and commercialize BBO-8520, BBO-10203 and BBO-11818 and future product candidates from BBOT's discovery programs. A research candidate can unexpectedly fail at any stage of development. The historical failure rate for research candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other research candidates that BBOT may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of preclinical studies and clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials;
- adverse events in clinical trials; and
- addressing any delays resulting from factors related to public health emergencies, natural disasters or geopolitical events.

Even if BBOT successfully advances any research candidates into preclinical and clinical development, their success will be subject to all of the preclinical, clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, there can be no assurance that BBOT will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates.

BBOT's approach to the discovery and development of product candidates is unproven, and BBOT may not be successful in its efforts to use and expand its approach to build a pipeline of product candidates with commercial value.

A key element of BBOT's strategy, which is unproven, is to use and expand BBOT's expertise in chemistry, structure-based drug design and patient-driven approach to build a pipeline of product candidates and progress these product candidates through clinical development. Although BBOT's research and development efforts to date have resulted in the discovery of and initiation of clinical development of BBO-8520, BBO-10203 and BBO-11818, such product candidates and any other product candidates BBOT may develop may not be determined to be safe or effective as cancer therapeutics, and BBOT may not be able to develop any other product candidates. For example, the potential product candidates that BBOT has identified or identifies in the future may not generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval from the FDA, EMA or other regulatory authorities or achieve market acceptance. If BBOT does not successfully develop and commercialize product candidates, BBOT will not be able to generate product revenue in the future, which would result in significant harm to BBOT's financial position and adversely affect its business.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If BBOT is ultimately unable to obtain regulatory approval of its product candidates, BBOT will be unable to generate product revenue and its business will be substantially harmed.

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that BBOT's data are insufficient for approval and require additional preclinical, clinical or other data. In addition, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. Even if BBOT eventually completes clinical testing and receives approval for its product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve BBOT's product candidates for a more limited indication or a narrower patient population than BBOT originally requested or may impose other prescribing limitations or warnings that limit the product candidate's commercial potential. Even if approved, BBOT may be required to conduct additional studies to or obtained, regulatory approval for any product candidate, and it is possible that none of BBOT's product candidates will ever obtain regulatory approval. Further, development of BBOT's product candidates and/or regulatory approval may be delayed for reasons beyond its control.

Applications for BBOT's product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of BBOT's clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that BBOT's product candidates are not safe and effective, are only moderately effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude BBOT obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which BBOT seeks approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with BBOT's interpretation of data from preclinical studies or clinical trials;
- the clinical data of the clinical trial may fail to meet the level of statistical significance required to obtain approval of BBOT's product candidates by the FDA, EMA or other comparable foreign regulatory authorities;
- BBOT may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that BBOT's product candidates' risk-benefit ratios for their proposed indications are acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which BBOT contracts for clinical and commercial supplies;

- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for BBOT's product candidates;
- BBOT may not obtain or maintain adequate funding to complete its clinical trials in a manner that is satisfactory to the FDA, EMA or other comparable foreign regulatory authorities; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering BBOT's clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in BBOT failing to obtain regulatory approval to market any of its product candidates, which would significantly harm BBOT's business, results of operations and prospects.

BBOT may not be able to submit INDs, CTAs or comparable applications to commence clinical trials on the timelines BBOT expects, and even if BBOT is able to, the FDA, EMA or any comparable foreign regulatory authority may not permit BBOT to proceed.

BBOT's research and development efforts to date have resulted in the initiation of clinical development of BBO-8520, BBO-10203 and BBO-11818. BBOT may not be able to submit INDs for any future product candidates it may identify on the timelines it expects, or such submissions may not take effect on the timeline that BBOT anticipates, or at all. For example, BBOT may experience manufacturing delays or other delays with IND-enabling studies. Moreover, BBOT cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause BBOT or regulatory authorities to suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, BBOT cannot guarantee that the FDA will not change its requirements in the future. These considerations also apply to new clinical trials BBOT may submit as amendments to existing INDs or to a new IND. Any failure to submit INDs, CTAs or comparable applications on the timelines BBOT expects or to obtain regulatory approvals for BBOT's planned clinical trials may prevent BBOT from initiating or completing its clinical trials or commercializing its product candidates on a timely basis, if at all.

BBOT's product candidates may cause significant adverse events, toxicities or other undesirable adverse events when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If BBOT's product candidates are associated with undesirable adverse events or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, BBOT may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable adverse events or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related adverse events could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent BBOT from achieving or maintaining market acceptance of the affected product candidate and may harm BBOT's business, financial condition and prospects significantly. There have been, and it is likely that there will be additional, adverse events associated with the use of BBOT's product candidates as is typically the case with oncology drugs. Results of BBOT's studies or trials could reveal a high and unacceptable severity and prevalence of these or other adverse events. In such an event, BBOT's trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order BBOT to cease further development of or deny approval of BBOT's product candidates for any or all targeted indications. Drug-related adverse events could also 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 BBOT's business, financial condition and prospects significantly.

In addition, BBOT's product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory authorities. BBOT's product candidates may be studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with BBOT's product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause adverse events that are unrelated to BBOT's product candidates but may still impact the success of BBOT's clinical trials. The inclusion of critically ill patients in BBOT's 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.

If significant adverse events are observed in any of BBOT's current or future clinical trials, BBOT may have difficulty recruiting patients to the clinical trials, patients may drop out of BBOT's trials, or BBOT may be required to abandon the trials or its development efforts of that product candidate altogether. BBOT, the FDA, EMA, other comparable foreign regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse events. Some potential therapeutics developed in the biotechnology industry

that initially showed therapeutic promise in early-stage trials have later been found to cause adverse events that prevented their further development. Even if the adverse events do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable adverse events may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm BBOT's business, financial condition and prospects. Further, if any of BBOT's product candidates obtain marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. BBOT cannot predict whether its product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

Interim, preliminary and topline data from BBOT's preclinical studies and clinical trials that BBOT announces or publishes from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

BBOT expects to publicly disclose interim, preliminary or topline data from its clinical trials in the future. These interim updates are anticipated to be based on preliminary analyses of then-available data, and the results and related findings and conclusions may be subject to change following a more comprehensive review of the data related to the particular study or trial. For example, BBOT may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. BBOT also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, and BBOT may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, preliminary or topline results that BBOT reports 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. Interim, preliminary and topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, preliminary or topline data previously published. As a result, interim, preliminary and topline data should be viewed with caution until the final data are available. In addition, BBOT may report interim analyses of only certain endpoints rather than all endpoints. Interim, preliminary and topline data from clinical trials are 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 changes between interim, preliminary or topline data and final data could significantly harm BBOT's business and prospects. Further, additional disclosure of interim, preliminary or topline data by BBOT or by its competitors in the future could result in volatility in the price of BBOT's common stock.

In addition, the information BBOT chooses to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what BBOT determines is the material or otherwise appropriate information to include in its public disclosures, and any information BBOT determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or BBOT's business. If the interim, preliminary or topline data that BBOT reports differs from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, BBOT's ability to obtain approval for, and commercialize, any of its product candidates may be harmed, which could harm BBOT's business, financial condition, results of operations and prospects.

If BBOT experiences delays or difficulties in the enrollment or maintenance of patients in clinical trials, BBOT's regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

BBOT may not be able to initiate or continue clinical trials for its product candidates if BBOT is unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. BBOT's ability to enroll eligible patients may be limited or may result in slower enrollment than anticipated. BBOT utilizes profiling of patients' tumors to identify suitable patients for recruitment into its clinical trials. For these clinical trials, BBOT seeks patients who carry specific gene mutation or amplification that its product candidates are designed to precisely target. BBOT cannot be certain (i) how many patients will have the requisite mutation or amplification that qualify for inclusion in its clinical trials, (ii) that the number of patients enrolled in each program will suffice for regulatory approval or (iii) if regulatory approval is obtained, whether each specific mutation or amplification will be included in the approved drug label. Additionally, BBOT faces competition, including from large pharmaceutical companies with significantly more resources than BBOT, for enrollment of BBOT's targeted patient populations, which may impact BBOT's ability to successfully recruit patients for its clinical trials. If BBOT's strategies for patient identification and enrollment prove unsuccessful, BBOT may have difficulty enrolling or maintaining patients appropriate for its product candidates.

Patient enrollment may be affected if BBOT's competitors have ongoing clinical trials for programs that are under development for the same indications as BBOT's product candidates, and patients who would otherwise be eligible for BBOT's clinical trials instead enroll in clinical trials of its competitors' programs. Patient enrollment for BBOT's current or future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol, including biomarker-driven identification and/or certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for BBOT's clinical trials to a greater extent than competing clinical trials for the same indication that do not have a biomarker-driven patient eligibility criteria;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications BBOT is investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in BBOT's clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

BBOT's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays or may require BBOT to abandon one or more clinical trials altogether. Enrollment delays in BBOT's clinical trials may result in increased development costs for its product candidates and jeopardize its ability to obtain marketing approval for the sale of its product candidates. Furthermore, even if BBOT is able to enroll a sufficient number of patients for its clinical trials, BBOT may have difficulty maintaining participation in its clinical trials through treatment and any follow-up periods.

BBOT has limited resources and is currently focusing its efforts on the development of BBO-8520, BBO-10203 and BBO-11818 in particular indications and advancing its discovery programs. As a result, BBOT may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.

BBOT is currently focusing its resources and efforts on its lead product candidates, BBO-8520 a KRAS inhibitor for KRASG12C NSCLC, BBO-10203 a PI3K α :RAS breaker for PIK3CAmut BC, HER2amp BC, KRASmut NSCLC, KRASmut PDAC, and KRASmut CRC, and BBO-11818 a Pan-KRAS inhibitor for KRASG12X NSCLC, KRASG12X PDAC, KRASG12X CRC, and on advancing BBOT's discovery programs. As a result, because BBOT has limited resources, BBOT may forgo or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. BBOT's resource allocation decisions may cause BBOT to fail to capitalize on viable commercial products or profitable market opportunities. BBOT's spending on current and future research and development activities for BBO-8520, BBO-10203 and BBO-11818 and BBOT's discovery programs may not yield any commercially viable products. If BBOT does not accurately evaluate the commercial potential or target markets for BBO-8520, BBO-10203 and BBO-11818 or any future product candidates identified through BBOT's discovery programs, BBOT may enter into collaboration, licensing or other strategic arrangements with the effect of relinquishing valuable rights in cases in which it would have been more advantageous for BBOT to retain sole development and commercialization rights. In addition, given the similar approaches being utilized by BBOT's lead product candidates, negative developments for one candidate in the pipeline may have negative implications for other candidates in the pipeline.

BBOT currently relies on third parties to supply and manufacture preclinical and clinical drug supplies, and BBOT intends to rely on third parties to produce commercial supplies of any approved product, which increases the risk that BBOT will not have sufficient quantities of these product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair BBOT's development or commercialization efforts.

BBOT does not own or operate manufacturing facilities for the production of preclinical, clinical or commercial supplies of the product candidates that BBOT is developing or evaluating in its drug development programs. BBOT has limited personnel with experience in drug manufacturing and lacks the resources and the capabilities to manufacture any of BBOT's product candidates on a preclinical, clinical or commercial scale. BBOT relies on third parties for supply of its preclinical and clinical drug supplies (including key active pharmaceutical ingredients, or API, drug product, and starting and intermediate materials), and BBOT's strategy is to outsource to third parties all manufacturing of BBOT's product candidates and products from preclinical development through clinical trials and commercialization, if any product candidates are approved.

In order to conduct clinical trials of product candidates, BBOT will need to have them manufactured in potentially large quantities, particularly for later-stage trials. BBOT's third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of its clinical drug supplies (including API, drug product, and key starting and intermediate materials) in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. If these third-party manufacturers are unable to successfully scale up the manufacture of BBOT's product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained.

In addition, some of BBOT's third-party suppliers (including suppliers of key active pharmaceutical ingredients, or API, drug product, and starting and intermediate materials) are currently BBOT's sole source of supplies and, as a result, an issue with one of these suppliers may more significantly impact or delay BBOT's development or commercial plans, as discussed further under the risk factor titled, "Some of the third parties upon whom BBOT currently relies for the supply of the active pharmaceutical ingredients, drug product and starting materials used in BBOT's product candidates are BBOT's sole source of supply, and the loss of any of these suppliers could delay BBOT's development efforts and harm BBOT's business."

BBOT's use of new third-party manufacturers or suppliers also increases the risk of delays in production or insufficient supplies of BBOT's product candidates (and the key API, drug product, and starting and intermediate materials for such product candidates) as BBOT transfers its manufacturing technology to these manufacturers or suppliers and as they gain experience manufacturing or producing BBOT's product candidates (and the key API, drug product, and starting and intermediate materials for these product candidates).

Even after a third-party manufacturer has gained significant experience in manufacturing BBOT's product candidates (or the key API, drug product, and starting and intermediate materials for such product candidates), or even if BBOT believes it has succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will supply or produce sufficient quantities of BBOT's product candidates (or the key API, drug product, and starting and intermediate materials for such product candidates) in a timely manner or continuously over time, or at all. BBOT may be delayed if BBOT needs to change the manufacturing process used by a third party. Further, if BBOT changes an approved manufacturing process, then BBOT may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used.

Reliance on third-party manufacturers for preclinical, clinical and commercial supplies entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing or master services agreement by the third party;
- the possible misappropriation of BBOT's proprietary information, including trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for BBOT.

While BBOT has entered into master services agreements with its current suppliers under which work is performed on an as-needed basis pursuant to quotations or proposals, BBOT does not currently have any agreements with third-party manufacturers for long-term commercial supply. In the future, BBOT may be unable to enter into agreements with third-party manufacturers for commercial supplies of any of BBOT's product candidates, or may be unable to do so on acceptable terms. Even if BBOT is able to establish and maintain arrangements with third-party manufacturers for commercial supply, reliance on third-party manufacturers entails risks, including those described above.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. BBOT's failure, or the failure of its third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on BBOT, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of BBOT's product candidates.

BBOT's future product candidates and any products that BBOT may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements particularly that use chromatography or purification technology necessary for the manufacture of BBO-10203, and that might be capable of manufacturing for BBOT.

BBOT is also unable to predict how changing regulatory requirements, global economic conditions or ongoing geopolitical conflicts, trade policy, and related global economic sanctions, or potential global health concerns will affect BBOT's third-party suppliers and manufacturers. Any negative impact of such matters on BBOT's third-party suppliers and manufacturers may also have an adverse impact on BBOT's results of operations or financial condition. For example, in 2024, there was Congressional activity related to interactions with Chinese biopharmaceutical companies, including the introduction of the BIOSECURE Act. Although the BIOSECURE Act has not been passed by Congress, if this bill is re-introduced and is passed, or if similar laws are passed in the future, they would have the potential to restrict the ability of U.S. biopharmaceutical companies like BBOT to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. Some of BBOT's sole source suppliers are companies in China, including some named in these bills, and it is possible some of BBOT's contractual counterparties could be impacted by the legislation described above.

If the third parties that BBOT engages to supply any materials or manufacture product for its preclinical tests and clinical trials should cease to continue to do so for any reason, BBOT likely would experience delays in advancing these tests and trials while BBOT identifies and qualifies replacement suppliers or manufacturers, and BBOT may be unable to obtain replacement supplies on terms that are favorable to BBOT or at all. In addition, if BBOT is not able to obtain adequate supplies of its product candidates or the substances used to manufacture them, it will be more difficult for BBOT to develop its product candidates and compete effectively.

BBOT's current and anticipated future dependence upon others for the manufacture of BBOT's product candidates (or the key API, drug product, and starting and intermediate materials for such product candidates) may adversely affect BBOT's future profit margins and ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

BBOT faces substantial competition which may result in others discovering, developing or commercializing products before or more successfully than BBOT does.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. BBOT's competitors have developed, are developing or may develop products, product candidates and processes competitive with BBOT's product candidates. Any product candidates that BBOT successfully develops and commercializes will compete with existing therapies and new therapies that may become available in the future. BBOT believes that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which BBOT is currently attempting and may in the future attempt to develop product candidates. In addition, BBOT's product candidates may need to compete with drugs physicians use off-label to treat the indications for which BBOT seeks approval. This may make it difficult for BBOT to replace existing therapies with BBOT's product candidates.

In particular, there is intense competition in the field of oncology. BBOT has competitors both in the U.S. and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. BBOT also competes with these organizations to recruit and retain qualified scientific and management personnel, which could negatively affect BBOT's level of expertise and BBOT's ability to execute its business plan. BBOT will also face competition in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, BBOT's programs.

For BBO-8520, there are currently two KRASG12C inhibitors approved by the FDA for use in KRASG12C mutant advanced or metastatic NSCLC.

For BBO-10203, there is one PI3K α inhibitor approved by the FDA for the treatment of HR+ / HER2- advanced or metastatic PIK3CAmut breast cancer.

For BBO-11818, there are no pan-KRAS inhibitors approved by the FDA for the treatment of KRASG12X mutant lung, colorectal, or pancreatic cancers.

Many of BBOT's competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than BBOT. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and

manufacturing biotechnology product candidates. These companies also have significantly greater research and marketing capabilities than BBOT and may also have product candidates that have been approved or are in late stages of development, and collaborative arrangements in BBOT's target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that BBOT develops obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, BBOT's programs. As a result of all of these factors, BBOT's competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in BBOT's field before BBOT does.

BBOT's potential commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe adverse events, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that BBOT may develop. Physicians may be more willing to prescribe competitors' products for various reasons, and may rely on guidelines related to treatment of patients issued by medical societies, industry groups or other organizations, which may not include, and may never include, BBOT's products. BBOT's competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than BBOT may obtain approval for its product candidates, which could result in competitors establishing a strong market position before BBOT is able to enter the market, or make BBOT's development and marketing more complicated. Even if the product candidates BBOT develops achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by BBOT's competitors may render BBOT's technologies or product candidates obsolete, less competitive or not economical. If BBOT is unable to compete effectively, BBOT's opportunity to generate revenue from the sale of products BBOT may develop, if approved, could be adversely affected.

BBOT's product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if BBOT's product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of BBOT's approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of BBOT's product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- willingness of physicians to use BBOT's product candidates, if approved, in lieu of (or in conjunction with) other approved therapies;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to BBOT's product candidates; and
- the approval of other new therapies for the same indications.

If any of BBOT's product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, BBOT may not generate or derive sufficient revenue from that product candidate and BBOT's financial results could be negatively impacted.

The market opportunities for any product candidates BBOT develops, if approved, may be limited to certain smaller patient subsets and may be smaller than BBOT estimates them to be.

When cancer is detected early (referred to as localized disease), conventional treatments, which include chemotherapy, hormone therapy, surgery and radiation therapy and/or selected targeted therapies, may be adequate to cure the patient in many cases. However, once cancer has spread to other areas (advanced or metastatic disease), cancer treatments may not be sufficient to provide a cure but often can significantly prolong life without curing the cancer. First-line therapies designate treatments that are initially administered to patients with advanced or metastatic disease, while second and third-line therapies are administered to patients when the prior therapies lose their effectiveness. The FDA, EMA and other regulatory bodies often approve cancer therapies for a particular line of treatment. Typically, drug approvals are initially granted for use in later lines of treatment, but with additional evidence of significant efficacy from clinical trials, biopharmaceutical companies can successfully seek and gain approval for use in earlier lines of treatment.

In most instances, BBOT plans to initially seek approval of BBO-8520, BBO-10203 and BBO-11818 and any other future product candidates for previously treated patients with advanced or metastatic cancer where at least one prior therapy has limited clinical benefit or where tumors have developed resistance to such therapy. For those product candidates that prove to be sufficiently safe and effective, if any, BBOT would potentially expect to seek approval ultimately as a first line therapy. There is no guarantee that BBOT's product candidates, even if approved for previously treated patients, would be approved for an earlier line of therapy, and prior to any such approvals BBOT may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

BBOT's projections of both the number of people who have the cancers BBOT is targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with BBOT's product candidates, are based on BBOT's beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new data and studies may change the estimated incidence or prevalence of the cancers that BBOT is targeting, especially if new therapies that are approved while BBOT advances its product candidates affect the treatment paradigm and/or the size of the target population. The potentially addressable patient population for BBOT's product candidates may be limited or may not be amenable to treatment with BBOT's product candidates. Consequently, even if BBOT's product candidates are approved, the number of patients that may be eligible for treatment with BBOT's product candidates may turn out to be much lower than expected. In addition, BBOT has not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type. Even if BBOT obtains significant market share for its products, if approved, if the potential target populations are small, BBOT may never achieve profitability without obtaining regulatory approval for additional indications.

Any product candidates BBOT develops may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

Patients rely on insurance coverage by third-party payors (third-party payors include Medicare and Medicaid (government payors) and commercial insurance companies such as Blue Cross Blue Shield, Humana, Cigna, etc.), to pay for products. The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of BBOT's product candidates that receive marketing approval will depend substantially, both in the U.S. and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. No uniform policy exists for coverage and reimbursement in the U.S. If reimbursement is not available, or is available only to limited levels, BBOT may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow BBOT to establish or maintain pricing sufficient to realize an adequate return on BBOT's investment. Further, it is possible that a third-party payor may consider BBOT's product candidates as substitutable with competitor products and offer to reimburse patients only for the less expensive competitor product. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which BBOT obtains marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, BBOT may not successfully commercialize any product candidate for which BBOT obtains marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by the Center for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services (“HHS”). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS’s decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor’s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. This process will require BBOT to provide scientific and clinical support for the use of BBOT’s products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, BBOT cannot be sure that its products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. Such other actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for BBOT’s products if approved, BBOT’s revenue, and its ability to compete with other marketed products and to recoup the costs of its research and development. For further discussion, see “- Current and future legislation may increase the difficulty and cost for BBOT to obtain reimbursement for its product candidates;” and “- The prices of prescription pharmaceuticals in the U.S. and foreign jurisdictions are the subject of considerable legislative and executive actions and could impact the prices BBOT obtains for its products, if and when licensed for marketing.”

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. BBOT may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of its products. Nonetheless, BBOT’s product candidates may not be considered medically necessary or cost effective. BBOT cannot be sure that coverage and reimbursement will be available for any product that BBOT commercializes and, if reimbursement is available, what the level of reimbursement will be.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for BBOT’s product candidates, if approved.

Outside the U.S., the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and BBOT believes the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as BBOT’s product candidates. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, BBOT may be required to conduct a clinical trial that compares the cost-effectiveness of BBOT’s product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that BBOT is able to charge for its product candidates. Accordingly, in markets outside the U.S., the reimbursement for BBOT’s products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

If BBOT is unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which BBOT receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

BBOT's business entails a significant risk of product liability and if BBOT is unable to obtain sufficient insurance coverage such inability could have an adverse effect on BBOT's business and financial condition.

BBOT's business exposes BBOT to significant product liability and other risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability and other claims or incidents, such as cyber incidents and breaches, could delay or prevent completion of BBOT's development programs. If BBOT succeeds in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of BBOT's products, manufacturing processes and facilities or BBOT's marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of BBOT's products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for BBOT's products, injury to BBOT's reputation, costs to defend the related litigation, a diversion of management's time and BBOT's resources and substantial monetary awards to trial participants or patients. BBOT currently has product liability and other insurance that BBOT believes is appropriate for its stage of development and may need to obtain higher levels prior to advancing BBOT's product candidates into later stages of development or marketing any of BBOT's product candidates, if approved. Any insurance BBOT has or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial, product liability, and other types of insurance (such as cyber insurance) are becoming increasingly expensive and difficult to obtain. As a result, BBOT may be unable to obtain sufficient insurance at a reasonable cost to protect BBOT against losses caused by product liability or other claims or incidents, including data breach and incidents, that could have an adverse effect on BBOT's business and financial condition.

Certain of BBOT's product candidates are novel, complex and difficult to manufacture. BBOT could experience manufacturing problems that result in delays in BBOT's development or commercialization or otherwise harm BBOT's business.

The manufacturing processes BBOT's third-party contract manufacturing organizations ("CMOs") use to produce its product candidates are complex, novel and have not been validated for commercial use. Several factors have caused and may cause future production interruptions, including restrictions on certain manufacturing operations and shortages in on-site personnel at BBOT's CMOs' manufacturing facilities, equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of BBOT's suppliers, including historical disruptions, which could reoccur in connection with any future global pandemic or health emergency.

Several of BBOT's small molecule product candidates are particularly complex and difficult to manufacture, in some cases due to the number of steps required, the process complexity and the toxicity of end or intermediate-stage products. BBOT's product candidates require processing steps that are more complex than those required for most small molecule drugs. As a result, assays of the finished product may not be sufficient to ensure that the product is consistent from lot-to-lot or will perform in the intended manner. Accordingly, BBOT's CMOs must employ multiple steps to control the manufacturing process to assure that the process is reproducible and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory to conduct clinical trials or supply commercial markets. BBOT may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet the FDA, the EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA and other foreign regulatory authorities may require BBOT to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that BBOT not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause BBOT to delay clinical trials, which could be costly to BBOT and otherwise harm BBOT's business, financial condition, results of operations and prospects.

BBOT's CMOs also may encounter problems hiring and retaining the experienced scientific, quality assurance, quality-control and manufacturing personnel needed to operate BBOT's manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in BBOT's CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make BBOT a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit access to additional attractive development programs. Problems in BBOT's manufacturing process could also restrict BBOT's ability to meet potential future market demand for any products that may be approved.

Certain of BBOT's product candidates are under development for the treatment of patient populations with significant comorbidities that may result in deaths or serious adverse or unacceptable side effects and require BBOT to abandon or limit its clinical development activities.

Patients in certain of BBOT's ongoing and planned clinical trials of product candidates in genetically driven cancers, as well as patients who may undergo treatment with other product candidates that BBOT may develop, may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or AEs, including death, that are unrelated to BBOT's product candidates. While these side effects or AEs may be unrelated to BBOT's product candidates, they may still affect the success of BBOT's clinical trials. The inclusion of critically ill patients in BBOT's clinical trials may also result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent BBOT from advancing its product candidates through clinical development, and from obtaining regulatory approval, and would impair BBOT's ability to commercialize its product candidates. Any inability to advance BBOT's product candidates through clinical development may harm BBOT's business, financial condition, results of operations and prospects.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

BBOT may be unable to obtain U.S. or foreign regulatory approval and, as a result, may be unable to commercialize its product candidates.

BBOT's product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the U.S. and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. BBOT cannot provide any assurance that any product candidate BBOT may develop will progress through required clinical testing and obtain the regulatory approvals necessary for BBOT to begin selling them.

BBOT does not have experience conducting, managing or completing large-scale or pivotal clinical trials nor managing the regulatory approval process with the FDA, EMA or any other regulatory authority. The time required to obtain approvals from the FDA, EMA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can change during drug development, which makes it difficult to predict with any certainty how such standards will be applied. BBOT may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, changes in applicable FDA, EMA or other regulatory policy during the period of drug development, clinical trials and regulatory review, or significant changes to FDA personnel during the regulatory review.

Applications for BBOT's product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of BBOT's clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that BBOT's product candidates are not safe and effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude BBOT obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which BBOT seeks approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with BBOT's interpretation of data from preclinical studies or clinical trials;
- BBOT may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that BBOT's product candidates' risk-benefit ratios for their proposed indications are acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which BBOT contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering BBOT's clinical data insufficient for approval.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on BBOT's ability to generate revenue from any particular product candidates BBOT is developing and for which BBOT is seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which BBOT may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of approving a New Drug Application ("NDA"), or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria, distribution through controlled distribution channels, and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

BBOT is also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

BBOT plans to develop certain of its current product candidates and potentially future product candidates in combination with other therapies, which would expose BBOT to additional risks.

BBOT plans to develop certain of its current product candidates in combination with one or more currently approved cancer therapies or therapies in development and may pursue a similar strategy for future product candidates. For example, the ongoing Phase 1 trial of BBO-8520 is evaluating BBO-8520 both as a monotherapy and in combination with pembrolizumab. On January 7, 2026, BBOT reported positive preliminary safety and antitumor data across its three orally bioavailable, differentiated small molecule RAS and PI3Ka programs. The data updates included BBO-8520, a direct inhibitor targeting both the ON and OFF states of KRASG12C; BBO-11818, a panKRAS inhibitor targeting mutant KRAS in both the ON and OFF states, and BBO-10203, a RAS-PI3Ka breaker with a novel mechanism of action designed to inhibit the physical interaction between RAS and PI3Ka. Even if any of BBOT's current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, BBOT would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of BBOT's product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which BBOT's product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for BBOT's product candidates or BBOT's own products being removed from the market or being less successful commercially.

BBOT may also evaluate its current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. For example, none of BBOT's product candidates have obtained approval for marketing from any regulatory authority, and BBOT plans to evaluate certain of its product candidates in combination with each other. BBOT will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies BBOT chooses to evaluate in combination with any of its current or future product candidates, BBOT may be unable to obtain approval of or successfully market any one or all of the current or future product candidates BBOT develops. Additionally, if the third-party providers of therapies or therapies in development used in combination with BBOT's current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of BBOT's current or future product candidates, or if the cost of combination therapies are prohibitive, BBOT's development and commercialization efforts would be impaired, which would have an adverse effect on BBOT's business, financial condition, results of operations and growth prospects.

BBOT has conducted and intends to continue conducting certain of its clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case BBOT's development plans may be delayed, which could materially harm BBOT's business.

BBOT has conducted and intends to continue conducting certain of its clinical trials globally. The acceptance by the FDA or other regulatory authorities of study data from clinical trials conducted outside of their respective jurisdictions 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 marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice (“GCP”) regulations; and (iii) 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, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-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 approval requirements.

In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction and FDA has discussed proposals to increase user fees for marketing applications containing certain foreign clinical data. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of BBOT's business plan, and which may result in BBOT's product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the U.S. also exposes BBOT to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in BBOT's trials resulting from geopolitical events, including civil or political unrest or military conflicts.

Obtaining and maintaining regulatory approval of BBOT's product candidates in one jurisdiction does not mean that BBOT will be successful in obtaining regulatory approval of its product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of BBOT's product candidates in one jurisdiction does not guarantee that BBOT will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the marketing of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must obtain pricing and/or reimbursement determinations before it can achieve broad commercial access. In some cases, the price that BBOT intends to charge for its products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for BBOT and could delay or prevent the introduction of BBOT's products in certain countries. If BBOT or any future collaborator fails to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, BBOT's target market will be reduced and BBOT's ability to realize the full market potential of BBOT's product candidates will be harmed.

Further, BBOT could face heightened risks with respect to obtaining marketing authorization in the United Kingdom (“U.K.”) as a result of the withdrawal of the U.K. from the EU, commonly referred to as Brexit. Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the U.K. is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into U.K. law through secondary legislation remain applicable in

the U.K., however, new legislation such as the EU Clinical Trials Regulation is not applicable in the U.K.. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, (“MHRA”), is the UK's standalone medicines and medical devices regulator. From January 1, 2025, under the Windsor Framework, the MHRA regulates medicines through UK-wide marketing authorizations, including for Northern Ireland. As a result, BBOT will be required to obtain separate authorizations in order to market its product candidates in the U.K. and EU.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review and reform process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission’s proposal for the revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A provisional political agreement on the reform was reached and a common position on the text was agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The revised legislation must still be formally adopted by the European Parliament and the Council of the European Union and the final text may be further refined before formal adoption and publication. The proposed revisions are not expected to become applicable before 2028. The revisions may however have a significant impact on the pharmaceutical industry and BBOT’s business in the long term.

Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force BBOT to restrict or delay efforts to seek regulatory approval in the U.K. for its product candidates, which could significantly and materially harm BBOT’s business. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for BBOT’s product candidates may be withdrawn. If BBOT fails to comply with the applicable regulatory requirements, BBOT’s target market will be reduced, BBOT’s ability to realize the full market potential of its product candidates will be harmed, and BBOT’s business, financial condition, results of operations and prospects could be harmed.

Even if BBOT’s product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that BBOT may receive for its product candidates will require the submission of reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product candidate, 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 and regulatory inspection. For example, the FDA may require a REMS in order to approve BBOT’s product candidates, which could entail requirements for a medication guide, physician training and 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, EMA or foreign regulatory authorities approve BBOT’s product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for BBOT’s product candidates 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 ongoing compliance with cGMP and GCP for any clinical trials that BBOT conducts post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. If BBOT or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or BBOT, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject BBOT to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on BBOT’s ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;

- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions; and
- requirements to conduct additional post-market clinical trials to assess the safety of the product.

The FDA, EMA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of BBOT's product candidates. BBOT cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If BBOT is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if BBOT is not able to maintain regulatory compliance, BBOT may lose any marketing approval that BBOT may have obtained and BBOT may not achieve or sustain profitability.

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

If any of BBOT's product candidates are approved and BBOT is found to have improperly promoted off-label uses of those products, BBOT may become subject to significant liability. The FDA, competent authorities of the EU Member States and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as BBOT's product candidates, if approved. In particular, a product may not be promoted in the U.S. for uses that are not approved by the FDA as reflected in the product's approved labeling, or in other jurisdictions for uses that differ from the labeling or uses approved by the applicable regulatory authorities. While physicians may prescribe products for off-label uses, the FDA, competent authorities of the EU Member States and other regulatory authorities actively enforce laws and regulations that prohibit the promotion of off-label uses by companies, including promotional communications made by companies' sales forces with respect to off-label uses that are not consistent with the approved labeling, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. If BBOT is found to have promoted such off-label uses, BBOT 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 FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If BBOT cannot successfully manage the promotion of its product candidates, if approved, BBOT could become subject to significant liability, which would materially adversely affect BBOT's business and financial condition.

If BBOT is required by the FDA, EMA or comparable regulatory authority to obtain clearance or approval of a companion diagnostic test in connection with approval of any of BBOT's product candidates or a group of therapeutic products, and BBOT does not obtain or BBOT faces delays in obtaining clearance or approval of a diagnostic test, BBOT may not be able to commercialize the product candidate and BBOT's ability to generate revenue may be materially impaired.

If BBOT is required by the FDA, EMA or a comparable regulatory authority to obtain clearance or approval of a companion diagnostic test in connection with approval of any of BBOT's product candidates, such companion diagnostic test would be used during BBOT's more advanced phase clinical trials as well as in connection with the commercialization of BBOT's product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, BBOT or its collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to ensuring the safe and effective use of a novel therapeutic product or new 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. In certain circumstances (for example, when a therapeutic product is intended to treat a serious or life-threatening condition for which no satisfactory available therapy exists or when the labeling of an approved product needs to be revised to address a serious safety issue), however, the FDA may approve a therapeutic product without the prior or contemporaneous marketing authorization of a companion diagnostic. In this case, approval of a companion diagnostic may be a post-marketing requirement or commitment.

Co-development of companion diagnostics and therapeutic products is critical to the advancement of precision medicine. Whether initiated at the outset of development or at a later point, co-development should generally be conducted in a way that will facilitate obtaining contemporaneous marketing authorizations for the therapeutic product and the associated companion diagnostic. If a companion diagnostic is required to identify patients who are most likely to benefit from receiving the product, to be at increased risk for serious adverse events as a result of treatment with a particular therapeutic product, or to monitor response to treatment with a

particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness, then the FDA has required marketing approval of all companion diagnostic tests essential for the safe and effective use of a therapeutic product for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any future diagnostics BBOT may develop, which BBOT expects will require separate regulatory clearance or approval prior to commercialization in those countries.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genomic alteration or mutation alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires clearance or approval of a companion diagnostic for any of BBOT's product candidates, whether before, concurrently with approval, or post-approval of the product candidate, BBOT and/or future collaborators, may encounter difficulties in developing and obtaining clearance or approval for these companion diagnostics. The process of obtaining or creating such diagnostic is time consuming and costly. The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to a product candidate to obtain pre-market approval ("PMA"), simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre-market review during which the sponsor must prepare and provide 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. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting.

Any delay or failure by BBOT or third-party collaborators to develop or obtain regulatory clearance or approval of a companion diagnostic could delay or prevent approval or continued marketing of BBOT's related product candidates. Changes in policy or approach to regulation by the FDA, EMA and other regulatory authorities may impact BBOT's development of a companion diagnostic for BBOT's product candidates and could result in delays in regulatory clearance or approval or a change in the determination for whether or not a companion diagnostic is still required for BBOT's product candidates. BBOT may be required to conduct additional studies to support a broader claim or more narrowed claim for a subset population. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include any of BBOT's future approved product candidates' covered indications, BBOT may no longer need to continue its companion diagnostic development plans or BBOT needs to alter those companion diagnostic development strategies, which could adversely impact BBOT's ability to generate revenue from the sale of BBOT's companion diagnostic test.

Additionally, BBOT may rely on third parties for the design, development and manufacture of companion diagnostic tests for BBOT's product candidates. If BBOT enters into such collaborative agreements, BBOT will be dependent on the sustained cooperation and effort of its future collaborators in developing and obtaining clearance or approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/ specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory clearance or approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. BBOT and its future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for, manufacturing and commercializing companion diagnostics similar to those BBOT faces with respect to its product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If BBOT is unable to successfully develop companion diagnostics for its product candidates, or experiences delays in doing so, the development of BBOT's product candidates may be adversely affected, BBOT's product candidates may not obtain marketing approval, and BBOT may not realize the full commercial potential of any of its product candidates that obtain marketing approval. As a result, BBOT's business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom BBOT contracts may decide to discontinue selling or manufacturing the companion diagnostic test that BBOT anticipates using in connection with development and commercialization of product candidates or BBOT's relationship with such diagnostic company may otherwise terminate. BBOT may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of BBOT's product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the co-development or commercialization of BBOT's companion diagnostic and therapeutic product candidates.

Where appropriate, BBOT plans to pursue approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If BBOT is unable to obtain such approval, BBOT may be required to conduct additional preclinical studies or clinical trials beyond those that BBOT contemplates, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if BBOT receives accelerated approval from the FDA, EMA or comparable regulatory authorities, if BBOT's confirmatory trials do not verify clinical benefit, or if BBOT does not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval.

Where appropriate, BBOT plans to pursue accelerated development strategies in areas of medical need. BBOT may seek an accelerated approval pathway for one or more of its product candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, 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. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing confirmatory clinical trials. These confirmatory trials must be completed with due diligence. Under FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory trial or trials be underway prior to approval or within a specified time period after the date accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Furthermore, under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory trial or submit timely reports to the agency on their progress. In the Consolidated Appropriations Act, Congress provided FDA with additional authorities to help prevent such delays, including that FDA may, when appropriate, require a confirmatory study or studies to be underway prior to approval. In addition, for products under consideration for accelerated approval, the FDA currently requires, unless otherwise requested by the agency, pre-approval of promotional materials prior to dissemination or publication, which could adversely impact the timing of the commercial launch of the product.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available but where the medicinal product meets certain other criteria, including that the medicine fulfils an unmet medical need and the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data are still required. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Prior to seeking accelerated approval, BBOT will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate BBOT's ability to seek and receive such accelerated approval. There can be no assurance that after BBOT's evaluation of the feedback and other factors BBOT will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, BBOT will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if BBOT initially decides to do so. Furthermore, if BBOT decides to submit an application for accelerated approval or any other form of expedited development, review or approval, 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, EMA or other comparable foreign regulatory authorities could also require BBOT to conduct further studies prior to considering BBOT's application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for BBOT's product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm BBOT's competitive position in the marketplace.

BBOT may seek certain designations for its product candidates, including Breakthrough Therapy, Fast Track and Priority Review in the U.S., and PRIME (priority medicines) in the EU, but BBOT might not receive such designations, and even if BBOT does, such designations may not lead to a faster development or regulatory review or approval process.

BBOT may seek certain designations for BBO-8520, BBO-10203 and BBO-11818 or future product candidates that could expedite review and approval by the FDA, such as Breakthrough Therapy or Fast Track designation for its product candidates, or priority review for its marketing applications for its candidates. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, early and frequent interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development. Sponsors may also have greater interactions with the FDA and the FDA may initiate review of sections of the NDA of a product candidate with Breakthrough Therapy designation before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of data submitted by the sponsor, that a product with Breakthrough Therapy designation may be effective.

BBOT may also seek Fast Track designation for one or more of its product candidates. The FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Like with Breakthrough Therapy designation, sponsors with Fast Track products may have greater FDA interactions and the FDA may initiate review of sections of a Fast Track product's NDA before the application is complete if it determines, after its preliminary data evaluation, that the product may be effective.

BBOT may also seek a priority review designation for one or more of its product candidates. If the FDA determines that a product candidate intended to treat a serious condition and, if approved, offers a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation shortens the goal for the FDA to review an application within six months, rather than the standard review period of ten months.

These designations require a sponsor to submit an application for review and approval by the FDA. Accordingly, even if BBOT believes that one of its product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if BBOT receives a designation, such as the Fast Track designation BBOT has received for BBO-8520 for the treatment of adult patients with previously treated, KRASG12C-mutated metastatic non-small cell lung cancer, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if BBOT's product candidates qualify for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the EU, BBOT may seek support under the EMA's PRIME scheme for some of its product candidates in the future. PRIME is a voluntary program launched by the EMA that is aimed at enhancing the scientific and regulatory support for the development and accelerated assessment of new product candidates that target an unmet medical need. PRIME aims to offer early and proactive support to sponsors to optimize the generation of robust data on the product's benefits and risks and enable accelerated regulatory assessment of new marketing authorization applications. To be eligible for PRIME, a product candidate must meet the eligibility criteria with respect to its potential to offer a major therapeutic advantage over existing treatments, or benefit patients who do not have any treatment options. The benefits of PRIME include the appointment of a rapporteur from CHMP to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. BBOT may apply for support under the PRIME scheme for some of its product candidates and it may not be granted. Even if BBOT receives PRIME designation for any of its product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

BBOT may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for its product candidates and, even if BBOT does, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the U.S. and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of researching and developing the drug will be recovered from sales in the U.S. BBOT's target indications may include diseases with large patient populations or may include orphan indications. There can be no assurances that BBOT will be able to obtain orphan designation for its current product candidates or candidates BBOT may discover and develop in the future.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product candidate is entitled to orphan drug exclusivity. Orphan drug exclusivity in the U.S. provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in the EU. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, it is determined that a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if BBOT obtains orphan drug designation for a product candidate, BBOT may not be able to obtain or maintain orphan drug exclusivity for that product candidate. BBOT may not be the first to obtain marketing approval of any product candidate for which BBOT has obtained orphan drug designation, if applicable, for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the U.S. may be limited if BBOT seeks approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if BBOT is unable to ensure that BBOT will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if BBOT obtains orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to Priority Review.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use" for which a product is approved. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court's order, the FDA would continue to apply its existing regulations tying orphan drug exclusivity to the uses or indications for which the orphan drug was approved. BBOT does not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect BBOT's business. Depending on what changes the FDA may make to its orphan drug regulations and policies, BBOT's business could be adversely impacted.

Current and future legislative and regulatory reform measures and cost containment initiatives may increase the difficulty and cost for BBOT to obtain adequate reimbursement for its product candidates and may adversely affect the prices we may set.

Current and future legislation and regulations may increase the difficulty and cost for us to commercialize our drugs, if approved, and affect the prices we may obtain, including changes in coverage and reimbursement policies in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably. If any such changes were to be imposed, they could adversely affect the operation of our business.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, including MFN proposals such as GLOBE, GUARD, and GENEROUS, bundled payment models, or other drug pricing reforms. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal 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 pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

In the U.S. and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of BBOT's product candidates, restrict or regulate post-approval activities and affect BBOT's ability to profitably sell any products for which BBOT obtains marketing approval. BBOT expects that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that BBOT may receive for any approved products. If reimbursement of BBOT's products is unavailable or limited in scope, BBOT's business could be materially harmed.

These laws and other healthcare reform measures may result in additional reductions in Medicare and other healthcare funding and otherwise affect the reimbursement BBOT may obtain for any of its product candidates for which BBOT may obtain regulatory approval or the frequency with which any such product is prescribed or used. BBOT expects that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in coverage and payments from private payors. Accordingly, the implementation of cost containment measures or other healthcare reforms may prevent BBOT from being able to generate revenue, attain profitability or commercialize its product candidates.

At the U.S. state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient 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 health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other health care programs. These measures could reduce the ultimate demand for BBOT's products, once approved, or put pressure on product pricing. In addition, in some countries, including member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take a significant amount of time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices, and in certain instances render commercialization in certain markets infeasible or disadvantageous from a financial perspective. In some countries, BBOT or its collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of BBOT's products to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or government authorities may lead to further pressure on the prices or reimbursement levels. If reimbursement of BBOT's products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the commercial launch of BBOT's products could be delayed, possibly for lengthy periods of time, BBOT or its collaborators may not launch at all in a particular country, BBOT may not be able to recoup its investment in one or more products, and there could be a material adverse effect on BBOT's business.

BBOT is or may become subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject BBOT to significant fines and penalties, which may have a material adverse effect on BBOT's business, financial condition or results of operations.

There are multiple privacy and data security laws that may impact BBOT's business activities in the U.S. and in other countries where BBOT conducts trials or where BBOT may do business in the future. These laws are evolving and may increase both BBOT's obligations and its regulatory risks in the future. In the health care industry generally, for example, under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HHS has issued regulations to protect the privacy and security of protected health information (PHI) used or disclosed by specific covered entities including certain healthcare providers, health plans and healthcare clearinghouses. BBOT is not currently classified as a covered entity or business associate under HIPAA. Thus, BBOT is not directly subject to HIPAA's requirements or penalties. The healthcare providers, including certain research institutions from which BBOT may obtain patient or subject health information, may be subject to privacy, security, and breach notification requirements under HIPAA. Additionally, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, BBOT could face criminal penalties if BBOT knowingly receives individually identifiable health information from a HIPAA covered entity, business associate or subcontractor that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, BBOT may maintain sensitive personally identifiable information, including health and genetic information, that BBOT receives throughout the clinical trial process, in the course of BBOT's research collaborations, and directly from individuals (or their healthcare

providers) who may enroll in patient assistance programs if BBOT chooses to implement such programs. As such, in addition to risks and obligations related to HIPAA, BBOT also may be subject to various state and federal laws regulating the use or disclosure of this information or requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Refer to “Other U.S. Regulatory Matters” for more information on these state and federal laws.

Data breach notification laws, consumer protection laws and genetic information laws may also apply directly to BBOT’s operations and/or those of BBOT’s collaborators and may impose restrictions on BBOT’s collection, use and dissemination of individuals’ health information. Individuals from whom BBOT or its collaborators may obtain health information, as well as the healthcare providers who may share this information with BBOT, may have statutory or contractual rights that limit the ability to use and disclose the information. BBOT may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that BBOT has violated individuals’ privacy rights or breached its contractual obligations, even if BBOT is not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm BBOT’s business.

Additionally, the collection, use, disclosure, transfer or other processing of personal data regarding individuals in the European Economic Area or EEA and the UK, including data concerning health, is subject to the EU General Data Protection Regulation, or EU GDPR, with respect to the EEA, and the UK General Data Protection Regulation, or UK GDPR, with respect to the UK, and collectively with the EU GDPR referred to as the “GDPR” in this report unless specified otherwise. The GDPR applies to companies established in the EEA/UK, as well as to any company established outside the EEA/UK, if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA/UK or the monitoring of their behavior in the EEA/Switzerland/UK. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, having legal bases and/or conditions for processing personal data, providing details to those individuals regarding the processing of their personal data, implementing safeguards to protect the security and confidentiality of personal data, having data processing agreements with third parties who process personal data, responding to individuals’ requests to exercise their rights in respect of their personal data, ensuring appropriate technical and organisational measures are in place and reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, ensuring certain accountability measures are in place and record keeping. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million under the UK GDPR) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action 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.

Brexit may adversely impact BBOT’s ability to obtain regulatory approvals for its product candidates in the EU, result in restrictions or imposition of taxes and duties for importing BBOT’s product candidates into the EU, and may require BBOT to incur additional expenses in order to develop, manufacture and commercialize BBOT’s product candidates in the EU.

Disruptions at the FDA, the SEC and other government agencies or comparable regulatory authorities caused by funding shortages or global health concerns, in addition to continued uncertainty regarding the U.S. presidential administration’s initiatives and staffing cuts and how these might impact the FDA, its implementation of laws, regulations, policies and guidance, and its personnel, could hinder government agencies’ ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which BBOT’s business operations rely, including timely reviews, which could negatively impact BBOT’s business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes that may otherwise affect the FDA’s or comparable foreign regulatory authorities’ ability to perform routine functions. In addition, government funding of the SEC and other government agencies or comparable foreign regulatory authorities on which BBOT’s operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including substantial leadership departures, personnel cuts, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would harm BBOT’s business. Changes and cuts in FDA staffing could result in delays in the FDA’s responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Similar consequences would also result in the event of another significant shutdown of the federal government. For example, over the last several years, the U.S. federal government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or 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 to timely review and process BBOT's regulatory submissions, which could materially adversely affect BBOT's business, financial condition, results of operations and prospects. Such changes could significantly impact the ability of the FDA to timely review and take action on BBOT's regulatory submissions, which could have a material adverse effect on BBOT's business, including INDs placed on clinical holds or delayed new drug approvals. Further, in BBOT's operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact BBOT's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue BBOT's operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, BBOT's business may be negatively impacted.

With the change in the U.S. presidential administration in 2025, there continues to be substantial uncertainty as to whether and how the administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over BBOT's product candidates and any products for which BBOT obtains approval. This uncertainty could present new challenges and/or opportunities as BBOT navigates development and approval of BBOT's product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on BBOT's ability to obtain guidance from the FDA on BBOT's product candidates in development and obtain the requisite regulatory approvals in the future. There remains general uncertainty regarding future activities. The current administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect BBOT or create a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to BBOT's operations. If BBOT becomes negatively impacted by future governmental orders, regulations, policies or guidance as a result of the new administration, there could be a material adverse effect on BBOT and its business.

If BBOT's product candidates are licensed for marketing and receive federal healthcare reimbursement, any relationships BBOT may have with healthcare providers will be subject to applicable healthcare fraud and abuse laws and regulations, which could expose BBOT to criminal and civil penalties and exclusion from participation in government healthcare programs.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which BBOT is able to obtain marketing approval. Any arrangements BBOT has with healthcare providers, third-party payors and customers will subject BBOT to broadly applicable fraud and abuse and other healthcare laws and regulations. The laws and regulations may constrain the business or financial arrangements and relationships through which BBOT conducts clinical research, markets, sells and distributes any products for which BBOT obtains marketing approval. These include the laws and regulations described in the section titled "Other U.S. Regulatory Matters" included elsewhere in this Form 10-K.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU Member States. BBOT's failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that any business arrangements BBOT has with third parties and BBOT's business generally will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that BBOT's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If BBOT's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to BBOT, BBOT may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, additional reporting requirements and oversight if BBOT becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of BBOT's operations.

Defending against any such actions in connection with these laws 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. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

BBOT's employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

BBOT is exposed to the risk that its employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage or may have engaged in fraud, misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA, EMA or comparable foreign regulatory authority regulations, provide accurate information to the FDA, EMA or comparable foreign regulatory authorities, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to BBOT. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to BBOT's reputation. BBOT has adopted a code of conduct and engages contractors that agree to undertake certain measures with respect to their employees, but it is not always possible to identify and deter misconduct by these parties, and the precautions BBOT takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting BBOT from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against BBOT, and BBOT is not successful in defending itself or asserting its rights, those actions could have a significant impact on BBOT's business, including the imposition of 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 BBOT's operations.

BBOT's business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which BBOT operates, as well as U.S. and certain foreign export controls, economic sanctions, import, and trade and national security laws and regulations. Compliance with these legal requirements could limit BBOT's ability to compete in foreign markets and subject BBOT to liability if BBOT violates them.

BBOT's business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which BBOT operates. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. BBOT's business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. The biotechnology and pharmaceutical industries have historically presented a heightened risk profile for FCPA enforcement. There is no certainty that all of BBOT's employees, agents or contractors, or those of BBOT's affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against BBOT, its officers or employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of BBOT's business. Any such violations could include prohibitions on BBOT's ability to offer its products in one or more countries and could materially damage BBOT's reputation, brand, international activities, ability to attract and retain employees and business, prospects, operating results and financial condition.

In addition, BBOT's business activities (including conduct of clinical trials) and products may be subject to U.S. and foreign export controls, economic sanctions, import and trade and national security laws and regulations. Governmental regulation of the import or export of BBOT's products, or BBOT's failure to obtain any required import or export authorization for its products, when applicable, could harm BBOT's international or domestic sales and adversely affect revenue. Compliance with applicable regulatory requirements regarding the conduct of clinical trials and export of BBOT's products may create delays in the introduction of BBOT's products in international markets or, in some cases, prevent the export of BBOT's products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit certain transactions and the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If BBOT fails to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges and reputational harm.

Moreover, any new export controls, import restrictions, economic sanctions, national security policy, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of BBOT's products by, or in BBOT's decreased ability to export its products to, existing or potential customers with international operations, in addition to adversely affecting cross-border operations and transactions. Any decreased use of BBOT's products or limitation on BBOT's ability to export or sell its products, or import materials for its products, would likely adversely affect BBOT's business. For instance, the U.S. Department of Justice's Bulk Data Rule, which went into effect April 8, 2025 prohibits certain covered data transactions (including for human 'omic and personal health data) and establishing data security requirements for restricted transactions involving China, Russia, and other countries of concern on national security grounds. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs. More recently, tariffs have been proposed on products from Canada, China, Mexico and potentially other countries, which could have the effect of disrupting, and increasing costs associated with, BBOT's supply chain of materials and other imports needed for its operations and business in the United States. The course of trade relations between the United States and other countries is difficult to predict, including how operations, transactions, products, and services may be impacted by the respective trade policies of the United States and other countries (including those in retaliation). If BBOT is unable to conduct transactions, obtain or use services, or export or sell products or services to third parties, including vendors, customers, and partners in other countries, BBOT's business, liquidity, financial condition, or operations would be materially and adversely affected.

If BBOT fails to comply with applicable environmental, health and safety laws and regulations, BBOT could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of BBOT's business.

BBOT is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, and the handling, use, storage, treatment and disposal of hazardous materials and wastes. BBOT's operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. BBOT's operations also produce hazardous waste products. BBOT generally contracts with third parties for the disposal of these materials and wastes. BBOT cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from BBOT's use of hazardous materials, BBOT could be held liable for any resulting damages, and any liability could exceed BBOT's resources. BBOT also could incur significant costs associated with civil or criminal fines and penalties.

Although BBOT maintains workers' compensation insurance to cover BBOT for costs and expenses BBOT may incur due to injuries to its employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. BBOT does not maintain insurance for environmental liability or toxic tort claims that may be asserted against BBOT in connection with BBOT's storage or disposal of biological, hazardous or radioactive materials. Compliance with applicable environmental, health and safety laws and regulations is expensive, and current or future environmental regulations may impair BBOT's business, prospects, financial condition or results of operations.

Risks Related to BBOT's Business

BBOT's success is highly dependent on BBOT's ability to attract, hire and retain highly skilled executive officers and employees, and BBOT may experience difficulties in managing the future growth of BBOT's organization.

BBOT currently has a small team focused on research and development of RAS-pathway targeted small molecules. To succeed, BBOT must recruit, hire, retain, manage and motivate qualified clinical, scientific, technical, financial and management personnel, and BBOT faces significant competition for experienced personnel. Personnel with the required skills and experience may be scarce or may not be available at all. In addition, competition for these skilled personnel is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage company such as BBOT. Even if BBOT is successful in identifying, attracting, hiring and retaining qualified employees, recent market changes, including labor shortages, and rising inflation have increased employee-related costs substantially, which may negatively affect BBOT's operating results.

BBOT is highly dependent on the principal members of its management and scientific and medical staff. If BBOT does not succeed in attracting and retaining qualified personnel in these positions, it could adversely affect BBOT's ability to execute its business plan and harm its operating results. In particular, the loss of one or more of BBOT's executive officers could be detrimental if BBOT cannot recruit suitable replacements in a timely manner.

Many of the other biotechnology companies that BBOT competes against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than BBOT does. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what BBOT has to offer. If BBOT is unable to continue to attract and retain high-quality personnel, the rate and success at which BBOT can discover, develop and commercialize its product candidates will be limited and the potential for successfully growing BBOT's business will be harmed.

Additionally, BBOT relies on its clinical advisory board and other scientific and clinical advisors and consultants to assist BBOT in formulating its research, development and clinical strategies. Most of these advisors and consultants are not BBOT's employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability. In addition, these advisors and consultants typically will not enter into non-compete agreements with BBOT. If a conflict of interest arises between their work for BBOT and their work for another entity, BBOT may lose their services. Furthermore, BBOT's advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with BBOT's. In particular, if BBOT is unable to maintain consulting or employment relationships with other scientific and clinical advisors, or if they provide services to BBOT's competitors, BBOT's development and commercialization efforts will be impaired and BBOT's business will be significantly harmed. For example, if BBOT is no longer able to access its network of physician-scientists, BBOT's ability to define and characterize patients' needs for future product candidate development may be negatively affected.

In order to successfully implement BBOT's development and commercialization plans and strategies, and as BBOT grows as a public company, BBOT expects to need significant additional managerial, operational, financial, sales, marketing and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining and motivating BBOT's current and additional employees;
- managing BBOT's internal development efforts effectively, including the preclinical, clinical, FDA, EMA and other comparable foreign regulatory authorities' review process for BBO-8520, BBO-10203 and BBO-11818 and BBOT's discovery programs, while complying with any contractual obligations to contractors and other third parties;
- managing increasing operational and managerial complexity; and
- improving BBOT's operational, financial and management controls, reporting systems and procedures.

BBOT currently relies, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of research, clinical development and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to BBOT on a timely basis when needed, or that BBOT can find qualified replacements. In addition, if BBOT is unable to effectively manage its outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, BBOT's preclinical studies and clinical trials may be extended, delayed or terminated, and BBOT may not be able to obtain marketing approval for any of its product candidates or otherwise advance its business. There can be no assurance that BBOT will be able to manage its existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If BBOT is not able to effectively expand its organization by hiring new employees and/or engaging additional third-party service providers, BBOT may not be able to successfully implement the tasks necessary to further develop and commercialize BBO-8520, BBO-10203 and BBO-11818 or any future product candidate from BBOT's discovery programs and, accordingly, may not achieve its research, development and commercialization goals.

BBOT's reliance on a limited number of employees who provide various administrative, research and development, and other services across BBOT's organization presents operational challenges that may adversely affect BBOT's business.

As of December 31, 2025, BBOT had 92 full-time employees, upon whom BBOT relies for various administrative, research and development, and other services. The small size of BBOT's team may limit BBOT's ability to devote adequate personnel, time, and resources to support BBOT's operations or research and development activities, and the management of financial, accounting, and reporting matters. If BBOT's team fails to provide adequate administrative, research and development, or other services across BBOT's organization, its business, financial condition, and results of operations could be harmed.

BBOT's internal computer systems, or those of any of BBOT's CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected security incidents, data breaches or other unauthorized or improper access to, use of, or destruction of BBOT's proprietary or confidential data, employee data, or personal data. Such security incidents, data breaches, and other unauthorized activities could result in additional costs, loss of revenue, significant liabilities, harm to BBOT's brand, material disruption of BBOT's operations, and potentially significant delays in BBOT's delivery to market.

Despite the implementation of security measures, BBOT's systems and the systems of BBOT's third-party CROs, other contractors (including sites performing BBOT's clinical trials) and consultants may be vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security incidents or data breaches. BBOT and the third parties upon which BBOT relies face a variety of evolving threats, including from inadvertent or intentional actions by BBOT's employees, contractors, consultants, business partners, and/or other third parties as well as from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering (including phishing attacks) and other means to affect service reliability and threaten the confidentiality, integrity and availability of information). Security incidents, data breaches and other adverse activity may compromise BBOT's system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, BBOT's data. These attacks and activity are also being facilitated or enhanced by evolving technologies, including artificial intelligence. The risk of a security incident, data breach or other disruption through cyber-attacks has generally increased as the number, intensity and sophistication of attempted attacks from around the world have increased. Attempts to disrupt or gain unauthorized access to BBOT's and BBOT's third-party vendors' information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by artificial intelligence. Also, many of BBOT's employees are working remotely. As a result, BBOT may have increased cybersecurity and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While BBOT implements IT controls to reduce the risk of a security incident or data breach, there is no guarantee that these measures will be adequate to safeguard all systems.

Like other companies in the industry, BBOT, and BBOT's third party vendors, have experienced threats and security incidents relating to their information technology systems and infrastructure. To the extent that any disruption, security incident, or data breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, BBOT's data (including confidential information and personal data) or applications, or for it to be believed or reported that any of these occurred, BBOT could incur liability and reputational damage. Further, in such an event, the development and commercialization of BBOT's product candidates could be delayed. There can be no assurance that BBOT's data protection efforts, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns, data breaches or other security incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, BBOT's data. Such events could have a material adverse effect upon BBOT's reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in BBOT's operations, it could result in a material disruption of BBOT's programs and the development of BBOT's product candidates could be delayed. In addition, the loss of clinical trial data for BBOT's product candidates could result in delays in BBOT's marketing approval efforts and significantly increase BBOT's costs to recover or reproduce the data, as well as claims or investigations from regulators or other third parties. Furthermore, significant disruptions of BBOT's internal information technology systems, security incidents or data breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal data), which could result in financial, legal, business, and reputational harm to BBOT. Such harm may include significant expenses, remediation costs, litigation, disputes, claims by third parties and regulatory actions or investigations. For example, any such event that leads to unauthorized access, use, or disclosure of personal data, including personal data regarding BBOT's clinical trial subjects or employees, could harm BBOT's reputation directly, compel BBOT to comply with federal and/or

state breach notification laws and foreign law equivalents, subject BBOT to financial exposure related to the investigation of the security incident or data breach (including cost of forensic examinations), subject BBOT to mandatory corrective action, and otherwise subject BBOT to liability under laws and regulations that protect the privacy and security of data, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse effect on BBOT's business.

Notifications, follow-up actions, claims and investigations related to a security incident or data breach could impact BBOT's reputation and cause BBOT to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in BBOT's regulatory approval efforts and significantly increase BBOT's costs to recover or reproduce the lost data. BBOT expects to incur significant costs in an effort to detect and prevent security incidents and data breaches, and BBOT may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident or data breach. BBOT also relies on third parties to manufacture its product candidates, and similar events relating to their computer systems could also have a material adverse effect on BBOT's business. To the extent that any disruption, data breach or security incident were to result in a loss, destruction or alteration of, or damage to, BBOT's data (including personal data), or inappropriate disclosure of confidential or proprietary information, BBOT could be exposed to litigation and governmental investigations. Moreover, the further development and commercialization of BBOT's product candidates could be delayed, and BBOT could be subject to significant fines or penalties for any noncompliance with state, federal and/or international privacy and security laws.

BBOT's contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in those contracts are sufficient to protect BBOT from liabilities, damages, or claims related to its privacy and data security obligations. BBOT's insurance policies may not be adequate to compensate BBOT for the potential losses arising from any such disruption in, or failure, security incident, or data breach of, BBOT's systems or third-party systems where information important to BBOT's business operations or commercial development is stored. In addition, such insurance may not be available to BBOT in the future on economically reasonable terms, or at all. Further, BBOT's insurance may not cover all claims made against BBOT and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

BBOT's use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact BBOT's business, including by posing cybersecurity and other risks to BBOT's confidential and/or proprietary information, including personal information, and as a result BBOT may be exposed to reputational harm and liability.

BBOT may use and integrate artificial intelligence into BBOT's business processes, and this innovation presents risks and challenges that could affect its adoption, and therefore BBOT's business. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect BBOT's business.

The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain BBOT products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The development of artificial intelligence models requires resources for design, development, testing and maintenance. If BBOT enables or uses models that contain actual or perceived biases, or otherwise draws controversy due to perceived or actual negative societal impact, BBOT may experience brand or reputational harm, competitive harm or legal liability.

In addition, the use of artificial intelligence technologies can give rise to intellectual property risks, including the disclosure or compromise of BBOT's confidential information or other proprietary intellectual property through the use of generative AI tools, or the ability to assert or defend ownership rights in intellectual property created with the use of generative artificial intelligence tools.

Further, BBOT expects to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act ("**AI Act**") originally entered into force on August 1, 2024, and is expected to undergo amendments as introduced in the EU's November 2025 Digital Omnibus on AI. As enacted, the AI Act imposes significant obligations on providers and deployers of high-risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on judicial interpretations and forthcoming legislative amendments, and non-compliance can lead to significant fines.

Likewise, in the U.S., the regulatory environment is complex and uncertain. President Trump's Executive Order "Ensuring a National Policy Framework for Artificial Intelligence," effective December 11, 2025, directed federal agency reviews of state AI laws and coordination between White House advisors and Congress to reach a legislative proposal for a uniform federal AI policy framework. At the same time, several states, including Colorado and California, passed laws that regulate various facets of AI, some of which have taken effect and will continue to take effect through 2026 and beyond. These laws address a wide range of AI-related topics, including consequential decisions, transparency, training data, among others, and it remains unclear which requirements, if any, will be superseded by the Executive Order. So far, these efforts have not been successful in curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. Various federal and state regulators have also issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If BBOT develops or uses AI systems that are governed by these laws or regulations, BBOT will need to meet higher standards of data quality, transparency, and human oversight, and BBOT would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. BBOT may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

BBOT's vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in BBOT's internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact BBOT and its vendors. The integration of AI systems, by BBOT or by its vendors, may increase cybersecurity risk. Any of these effects could damage BBOT's reputation, result in the loss of valuable property and information, cause BBOT to breach applicable laws and regulations, and adversely impact BBOT's business.

BBOT's operations are vulnerable to interruption by flood, fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond BBOT's control, which could harm BBOT's business.

BBOT's corporate headquarters are located in South San Francisco, California. BBOT has not undertaken a systematic analysis of the potential consequences to its business and financial results from a major flood, fire, earthquake, power loss, telecommunications failure, terrorist activity, pandemic or other disasters and BBOT does not have a recovery plan for such disasters. In addition, BBOT does not carry sufficient insurance to compensate for actual losses from interruption of BBOT's business that may occur, and any losses or damages incurred by BBOT could harm BBOT's operations and financial condition and increase costs and expenses.

BBOT has never commercialized a product candidate as a company before. If BBOT is unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market BBOT's product candidates, BBOT may not be able to successfully sell or market its product candidates that obtain regulatory approval.

BBOT has never commercialized a product and currently does not have and has never had a significant marketing or sales team. In order to commercialize any product candidates, if approved, BBOT must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which BBOT may have approval to sell or market its product candidates. BBOT may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize BBOT's product candidates will be expensive and time-consuming and will require significant attention of BBOT's executive officers to manage. Any failure or delay in the development of BBOT's internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of BBOT's product candidates that BBOT obtains approval to market if BBOT does not have arrangements in place with third parties to provide such services on its behalf. Alternatively, if BBOT chooses to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment BBOT's own sales force and distribution systems or in lieu of BBOT's own sales force and distribution systems, BBOT will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on BBOT's own. If BBOT is unable to enter into such arrangements when needed, on acceptable terms or at all, BBOT may not be able to successfully commercialize any of its product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If BBOT is unable to successfully commercialize its approved product candidates, either on its own or through collaborations with one or more third parties, BBOT's future product revenue will suffer, and BBOT may incur significant additional losses.

A variety of risks associated with marketing BBOT's product candidates internationally could materially adversely affect BBOT's business.

BBOT may seek regulatory approval of its product candidates outside of the U.S. and, accordingly, BBOT expects that it will be subject to additional risks related to operating in foreign countries if BBOT obtains the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the U.S.;
- foreign regulatory authorities may disagree with the design, implementation or results of BBOT's clinical trials or BBOT's interpretation of data from preclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering BBOT's clinical data insufficient for approval;
- the impact of pandemics or other public health emergencies, natural disasters and geopolitical events on BBOT's ability to produce its product candidates and conduct clinical trials in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing BBOT's contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical events, including war and terrorism, trade policies, treaties and tariffs.

These and other risks associated with international operations may materially adversely affect BBOT's ability to attain or maintain profitable operations.

Changes in tax law could adversely affect BBOT's business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U.S. Treasury Department and other applicable tax authorities. Changes to tax laws (which changes may have retroactive application) could adversely affect BBOT or holders of BBOT common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on BBOT's business, cash flow, financial condition or results of operations.

BBOT's ability to utilize its net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

BBOT's federal net operating loss ("NOL") carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Under the Tax Cut and Jobs Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, BBOT's federal NOLs may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of federal NOL carryforwards generated in tax years beginning after December 31, 2017 is limited to 80% of BBOT's current year taxable income. As of December 31, 2025, BBOT had available federal NOL carryforwards of approximately \$148.8 million and available state NOL carryforwards of approximately \$129.8 million.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points (by value) over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. BBOT may have experienced such ownership changes in the past, and BBOT may experience ownership changes in the future as a result of shifts in BBOT's stock ownership, some of which are outside BBOT's control. There is also a risk that due to regulatory changes, such as suspensions on the use of NOL carryforwards, or other unforeseen reasons, BBOT's existing NOL carryforwards could expire or otherwise be unavailable to offset future income tax liabilities. BBOT's ability to utilize BBOT's NOL carryforwards could have a material adverse effect on BBOT's cash flows and results of operations.

If BBOT engages in future acquisitions or strategic partnerships, this may increase BBOT's capital requirements, dilute BBOT's stockholders, cause BBOT to incur debt or assume contingent liabilities, and subject BBOT to other risks.

From time to time, BBOT evaluates various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of BBOT's equity securities;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of BBOT's management's attention from its existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in BBOT's ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products, product candidates and marketing approvals; and
- BBOT's inability to generate revenue from acquired technology and/or products sufficient to meet BBOT's objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if BBOT undertakes acquisitions or pursues partnerships in the future, BBOT may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Adverse events in the field of oncology or the biopharmaceutical industry could damage public perception of BBOT's current or future product candidates and negatively affect BBOT's business.

The commercial success of BBOT's products, if approved, will depend in part on public acceptance of the use of targeted cancer therapies. While a number of targeted cancer therapies have received regulatory approval and are being commercialized, BBOT's approach to targeting cancer cells carrying tumor causing mutations, including oncogenic RAS pathway mutations, is novel and unproven. Adverse events in clinical trials of BBOT's product candidates, or post-marketing activities, or in clinical trials of others developing similar products or that are related to approved targeted therapies, particularly those targeting oncogenic RAS pathway mutations, including sotorasib and adagrasib and the resulting publicity, as well as any other adverse events in the field of oncology that may occur in the future, could result in a decrease in demand for any product that BBOT may develop. If public perception is influenced by claims that the use of cancer therapies is unsafe, whether related to BBOT therapies or those of BBOT's competitors, BBOT's product candidates or products, if approved, may not be accepted by the general public or the medical community.

Future adverse events in oncology or the biopharmaceutical industry could also result in greater government regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of BBOT's products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for BBOT's current or future product candidates.

Risks Related to BBOT's Intellectual Property

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require BBOT to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by BBOT or declared by the U.S. Patent and Trademark Office ("USPTO") may be necessary to determine the priority of inventions with respect to one or more of BBOT's patents or patent applications or those of BBOT's future licensors. An unfavorable outcome may require BBOT to cease using the related technology or to attempt to license rights to it from the prevailing party. BBOT's business could be adversely affected if the prevailing party does not offer BBOT a license on commercially reasonable terms. BBOT's defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract BBOT's management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on BBOT's ability to raise the funds necessary to continue BBOT's clinical trials and development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help BBOT bring its product candidates to market.

If BBOT is unable to obtain, maintain and enforce patent protection for its technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, BBOT's competitors could develop and commercialize technology and products similar or identical to BBOT's, and BBOT's ability to successfully develop and commercialize its technology and product candidates may be adversely affected.

BBOT's success depends in large part on its ability to obtain and maintain protection of the intellectual property rights BBOT owns (either solely and jointly with others), or may in the future license from third parties (in particular, worldwide patents relating to any proprietary technology and product candidates BBOT develops). BBOT seeks to protect its proprietary position by filing patent applications in the U.S. and select other countries related to its technologies and product candidates that are important to its business and by in-licensing intellectual property related to such technologies and product candidates. BBOT does not yet have issued patents for all of its most advanced product candidates in all markets in which BBOT may commercialize them, but BBOT continues to actively pursue patent protection for its technology and product candidates in certain jurisdictions around the world. However, BBOT cannot guarantee that patents will be granted with respect to any of its pending patent applications or with respect to any patent applications BBOT may file in the future, nor can BBOT be sure that any patents that may be granted to BBOT in the future will be commercially useful in protecting BBOT's products, or the methods of use or manufacture of those products. If BBOT is unable to obtain and maintain meaningful patent protection in jurisdictions important to BBOT's business for its product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, or other proprietary technologies, BBOT's business, financial condition, results of operations and prospects could be adversely affected.

The patent prosecution process is expensive, time-consuming and complex, and BBOT may not be able to file, prosecute, maintain or defend all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that BBOT will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection. Moreover, in some circumstances involving technology that BBOT may license from third parties, BBOT may not have the sole right to control the preparation, filing and prosecution of patent applications or to maintain, enforce and defend the in-licensed patents. Therefore, any in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of BBOT's business.

The patent rights of pharmaceutical and biotechnology companies, like BBOT, generally are highly uncertain, involve complex legal and factual questions and have been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents, particularly those related to oncology, has emerged in the U.S. The relevant patent laws and their interpretation outside of the U.S. are also uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patent eligibility of certain inventions or discoveries relating to biotechnology. These decisions conclude, among other things, that abstract ideas, natural phenomena and laws of nature are not themselves patent eligible subject matter. Precisely what constitutes a law of nature or abstract idea is uncertain, and certain aspects of BBOT's technology could be considered ineligible for patenting under applicable law. In addition, the scope of patent protection outside the U.S. is uncertain, and laws of foreign countries may not protect BBOT's rights to the same extent as the laws of the U.S. or vice versa. For example, European patent law precludes the patentability of methods of treatment of the human body by surgery or therapy. BBOT cannot predict whether the patent applications BBOT is currently pursuing will issue as patents that protect BBOT's technology and product candidates, in whole or in part, in any particular jurisdiction or whether the claims of any issued patents will provide sufficient

protection from competitors. Changes in either the patent laws or interpretation of the patent laws in the U.S. or other countries may diminish the value of BBOT's patents and its ability to obtain, protect, maintain, defend and enforce BBOT's patent rights, narrow the scope of BBOT's patent protection and, more generally, affect the value or narrow the scope of BBOT's patent rights.

Further, third parties may have intellectual property rights relating to BBOT's product candidates of which BBOT is unaware. For example, third parties may have blocking patents that could be used to prevent BBOT from commercializing its product candidates and practicing its proprietary technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, neither BBOT nor its future licensors can know with certainty whether either BBOT or its future licensors were the first to make the inventions claimed in the patent applications BBOT owns or any patents or patent applications BBOT may own or in-license in the future, or that either BBOT or any of its future licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of BBOT's owned and future in-licensed patent rights are uncertain. For example, currently unpublished patent applications may later publish and limit BBOT's ability to obtain valid and enforceable patents.

Moreover, any issued patents BBOT does obtain or in-license may be challenged, invalidated, or circumvented. BBOT or its future licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO, or to a foreign patent office, or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging BBOT's patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, BBOT's patent rights, allow third parties to commercialize BBOT's technology or product candidates and compete directly with BBOT, without payment to BBOT, or result in BBOT's inability to manufacture or commercialize its products without infringing third-party patent rights. If the breadth or strength of protection provided by any patents BBOT obtains and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with BBOT to license, develop or commercialize current or future product candidates. Moreover, BBOT's competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents BBOT may obtain. For these reasons and others, BBOT may face competition with respect to its product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if BBOT's owned and any future in-licensed patent applications issue as patents, they may not issue in a form that will provide BBOT with any meaningful protection, prevent competitors from competing with BBOT, or otherwise provide BBOT with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and any patents BBOT does obtain may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit BBOT's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of BBOT's technology and product candidates. Such challenges also may result in substantial cost and require significant time from BBOT's management and employees, even if the eventual outcome is favorable to BBOT. Furthermore, BBOT's competitors may be able to circumvent any patents BBOT obtains or in-licenses in the future by developing similar or alternative technologies or products in a non-infringing manner. For these reasons, even if BBOT is successful in obtaining patents or in-licensing patents in the future, BBOT's patent portfolio may not provide BBOT with sufficient rights to exclude others from using or commercializing technology and products similar or identical to any of BBOT's technology and product candidates for any period of time.

Patent terms may not protect BBOT's competitive position for an adequate amount of time.

Issued patents can provide protection for varying periods of time, depending, for example, upon the type of patent, the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. However, patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The term of a patent outside of the U.S. varies in accordance with the laws of the foreign jurisdiction.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering BBOT's product candidates are obtained, once the patent life has expired, BBOT may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved for use or commercialized.

Changes to patent laws in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing BBOT's ability to protect its products.

Changes in either the patent laws or interpretation of patent laws in the U.S. or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of BBOT's owned and any future in-licensed patent applications and the maintenance, enforcement or defense of any issued patents BBOT may obtain or in-license.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals and biopharmaceuticals are particularly uncertain. For example, the USPTO regularly revises its policies and procedures for patent examination. Future political changes may impose new difficulties in obtaining patent protection. This combination of events has increased uncertainty with respect to the validity and enforceability of patents once obtained. Similarly, foreign courts and patent offices have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. BBOT cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect BBOT's patents or patent applications and BBOT's ability to obtain patent protection in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate patents or other intellectual property that BBOT owns or licenses. As a result, BBOT or its future licensors may need to file infringement, misappropriation or other intellectual property claims, which can be expensive and time-consuming. Any claims BBOT asserts against others could provoke them to assert counterclaims against BBOT alleging that BBOT infringes, misappropriates or otherwise violates their intellectual property rights. BBOT's ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe BBOT's intellectual property will depend in part on the extent to which BBOT obtains and enforces patent claims that cover BBOT's technology, inventions, and improvements.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. In a patent infringement proceeding, the perceived infringers could counterclaim that the patents BBOT or its licensors have asserted are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the U.S. 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, such as opposition proceedings in the European Patent Office. The outcomes of allegations of invalidity or unenforceability are unpredictable. With respect to validity, for example, even if BBOT is successful in obtaining patents or in-licensing patents, BBOT cannot be certain that there is no invalidating prior art of which the patent examiner and BBOT or its future licensing partners were unaware during prosecution.

An adverse result in any such proceeding could put one or more of the patents that BBOT may own or in-license in the future at risk of being invalidated or interpreted narrowly, and could put any of BBOT's present or future owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop a third party from using the technology at issue in a proceeding, for example, on the basis that BBOT owned or in-licensed patents do not cover that technology. Furthermore, if the breadth or strength of protection provided by BBOT's patent applications and any future patents is threatened, regardless of the outcome, it could dissuade companies from collaborating with BBOT to license, develop or commercialize current or future products, diagnostic tests or services.

In addition, interference or derivation proceedings provoked by third parties or brought by BBOT or declared by the USPTO may be necessary to determine the priority of inventions with respect to BBOT's patent applications or any future patents. An unfavorable outcome could require BBOT to cease using the related technology or to attempt to license rights to it from the prevailing party. BBOT's business could be adversely affected if the prevailing party does not offer BBOT a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and BBOT's competitors gain access to the same technology. BBOT's defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract BBOT's management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on BBOT's ability to raise funds as needed to continue BBOT's clinical trials and discovery programs, license necessary technology from third parties, or enter into development partnerships that would help BBOT bring its product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of BBOT's confidential information or trade secrets could be compromised by disclosure during litigation. Any of the foregoing could allow third parties to develop and commercialize competing technologies and products and have a material adverse impact on BBOT's business, financial condition, results of operations and prospects.

Third parties may allege that BBOT is infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on BBOT's business.

BBOT's commercial success depends upon its ability and the ability of its collaborators to develop, manufacture, market and sell BBOT's product candidates and use its proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. BBOT has been and may in the future be threatened with, and may in the future become party to, adversarial proceedings or litigation regarding intellectual property rights with respect to BBOT's technology and product candidates, including interference proceedings, post grant review, inter partes review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, including BBOT's competitors, exist in the fields in which BBOT is pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that BBOT's technologies or product candidates may be subject to claims that they infringe the patent rights of third parties. BBOT's competitors and others may have significantly larger and more mature patent portfolios than BBOT has. In addition, future litigation may be initiated by patent holding companies or other third parties who have no relevant product or service revenue and against whom BBOT's future patents, if any, may provide little or no deterrence or protection. Competitors may also assert that BBOT's product candidates infringe their intellectual property rights as part of a business strategy to impede BBOT's successful entry into those markets.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources and management attention to defend. The risks of being involved in such litigation and proceedings may increase if and as BBOT's product candidates near commercialization and as BBOT gains greater visibility as a public company. Third parties may assert infringement claims against BBOT based on existing patents or patents that may be granted in the future, regardless of merit. Even if BBOT believes third-party intellectual property claims are without merit, there is no assurance that a court would find in BBOT's favor on questions of infringement, validity, enforceability or priority. Because patent applications can take many years to issue, pending patent applications may result in issued patents that BBOT's product candidates infringe. For example, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the discovery, use or manufacture of BBOT's product candidates or technologies. BBOT may not be aware of all such intellectual property rights potentially relating to its technology and product candidates, or BBOT may incorrectly conclude that third-party intellectual property is invalid or that BBOT's activities and product candidates do not infringe the intellectual property rights of third parties. Thus, BBOT does not know with certainty that its technology and product candidates, or its development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property rights. Parties making claims against BBOT may also obtain injunctive or other equitable relief. For example, if any third-party patents were held to cover the manufacturing process of BBOT's product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block BBOT's ability to commercialize such product candidates. In the event of a successful claim of infringement against BBOT, BBOT may also have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, indemnify customers, collaborators or other third parties, seek new regulatory approvals, and redesign BBOT's infringing products, which may not be possible or practical. If BBOT is found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, BBOT may be required to obtain a license from such third party to continue developing, manufacturing and marketing its technology and product candidates. However, BBOT may not be able to obtain any required license on commercially reasonable terms or at all. Even if BBOT were able to obtain a license, it could be non-exclusive, thereby giving BBOT's competitors and other third parties access to the same technologies licensed to BBOT, and could require BBOT to make substantial licensing and royalty payments. Claims that BBOT has misappropriated the confidential information, trade secrets or other intellectual property rights of third parties could have a similar material adverse effect on BBOT's business, financial condition, results of operations and prospects.

If BBOT is unable to obtain licenses from third parties on commercially reasonable terms, BBOT's business could be adversely affected.

It may be necessary for BBOT to use the patented or proprietary technology of third parties to commercialize its products, in which case BBOT would be required to obtain a license from the third parties. The in-licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that BBOT may consider attractive or necessary. These established companies may have a competitive advantage over BBOT due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive BBOT to be a competitor may be unwilling to sell, assign or license rights to BBOT. In addition, BBOT expects that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to BBOT may increase in the future, which may mean fewer suitable opportunities for BBOT as well as higher acquisition or licensing costs. If BBOT is unable to license such technology, or if BBOT is forced to license such technology on unfavorable terms, such as substantial licensing or royalty payments, BBOT's business could be materially and adversely affected. If BBOT is unable to obtain a necessary license, the third parties owning such intellectual property rights could seek an injunction prohibiting BBOT's sales or BBOT may be unable to otherwise develop or commercialize the affected product

candidates, which could materially harm BBOT's business. Even if BBOT is able to obtain a license, it may be non-exclusive, thereby giving BBOT's competitors access to the same technologies licensed to BBOT.

If BBOT is unable to obtain rights to required third-party intellectual property rights, BBOT may be required to expend significant time and resources to redesign its technology, product candidates, or the methods for manufacturing them nor to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If BBOT is unable to do so, BBOT may be unable to develop or commercialize the affected technology and product candidates, which could harm BBOT's business, financial condition, results of operations, and prospects significantly.

If BBOT fails to comply with its obligations in any future intellectual property licenses with third parties that BBOT may enter into, or otherwise experiences disruptions to its business relationships with future licensors, BBOT could lose intellectual property rights that are important to BBOT's business.

BBOT may in the future enter into licensing and funding arrangements with third parties that may impose, among other things, diligence, development, and commercialization timelines, milestone payment, royalty, insurance and other obligations on BBOT. If BBOT fails to comply with those obligations, BBOT's counterparties may have the right to terminate these agreements, in which event BBOT might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements, or BBOT's counterparties may require BBOT to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of BBOT's rights under these agreements, or restrictions on BBOT's ability to freely assign or sublicense its rights under such agreements when it is in the interest of BBOT's business to do so, may result in BBOT having to negotiate new or reinstated agreements with less favorable terms, cause BBOT to lose its rights under these agreements, including its rights to important intellectual property or technology, which would have a material adverse effect on BBOT's business, financial condition, results of operations, and prospects, or impede, delay or prohibit the further development or commercialization of, one or more product candidates that rely on such agreements.

For example, disputes may arise regarding intellectual property that is or becomes subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other matters of contract interpretation;
- whether and the extent to which BBOT's technology and processes infringe the intellectual property rights of the licensor that are not subject to the licensing agreement;
- whether BBOT's licensee or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for BBOT's use of the intellectual property rights without their authorization;
- BBOT's involvement in the prosecution of licensed patents and BBOT's licensors' overall patent enforcement strategy;
- the amounts of royalties, milestones or other payments due under the license agreement;
- the sublicensing of patent and other rights under collaborative development relationships;
- BBOT's diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by BBOT's licensors and by BBOT and its partners; and
- the priority of application of patented technology.

If BBOT does not prevail in such disputes, BBOT may lose any or all of its rights under such license agreements.

In addition, intellectual property license agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what BBOT believes to be the scope of its rights to the relevant intellectual property or technology, or increase what BBOT believes to be its financial or other obligations under the relevant agreement, either of which could have a material adverse effect on BBOT's business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that BBOT may license prevent or impair BBOT's ability to maintain its licensing arrangements on commercially acceptable terms, BBOT may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on BBOT's business, financial condition, results of operations and prospects.

BBOT's future licensors may rely on third-party consultants or collaborators or on funds from third parties such that BBOT's licensors are not the sole and exclusive owners of the patents and patent applications BBOT may in-license. If other third parties have ownership rights to patents and/or patent applications BBOT may in-license, they may be able to license such patents to BBOT's competitors, and BBOT's competitors could market competing products and technology. In addition, BBOT may need the cooperation of any such co-owners of BBOT's in-licensed patents in order to enforce such patents against third parties, and BBOT may not receive such cooperation. This could have a material adverse effect on BBOT's competitive position, business, financial condition, results of operations and prospects.

Despite BBOT's efforts, BBOT's future licensors might conclude that BBOT has materially breached its license agreements and might therefore terminate the license agreements, thereby removing BBOT's ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors could seek regulatory approval for and market products and technologies identical to BBOT's. This could have a material adverse effect on BBOT's competitive position, business, financial condition, results of operations and prospects.

If BBOT is unable to adequately protect its proprietary technology or obtain and maintain patent protection for its technology and products or if the scope of the patent protection obtained is not sufficiently broad, BBOT's competitors could develop and commercialize technology and products similar or identical to BBOT's, and BBOT's ability to successfully commercialize its technology and products will be impaired.

BBOT's commercial success will depend in part on its ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for its product candidates, and its core technologies, including its novel target discovery technology and other know-how. BBOT seeks to protect its proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to its proprietary technology, inventions and improvements that are important to the development and implementation of its business. BBOT also relies on trade secrets, know-how and continuing technological innovation to develop and maintain its proprietary and intellectual property position.

BBOT may not be able to protect its intellectual property and proprietary rights throughout the world.

Third parties may attempt to develop and commercialize competitive products in foreign countries where BBOT does not have any patent protection and/or where legal recourse may be limited. This may have a significant commercial impact on BBOT's foreign business operations.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S., and even where such protection is nominally available, adequate judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, BBOT may not be able to prevent third parties from practicing BBOT's inventions in all countries outside the U.S., or from selling BBOT's inventions in such countries or importing products made using BBOT's inventions into the U.S. or other jurisdictions. Competitors may use BBOT's technologies in jurisdictions where BBOT has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where BBOT does obtain patent protection or future licenses but enforcement is not as strong as that in the U.S. These products may compete with BBOT's products, and BBOT's patents 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 pharmaceutical and biotechnology products, which could make it difficult for BBOT to stop the infringement of any patents BBOT does obtain or in-license or marketing of competing products in violation of BBOT's intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect, to the same extent as the U.S. or at all, inventions that constitute new methods of treatment.

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

BBOT works with third-party contractors located in China to develop certain of BBOT's intellectual property. On December 1, 2020, the Chinese government implemented a new Export Control Law which regulates the export of certain technologies outside of China. As currently implemented, BBOT does not believe the Export Control Law applies to its product candidates, and BBOT does not expect it to impact BBOT's business; however the Export Control Law could be amended in the future in a way that could adversely affect BBOT's business.

Many countries, including India, China and certain countries in Europe, 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 patents. If BBOT does obtain or in-license patents and BBOT or any of its licensors are forced to grant a license to third parties with respect to any patents relevant to BBOT's business, BBOT's competitive position may be impaired and BBOT's business, financial condition, results of operations, and prospects may be adversely affected.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to BBOT's product candidates or utilize similar technology but that are not covered by the claims of the patents that BBOT licenses or may own;
- BBOT or its licensors or collaborators, might not have been the first to apply for the issued patent or pending patent application that BBOT licenses or owns now or in the future;
- BBOT or its licensors or collaborators, might not have been the first to file patent applications covering certain of BBOT's or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of BBOT's technologies without infringing BBOT's owned or licensed intellectual property rights;
- it is possible that BBOT's present or future pending patent applications (whether owned or licensed) will not lead to issued patents;
- issued patents that BBOT holds rights to may be held invalid or unenforceable, including as a result of legal challenges by BBOT's competitors or other third parties;
- BBOT's competitors or other third parties might conduct research and development activities in countries where BBOT does not have patent rights and then use the information learned from such activities to develop competitive products for sale in BBOT's major commercial markets;
- BBOT may not develop additional proprietary technologies that are patentable;
- the patents of others may harm BBOT's business; and
- BBOT may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on BBOT's business, financial condition, results of operations and prospects.

BBOT may be subject to claims challenging the inventorship or ownership of its patents and other intellectual property.

BBOT or its future licensors may be subject to claims that current or former employees, collaborators, CROs, universities or other third parties have an interest in BBOT's owned or future in-licensed patents and patent applications, trade secrets or other intellectual property as an inventor, co-inventor, owner or co-owner. For example, BBOT or its future licensors may have inventorship or ownership disputes that arise from conflicting obligations of employees, consultants, CROs or others who are involved in developing BBOT's product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of any future owned or in-licensed patents, trade secrets or other intellectual property. If BBOT or its licensors fail in defending any such claims, BBOT may be required to pay monetary damages and BBOT may also lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to BBOT's product candidates. Even if BBOT is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Additionally, if residents of other countries can claim inventorship of BBOT's patents and patent applications, BBOT may be required to fulfill additional obligations. For example, some countries, including China, require a patent owner to provide remuneration to inventors who assign rights to inventions developed during course of their employment. Litigation may be necessary to defend against claims based on foreign inventors. Any of the foregoing could have a material adverse effect on BBOT's business, financial condition, results of operations and prospects.

BBOT may not identify relevant third-party patents or pending patent applications or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect BBOT's ability to develop and market its product candidates.

BBOT is developing certain product candidates in highly competitive areas and cannot guarantee that any patent searches or analyses that BBOT may conduct, including the identification of relevant patents or pending patent applications, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can BBOT be certain that it has identified each and every third-party patent and pending patent application in the U.S. and abroad that is or may be relevant to or necessary for the commercialization of BBOT's product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S. and elsewhere are published 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, patents or pending patent applications covering BBOT's product candidates could have been or may be filed in the future by third parties without BBOT's knowledge. Additionally, patents and pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover BBOT's product candidates or the manufacturing or use of BBOT's product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. BBOT's interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact BBOT's ability to market its product candidates. BBOT may incorrectly determine that BBOT's product candidates are not covered by a third-party patent or pending patent application or that BBOT is otherwise free to operate in relation to its product candidates. BBOT may also incorrectly predict whether a third party's pending application will issue with claims of relevant scope, or incorrectly determine the expiration date of any patent in the U.S. or abroad that BBOT considers relevant. Any failure by BBOT to identify and correctly interpret relevant patents or pending patent applications may negatively impact BBOT's ability to develop and market its product candidates.

If BBOT fails to identify or correctly interpret relevant patents, BBOT may be subject to infringement claims or otherwise be forced to obtain licenses to relevant patents or pending patent applications, which may require BBOT to pay significant royalties, license fees or other payments. BBOT cannot guarantee that it will be able to successfully settle or otherwise resolve any infringement claims. If BBOT fails in any such dispute, in addition to being forced to pay damages, potentially including in the form of future royalties, which may be significant, BBOT may be temporarily or permanently prohibited from commercializing any of its product candidates that are held to be infringing. BBOT might, if possible, also be forced to redesign product candidates so that BBOT no longer infringes the third-party intellectual property rights. Any of these events, even if BBOT were ultimately to prevail, could require BBOT to divert substantial financial and management resources that BBOT would otherwise be able to devote to its business and could adversely affect BBOT's business, financial condition, results of operations and prospects.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit BBOT's exclusive rights and limit BBOT's ability to contract with non-U.S. manufacturers.

Inventions contained within BBOT owned and in-licensed patents and patent applications have been, and BBOT may in the future develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any

governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require BBOT to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). If the U.S. government exercises its “march-in” rights in any future intellectual property rights that are generated through the use of U.S. government funding or grants, BBOT could be forced to license or sublicense intellectual property developed by BBOT or that BBOT may license on terms unfavorable to BBOT, and there can be no assurance that BBOT would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require BBOT to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the U.S. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit BBOT’s ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm BBOT’s competitive position, business, financial condition, results of operations and prospects.

BBOT may be subject to claims by third parties asserting that BBOT’s employees, consultants or contractors have wrongfully used or disclosed confidential information of such third parties, or that they have wrongfully used or disclosed alleged trade secrets of their current or former employers, or that BBOT has misappropriated their intellectual property, or that they own what BBOT regards as its own intellectual property.

Many of BBOT’s employees, physician-scientist partners, consultants and contractors are or were previously employed at or engaged by universities or other pharmaceutical or biotechnology companies, including BBOT’s competitors or potential competitors. Many of them executed proprietary rights, non-disclosure and/or non-competition agreements in connection with such previous employment or engagement. Although BBOT tries to ensure that the individuals who work for BBOT do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for BBOT, BBOT may be subject to claims that BBOT or they have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights, or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. BBOT may also be subject to claims that BBOT has improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. Any litigation or the threat of litigation may adversely affect BBOT’s ability to hire employees or engage consultants and contractors. A loss of key personnel or their work product could hamper or prevent BBOT from developing and commercializing products and product candidates, which could harm BBOT’s business.

In addition, while it is BBOT’s policy to require its employees, physician-scientist partners, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to BBOT, BBOT may be unsuccessful in obtaining such an agreement from each party who in fact develops intellectual property that BBOT regards as its own. BBOT’s intellectual property assignment agreements with them may not be self-executing or may be breached, and BBOT may be forced to bring claims against third parties, or defend claims they may bring against BBOT, to determine the ownership of what BBOT regards as its intellectual property. Additionally, assignment agreements and related agreements may be interpreted under the laws of a foreign country, which may be unpredictable. Such claims could have a material adverse effect on BBOT’s business, financial condition, results of operations, and prospects.

If BBOT fails in prosecuting or defending any such claims, BBOT may be required to pay monetary damages, and BBOT may also lose valuable intellectual property rights or personnel, which could have a material adverse effect on BBOT’s competitive position and prospects. Such intellectual property rights could be awarded to a third party, and BBOT could be required to obtain a license from such third party to commercialize BBOT’s technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if BBOT is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to BBOT’s management and employees.

If BBOT is unable to protect the confidentiality of its trade secrets and other proprietary information, BBOT’s business and competitive position would be adversely affected.

In addition to seeking patents for some of BBOT’s technology and product candidates, BBOT also relies on trade secrets and confidentiality agreements to protect its unpatented know-how, technology and other proprietary information to maintain BBOT’s competitive position. BBOT seeks to protect its 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 BBOT's employees, consultants, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. BBOT cannot guarantee that it has entered into such agreements with each party that may have or has had access to its trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose BBOT's proprietary information, including its trade secrets, unpublished patent applications or other confidential research, and BBOT may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and 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 U.S. are less willing or unwilling to protect trade secrets. If any of BBOT's trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, BBOT would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with BBOT.

Furthermore, BBOT expects that, over time, BBOT's trade secrets, know-how and proprietary information may be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel to and from academic and industry scientific positions. Consequently, without costly efforts to protect BBOT's proprietary technology, BBOT may be unable to prevent others from exploiting that technology, which could affect BBOT's ability to expand in domestic and international markets. If any of BBOT's trade secrets were to be disclosed to or independently developed by a competitor or other third party, BBOT's competitive position would be materially and adversely affected.

BBOT also seeks to preserve the integrity and confidentiality of its data and trade secrets by maintaining physical security of its premises and physical and electronic security of its information technology systems. These security measures may be breached or otherwise accessed in an unauthorized manner, and BBOT may not have adequate remedies for any breach.

If BBOT's trademarks and trade names are not adequately protected, BBOT may not be able to build name recognition in its markets of interest and BBOT's business may be adversely affected.

If BBOT's trademarks and trade names are not adequately protected, BBOT may not be able to build name recognition in its markets of interest and BBOT's business may be adversely affected. BBOT's trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce BBOT's trademark rights and prevent infringement, BBOT may be required to file trademark claims against third parties or initiate trademark opposition or cancellation proceedings. This can be time-consuming and expensive, particularly for a company of BBOT's size. In addition, in an infringement proceeding, a court may decide that a trademark of BBOT's is not valid or is unenforceable, or may determine another trademark is not infringing BBOT's trademarks. BBOT may not be able to protect its rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which BBOT needs to build name recognition among potential collaborators or customers in BBOT's markets of interest. At times, competitors may adopt trademarks or trade names similar to BBOT's, thereby impeding BBOT's ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name infringement claims brought by owners of other registered trademarks or trade names that incorporate variations of BBOT's trademarks or trade names. Over the long term, if BBOT is unable to successfully register its trademarks and trade names and establish name recognition based on its trademarks and trade names, BBOT may not be able to compete effectively and BBOT's business may be adversely affected. BBOT's efforts to enforce or protect its proprietary rights related to trademarks and trade names may be ineffective and could result in substantial costs and diversion of resources and could adversely impact BBOT's financial condition or results of operations.

Trademark applications BBOT may file in the future may not proceed to registration and/or may be opposed by third parties. Even if such applications proceed to registration, third parties may challenge BBOT's use of such trademarks or seek to invalidate BBOT's registration in the future. Other companies in BBOT's industry may be using trademarks that are similar to BBOT's and may in the future allege that the use of BBOT's trademarks in connection with BBOT's products infringes or otherwise violates their trademark rights. Trademark-granting authorities may decide to investigate BBOT's trademarks on their own initiative if they believe that there may be potential issues to be resolved. In addition, failure to maintain BBOT's trademark registrations, or to obtain new trademark registrations in the future, could limit BBOT's ability to protect and enforce its trademarks and impede BBOT's marketing efforts in the countries in which BBOT operates. Over the long term, if BBOT is unable to establish brand recognition based on its trademarks and trade names, then BBOT may not be able to compete effectively and BBOT's business may be adversely affected.

If BBOT does not obtain patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation, which if granted could extend the term of BBOT's marketing exclusivity for any product candidates BBOT may develop, BBOT's business may be materially and adversely affected.

In the U.S., the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, the patent term of only one patent applicable to an approved drug 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 provisions are available in Europe and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when BBOT's product candidates receive FDA approval, BBOT expects to apply for patent term extensions on any patents that issue covering those product candidates, there is no guarantee that the applicable authorities will agree with BBOT's assessment of whether such extensions should be granted and, even if granted, the length of such extensions. BBOT may not be granted patent term extension either in the U.S. or in any foreign country, even where BBOT obtains a patent that is eligible for patent term extension, if, for example, an applicable government authority determines that BBOT fails to exercise due diligence during the testing phase or regulatory review process, fails to apply within applicable deadlines, fails to apply prior to expiration of relevant patents or otherwise fails to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than BBOT requests. If BBOT obtains such an extension, it may be for a shorter period than BBOT had sought. If BBOT is unable to obtain any patent term extension or the term of any such extension is less than BBOT requests, BBOT's competitors may obtain approval of competing products following the expiration of BBOT's patent rights, and BBOT's business, financial condition, results of operations and prospects could be materially and adversely affected.

Furthermore, for any patents BBOT may in-license in the future, BBOT may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act. Thus, if a patent BBOT in-licenses in the future is eligible for patent term extension under the Hatch-Waxman Act, BBOT may not be able to control whether a petition to obtain a patent term extension is filed or whether the requested extension is obtained from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. BBOT may be unable to obtain or in-license patents covering BBOT's product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if BBOT or its future licensors submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of BBOT's product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to BBOT of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

Risks Related to BBOT's Dependence on Third Parties

BBOT relies on third parties to conduct its preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

BBOT utilizes and depends upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners (collectively, partners) to conduct and support its preclinical studies and clinical trials under agreements with BBOT and plans to continue to do so for future preclinical studies and clinical trials. These third parties have had and will continue to have a significant role in the conduct of BBOT's preclinical studies and clinical trials and the subsequent collection and analysis of data. For example, BBOT's partners contribute highly enabling technologies and services that include, among others: (i) clinical conduct support from CROs, (ii) support for BBOT's translational research efforts, (iii) crystallography to enable structure-based drug discovery, (iv) biochemical and cell-based assays to guide lead generation and optimization, and (v) patient-derived, cell and xenograft models to translate BBOT's findings to the clinical setting.

These third parties are not BBOT's employees, and except for remedies available to BBOT under BBOT's agreements with such third parties, BBOT has limited ability to control the amount or timing of resources that any such third party will devote to BBOT's preclinical studies or clinical trials. The third parties BBOT relies on for these services may also have relationships with other entities, some of which may be BBOT's competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on BBOT's behalf. Some of these third parties may terminate their engagements with BBOT at any time. BBOT also has to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and BBOT may not be

able to do so on favorable terms, which may result in delays to BBOT's development timelines and increased costs. If BBOT needs to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay BBOT's drug development activities, as well as materially impact BBOT's ability to meet its desired clinical development timelines.

BBOT's heavy reliance on these third parties for such drug development activities reduces BBOT's control over these activities. As a result, BBOT has less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if BBOT were relying entirely upon its own staff. Nevertheless, BBOT is responsible for ensuring that each of its studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and BBOT's reliance on third parties does not relieve BBOT of its regulatory responsibilities. For example, BBOT remains responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires BBOT to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires BBOT to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If BBOT or any of its CROs fail to comply with applicable GCP requirements, the clinical data generated in BBOT's clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require BBOT to perform additional clinical trials before approving BBOT's marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of BBOT's clinical trials substantially comply with GCP regulations. In addition, BBOT's clinical trials must be conducted with product produced under current cGMP regulations and require a large number of test patients. BBOT's failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require BBOT to repeat clinical trials, which would delay the regulatory approval process. Moreover, BBOT's business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct BBOT's clinical trials in accordance with regulatory requirements or BBOT's stated protocols, or if these third parties need to be replaced, BBOT will not be able to obtain, or may be delayed in obtaining, marketing approvals for its product candidates and will not be able to, or may be delayed in efforts to, successfully commercialize its product candidates. As a result, BBOT's financial results and the commercial prospects for its product candidates would be harmed, its costs could increase and its ability to generate revenue could be delayed.

BBOT's manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of BBOT's clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce BBOT's products either at a third party's facility or in any BBOT facility, BBOT will need to comply with the FDA's cGMP regulations and guidelines. BBOT may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. BBOT is subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of BBOT's precision medicines as a result of a failure of BBOT's facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair BBOT's ability to develop and commercialize its product candidates, including leading to significant delays in the availability of BBOT's product candidates for its clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for BBOT's product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for BBOT's product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage BBOT's reputation and business.

If BBOT's third-party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, BBOT may be liable for damages.

BBOT's research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by BBOT's third-party manufacturers. BBOT's manufacturers are subject to federal, state and local laws and regulations in the U.S. and local laws in other foreign jurisdictions governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although BBOT believes that its manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, BBOT cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, BBOT may incur liability or local, city, state,

federal or foreign authorities may curtail the use of these materials and interrupt BBOT's business operations. In the event of an accident, BBOT could be held liable for damages or penalized with fines, and the liability could exceed BBOT's resources. BBOT does not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair BBOT's research, development and production efforts, which could harm BBOT's business, prospects, financial condition or results of operations.

If BBOT decides to establish collaborations but is not able to establish those collaborations on commercially reasonable terms, BBOT may have to alter its development and commercialization plans.

BBOT's drug development programs and the potential commercialization of its product candidates may require additional cash to fund expenses. BBOT may seek to selectively form collaborations to expand its capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require BBOT to incur non-recurring and other charges, increase near and long-term expenditures, issue securities that dilute existing stockholders, or disrupt BBOT's management and business.

BBOT faces significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether BBOT reaches a definitive agreement for a collaboration depends, among other things, upon BBOT's assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical studies or clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to BBOT's ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with BBOT for its product candidate. Further, BBOT may not be successful in its efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if BBOT is successful in entering into a collaboration, the terms and conditions of that collaboration may restrict BBOT from entering into future agreements on certain terms with potential collaborators.

If and when BBOT seeks to enter into collaborations, BBOT may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If BBOT is unable to do so, BBOT may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its discovery programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own expense. If BBOT elects to increase its expenditures to fund development or commercialization activities on its own, BBOT may need to obtain additional capital, which may not be available to BBOT on acceptable terms or at all. If BBOT does not have sufficient funds, BBOT may not be able to further develop its product candidates or bring them to market and generate product revenue.

BBOT may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, BBOT may not be able to capitalize on the market potential of these product candidates.

If BBOT enters into any collaboration arrangements with any third parties for the development and commercialization of its product candidates, BBOT will likely have limited control over the amount and timing of resources that BBOT's collaborators dedicate to the development or commercialization of BBOT's product candidates. BBOT's ability to generate revenue from these arrangements will depend on its collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving BBOT's product candidates would pose numerous risks to BBOT, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of BBOT's product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with BBOT's product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than BBOT's;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of BBOT's product relative to other products;
- BBOT may grant exclusive rights to its collaborators that would prevent BBOT from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce BBOT's intellectual property rights or may use BBOT's proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate BBOT's proprietary information and intellectual property or expose BBOT to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and BBOT that result in the delay or termination of the research, development or commercialization of BBOT's product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide BBOT with timely and accurate information regarding development progress and activities under the collaboration or may limit BBOT's ability to share such information, which could adversely impact BBOT's ability to report progress to its investors and otherwise plan development of BBOT's product candidates;
- collaborators may own or co-own intellectual property covering BBOT's products or product candidates that result from BBOT collaborating with them, and in such cases, BBOT would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Some of the third parties upon whom BBOT currently relies for the supply of the active pharmaceutical ingredients, drug product and starting materials used in BBOT's product candidates are BBOT's sole source of supply, and the loss of any of these suppliers could delay BBOT's development efforts and harm BBOT's business.

The API, drug product and starting materials used in BBOT's product candidates are currently supplied to BBOT primarily from sole-source suppliers pursuant to quotations or proposals issued on an as-needed basis under master services agreements entered into between BBOT and the corresponding suppliers in the ordinary course, on terms customary in the industry for similarly-situated biopharmaceutical companies. BBOT's ability to successfully develop its product candidates, and to ultimately supply its commercial products in quantities sufficient to meet the market demand, depends in part on BBOT's ability to obtain the API, drug product and starting materials for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization.

In addition, BBOT does have arrangements in place for a redundant or second-source supply of API, drug product or starting materials in the event any of BBOT's current suppliers of such API, drug product or starting materials ceases its operations for any reason, although manufacturing with such second-source supply is currently expected to begin in 2026. Although BBOT believes such second-source supply or other alternative second-source supplies could be made available to it on the timelines necessary to operate in accordance with BBOT's current business plans, if any of BBOT's current or planned third-party suppliers or manufacturers ceases its operations for any reason or is unable or unwilling to supply API, drug product or starting material in sufficient quantities, on the timelines necessary, or at acceptable prices, to meet BBOT's needs, it could impede, delay, limit or prevent BBOT's development efforts, which could harm BBOT's business, results of operations, financial condition and prospects.

For all of BBOT's product candidates, BBOT intends to identify and qualify additional manufacturers to provide such API, drug product and starting materials prior to or after submission of an NDA to the FDA and/or an MAA to the EMA. BBOT is not certain, however, that its single-source suppliers will be able to meet BBOT's demand for their products, either because of the nature of

BBOT's agreements with those suppliers, BBOT's limited experience with those suppliers or BBOT's relative importance as a customer to those suppliers. It may be difficult for BBOT to assess their ability to timely meet BBOT's demand in the future based on past performance. While BBOT's suppliers have generally met BBOT's demand for their products on a timely basis in the past, they may subordinate BBOT's needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and starting materials used in BBOT's product candidates, if required, may not be accomplished within the timeframes required to avoid delays in BBOT's development and commercialization efforts. When BBOT finds a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in delays. While BBOT seeks to maintain adequate inventory of the API, drug product and starting materials used in its product candidates, any interruption or delay in the supply of components or materials, or BBOT's inability to obtain such API, drug product or starting materials from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent BBOT's development efforts, which could harm BBOT's business, results of operations, financial condition and prospects.

Risks Related to Operating as a Public Company

There may not be an active trading market for our common stock, which may make it difficult to sell shares of our common stock.

An active trading market for our common stock may not develop or be sustained. If an active trading market for our common stock does not develop or is not sustained, you may not be able to sell your shares at an attractive price or at all. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of common stock (or securities convertible into or exercisable for shares of our common stock) in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using shares of our common stock (or securities convertible into or exercisable for shares of our common stock) as consideration.

The market price of our common stock may be volatile, and investors could lose all or part of their investment.

The trading price of our common stock is likely to be, highly volatile and subject to wide fluctuations in response to various factors, many of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of its actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include, without limitation:

- the timing and results of INDs, preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or product candidates or our competitors' products or product candidates;
- actual or anticipated changes in our growth rate relative to its competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning our patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;

- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our common stock;
- announcement or expectation of additional financing efforts;
- sales of shares of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any public health emergencies, natural disasters, or geopolitical events, including civil or political unrest or military conflicts; and
- general economic, political, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding BBOT, BBOT’s business or BBOT’s market, the Company’s stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that securities or industry analysts publish about BBOT, BBOT’s business or BBOT’s market. If any of the analysts who cover BBOT issue adverse or misleading research or reports regarding BBOT, BBOT business model, intellectual property, stock performance or market, or if BBOT’s operating results fail to meet the expectations of analysts, BBOT’s stock price would likely decline. If one or more of these analysts cease coverage of BBOT or fail to publish reports on BBOT regularly, BBOT could lose visibility in the financial markets, which in turn could cause our common stock price or trading volume to decline.

BBOT’s operating results may fluctuate significantly, which makes BBOT’s future operating results difficult to predict and could cause BBOT’s operating results to fall below expectations or guidance.

BBOT’s quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for BBOT to predict its future operating results. From time to time, BBOT may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of BBOT’s revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in BBOT’s operating results from one period to the next.

In addition, BBOT measures compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, as determined by the BBOT Board, and recognizes the cost as an expense over the employee’s requisite service period. As the variables that BBOT uses as a basis for valuing these awards change over time, BBOT’s underlying stock price and stock price volatility, the magnitude of the expense that BBOT must recognize may vary significantly.

Furthermore, BBOT’s operating results may fluctuate due to a variety of other factors, many of which are outside of BBOT’s control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to BBOT’s programs, which will change from time to time;
- BBOT’s ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing BBOT’s current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of BBOT’s agreements with manufacturers;
- expenditures that BBOT will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of preclinical studies and clinical trials for BBO-8520, BBO-10203 and BBO-11818 and any product candidates from BBOT’s discovery programs, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;

- competition from existing and potential future products that compete with BBO-8520, BBO-10203 and BBO-11818 or any of BBOT's discovery programs, and changes in the competitive landscape of BBOT's industry, including consolidation among BBOT's competitors or partners;
- any delays in regulatory review or approval of BBO-8520, BBO-10203 and BBO-11818 or product candidates from any of BBOT's discovery programs;
- the level of demand for any of BBOT's product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to BBOT's product candidates, if approved, and existing and potential future products that compete with BBO-8520, BBO-10203 and BBO-11818 or any of BBOT's discovery programs;
- BBOT's ability to commercialize BBO-8520, BBO-10203 and BBO-11818 or product candidates from any of BBOT's discovery programs, if approved, inside and outside of the U.S., either independently or working with third parties;
- BBOT's ability to establish and maintain collaborations, licensing or other arrangements;
- BBOT's ability to adequately support future growth;
- potential unforeseen business disruptions that increase BBOT's costs or expenses;
- future accounting pronouncements or changes in BBOT's accounting policies; and
- the changing, volatile and instable global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in BBOT's quarterly and annual operating results. As a result, comparing BBOT's operating results on a period-to-period basis may not be meaningful. Investors should not rely on BBOT's past results as an indication of future performance. This variability and unpredictability could also result in BBOT failing to meet the expectations of industry or financial analysts or investors for any period. If BBOT's revenue or operating results fall below the expectations of analysts or investors or below any forecasts BBOT may provide to the market, or if the forecasts BBOT provides to the market are below the expectations of analysts or investors, the price of BBOT's common stock could decline substantially. Such a stock price decline could occur even when BBOT has met any previously publicly stated guidance BBOT may provide.

Several of our principal stockholders own a significant percentage of our Common Stock and can exert significant control over matters subject to stockholder approval.

Holders of 5% or more of BBOT's capital stock and their respective affiliates collectively beneficially own in excess of 44% of our outstanding Common Stock. In addition, several of BBOT's directors, including Frank McCormick, Michelle Doig, Neil Kumar, Raymond Kelleher and Bihua Chen are affiliated with certain of our large stockholders. BBOT's principal stockholders, acting together or on their own, could exert significant control over matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of the Company's Charter and Bylaws or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for the Company's common stock that investors may feel are in their best interest as one of the Company's stockholders. The interests of this group of stockholders may not always coincide with each investor's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our Common Stock.

Future sales, or the perception of future sales, by the Company or its stockholders in the public market could cause the market price for the Company's securities to decline.

The sale of the Company's securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of the Company's securities. These sales, or the possibility that these sales may occur, also might make it more difficult for the Company to sell equity securities in the future at a time and at a price that BBOT deems appropriate.

Shares of Common Stock reserved for future issuance under its equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. The compensation committee of the Company's board of directors may determine the exact number of shares to be reserved for future issuance under the Company's equity incentive plans at its discretion. the Company expects to file registration statements on Form S-8 under the Securities Act to

register shares of common stock or securities convertible into or exchangeable for shares of common stock issued pursuant to its equity incentive plans. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market.

In the future, BBOT may also issue its securities in connection with investments or acquisitions. The number of shares of BBOT's common stock issued in connection with an investment or acquisition could constitute a material portion of BBOT's then-outstanding shares of common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to BBOT's stockholders.

Raising additional capital may cause dilution to the Company's existing stockholders, restrict BBOT's operations or require BBOT to relinquish rights to its technologies or product candidates.

Until such time, if ever, as BBOT can generate substantial product revenues, BBOT expects to finance its cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that BBOT raises additional capital through the sale of equity or convertible debt securities, BBOT's stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of BBOT's stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on BBOT's ability to incur additional debt, limitations on BBOT's ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact BBOT's ability to conduct its business. If BBOT raises additional funds through future strategic partnerships and alliances and licensing arrangements with third parties, BBOT may have to relinquish valuable rights to its technologies or product candidates or grant licenses on terms unfavorable to BBOT.

BBOT has increased costs as a result of operating as a public company, and BBOT's management devotes substantial time to related compliance initiatives.

As a public company, BBOT incurs significant legal, accounting and other expenses. BBOT is subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social and governance focused disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. BBOT will have to hire additional accounting, finance, and other personnel in connection with becoming a public company. BBOT's management and other personnel devote a substantial amount of time to these compliance initiatives and BBOT cannot accurately predict or estimate the amount or timing of additional costs BBOT may incur to respond to these requirements.

In addition, as a public company BBOT is required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, BBOT is required to maintain effective disclosure and financial controls and to make a formal assessment of the effectiveness of BBOT's internal control over financial reporting.

BBOT has in the past identified a material weakness in its internal controls over financial reporting. If BBOT identifies additional material weaknesses in the future or otherwise fails to maintain effective internal controls over financial reporting and disclosure controls and procedures, the accuracy and timeliness of its financial and operating reporting may be adversely affected, and confidence in its operations and disclosures may be lost.

As a public company, BBOT is required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act (Section 404) requires that BBOT evaluate and determine the effectiveness of its internal control over financial reporting. This assessment needs to include the disclosure of any material weaknesses in such internal control. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of its annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the preparation and audit of BBOT's financial statements for the years ended December 31, 2024 and 2023, BBOT's management identified a material weakness in BBOT's internal control over financial reporting. The previous material weakness was as follows:

- BBOT did not have sufficient full-time accounting personnel, (i) to enable appropriate reviews over the financial close and reporting process, (ii) to allow for an appropriate segregation of duties, (iii) to perform an effective risk assessment process, and (iv) with the requisite experience and technical accounting knowledge to identify, review and resolve complex accounting issues under U.S. GAAP.

As a private company at the time, BBOT was not required to perform an evaluation of internal control over financial reporting as of December 31, 2024 and 2023 in accordance with the provisions of the Sarbanes-Oxley Act of 2002. Had such an evaluation been performed, additional control deficiencies may have been identified by BBOT's management, and those control deficiencies could have also represented one or more material weaknesses.

During 2025, BBOT identified and implemented remedial measures to address the control deficiencies that led to the material weakness and determined our internal controls over financial reporting were effective as of December 31, 2025.

Although BBOT has remediated this material weakness and has not identified any material weaknesses in connection with the finalization of its consolidated financial statements as of and for the year ended December 31, 2025, BBOT cannot provide assurance that it will not identify other material weaknesses in the future.

If BBOT is not able to maintain effective internal control over financial reporting and disclosure controls and procedures, or if material weaknesses are discovered in future periods, it may be unable to accurately and timely report its financial position, results of operations, cash flows or key operating metrics, which could result in late filings of annual or quarterly reports under the Exchange Act, restatements of financial statements or other corrective disclosures, an inability to access equity or debt capital or commercial lending markets, or other material adverse effects on its business, reputation, results of operations, financial condition or liquidity. BBOT's investors could lose confidence in BBOT's reported financial information, the market price of BBOT's common stock could decline, and BBOT could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Incorrect estimates, including those related to the size of BBOT's addressable patient populations and markets, or assumptions by management in connection with the preparation of BBOT's consolidated financial statements could adversely affect BBOT's reported assets, liabilities or expenses.

BBOT's projections of both the number of people who have the diseases its product candidates are targeting, as well as the subset of people with such disease who have the potential to benefit from treatment with any of BBOT's product candidates, are based on estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the diagnosis criteria included in the final label, and, if BBOT's product candidates are approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with RAS-dependent cancers may turn out to be lower than expected, patients may not be otherwise amenable to treatment with BBOT's products, or new patients may become increasingly difficult to identify or gain access to. BBOT may not be successful in its efforts to identify additional product candidates. Assumptions made by management in connection with the preparation of BBOT's consolidated financial statements could adversely affect BBOT's reported assets, liabilities or expenses if BBOT's estimates of the addressable patient populations and markets are incorrect.

BBOT's disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

BBOT is subject to the periodic reporting requirements of the Exchange Act. BBOT has designed its disclosure controls and procedures to reasonably assure that information BBOT must disclose in reports BBOT files or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. BBOT believes that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the fact that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in BBOT's control system, misstatements due to error or fraud may occur and not be detected.

BBOT does not intend to pay dividends on BBOT common stock so any returns will be limited to the value of BBOT's stock.

BBOT has never declared or paid any cash dividends on its common stock. BBOT currently anticipates that BBOT will retain future earnings for the development, operation and expansion of BBOT's business and does not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

General Risk Factors

Anti-takeover provisions in BBOT's Charter and Bylaws and Delaware law might discourage, delay or prevent a change in control of BBOT or changes in BBOT's management and, therefore, depress the market price of Common Stock.

BBOT's Charter and Bylaws contain provisions that could depress the market price of BBOT's Common Stock by acting to discourage, delay or prevent a change in control of the Company or changes in the Company's management that the stockholders of the Company may deem advantageous. These provisions, among other things, include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder actions through written consent, which requires that all stockholder actions be taken at a meeting of the Company stockholders;
- a requirement that special meetings of stockholders be called only by the Company's board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to the Company's board of directors;
- a requirement that no member of the Company's board of directors may be removed from office by The Company's stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of the Company's voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of the Company's voting stock to amend any bylaws by stockholder action; and
- the authority of the BBOT Board to issue preferred stock on terms determined by the Company's board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of the Company's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of the Charter, Bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for the Company's stockholders to receive a premium for their shares of the Company capital stock and could also affect the price that some investors are willing to pay for Common Stock.

BBOT's Bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by the Company's stockholders, which could limit the Company's stockholders' ability to obtain a favorable judicial forum for disputes with the Company or the Company's directors, officers, or employees.

BBOT's Bylaws provide that, unless the Company consents in writing to an alternative forum, the Court of Chancery of the State of Delaware are the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on the Company's behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of the Company's current or former directors, officers, and employees to the Company or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, the Charter or the Bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the "**Delaware Forum Provision**"). The Delaware Forum Provision does not apply to any causes of action arising under the Securities Act or the Exchange Act. The Bylaws further provide that, unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the "**Federal Forum Provision**"). In addition, the Bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived the Company's compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in the Bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in the Bylaws may limit the Company's stockholders' ability to bring a claim in a forum that they find favorable for disputes with the Company or the Company's directors, officers or employees, which may discourage such lawsuits against the Company and its directors, officers and employees even

though an action, if successful, might benefit the Company's stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce the Company's Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, the Company may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U.S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to the Company than the Company's stockholders.

We are currently in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by a new U.S. presidential administration and accompanying regulatory activities and economic policies and events related thereto, ongoing military conflicts and geopolitical instability and inflation and interest rates.

U.S. and global markets have recently been experiencing volatility and disruption caused by economic uncertainty, including as a result international trade disputes and ongoing military disputes and related geopolitical uncertainty. International trade disputes, including threatened or implemented tariffs by the Trump administration and threatened or implemented tariffs by foreign countries in retaliation, could adversely impact BBOT's business. Trade disputes could also adversely impact supply chains which could now or in the future increase costs for BBOT or delay delivery of key inventories and supplies. Trade disputes can also be highly disruptive to global financial markets. The length and impact of the ongoing trade disputes and military conflicts are highly unpredictable. BBOT is continuing to monitor the trade disputes, inflation, interest rates and the military conflicts and the impacts to global capital markets to BBOT's business.

We face risks associated with tariffs and other trade restrictions, which may have a material adverse impact on our results of operations and financial condition.

We face risks related to tariffs and other trade protection measures—including those that have been or may be imposed by the United States or other countries—as well as import or export licensing requirements, trade embargoes, sanctions (including those administered by the U.S. Department of the Treasury's Office of Foreign Assets Control), and other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade). These risks include protectionist or retaliatory measures that may limit or complicate the sourcing of raw materials, equipment, and other components critical to our research and development activities.

The United States has imposed significant tariffs on a range of imported goods, including a baseline tariff of 10% and higher rates targeting specific countries. In response, several countries have enacted retaliatory measures, and the situation remains unpredictable. While pharmaceutical end-products are currently excluded from certain tariffs, current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients (APIs), raw materials, laboratory equipment and research materials and components. In addition, the U.S. Department of Commerce is conducting a Section 232 investigation to assess the national security implications of pharmaceutical and API imports. The outcome of this investigation could result in additional trade restrictions, including tariffs, consistent with ongoing efforts to reshore pharmaceutical manufacturing. Further, the United States and the European Union have announced the framework of a trade agreement that could impose a 15% tariff on most imports from the EU, including pharmaceutical products and inputs. However, the details of this trade agreement remain uncertain, including whether and to what extent such agreement may be impacted by the results of the Section 232 investigation.

We may face increased costs and operational disruptions if existing or future tariffs are applied to materials or components used in the development and manufacture of our product candidates. These risks also extend to indirect effects, such as retaliatory tariffs imposed by other countries or additional non-tariff trade barriers. As a result, our research and development activities, manufacturing timelines, and overall financial condition could be materially adversely affected.

BBOT is an emerging growth company and a smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting companies, this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

BBOT is an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act. Accordingly, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor internal controls attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation

in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As a result, our shareholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years from the date of Helix's initial public offering in February 2024, although circumstances could cause us to lose that status earlier, including if the market value of our Common Stock held by non-affiliates exceeds \$700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, Helix was a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of financial statements.

Following the Closing of the Business Combination, the Company has determined it remains a smaller reporting company. The Company will be able to continue to take advantage of the smaller reporting company scaled disclosures since its voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured as of a date within four business days after the consummation of the Business Combination, or BBOT's annual revenue is less than \$100.0 million as of the most recently completed fiscal year reported in the Current Report on Form 8-K filed with Form 10 Information (as defined in Rule 144(i)(3) of the Securities Act).

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Our cybersecurity risk management program includes a number of components, such as information security program assessments and ongoing monitoring of critical risks from cybersecurity threats using automated tools. We periodically engage third parties to conduct risk assessments and testing of our systems, including penetration testing and other vulnerability analyses. Additionally, we have implemented an employee education program that is designed to raise awareness of cybersecurity threats, including risks posed by phishing attempts. We have implemented a process for this training to be included during the employee onboarding process and periodically thereafter. Our approach is designed to protect the confidentiality, integrity, and availability of our critical information systems and data, including intellectual property and confidential information.

As part of our cybersecurity risk management program, we maintain processes to assess and review the cybersecurity practices of third-party vendors and service providers. Our process includes a security assessment informed by vendor questionnaires and contractual security requirements related to data privacy for certain vendors.

We, like other companies in our industry, face a number of cybersecurity risks in connection with our business. Although our business strategy, results of operations, and financial condition have not, to date, been materially affected by risks from cybersecurity threats, including as a result of previously identified cybersecurity incidents, we have, from time to time, experienced threats to and security incidents related to our data and systems, including phishing attacks and attacks to the security of the systems of our third-party vendors and service providers.

We conduct periodic risk assessments to identify potential internal and external cybersecurity threats. These assessments evaluate the likelihood of occurrence and potential impact of such threats, as well as the adequacy of our existing policies, procedures, systems, and controls. The Board oversees our cybersecurity risk management process, and the Audit Committee has the authority and power to

provide specific oversight of cybersecurity matters. Our IT Director, who has extensive experience in information systems and cybersecurity, leads our cybersecurity strategy, policy, standards, architecture, and processes. The IT Director reports to the Chief Financial Officer (“CFO”). The CFO provides regular updates to the Board, Audit Committee, and executive management on the status of our cybersecurity posture and any material threats.

Our cybersecurity program employs industry-standard methodologies to manage cybersecurity risks, including secure network infrastructure design, continuous security updates, and automated alerts for suspicious activities. We also conduct regular training for employees at all levels on cybersecurity awareness and the protection of confidential information. In the event of a cybersecurity incident, our incident response process is designed to detect, respond to and mitigate the impact. Significant incidents are escalated to a team of business leaders, including our Chief Executive Officer and CFO, who work with our incident response team to assess and address the situation. The Audit Committee oversees management’s response to significant incidents and ensures compliance with disclosure requirements. To maintain high security standards, we leverage third-party tools and services that adhere to industry best practices, including multi-layer authentication. Despite our efforts, we acknowledge that cybersecurity threats are constantly evolving, and we remain vigilant in protecting our information systems and data.

The Board oversees our cybersecurity risk management process, and the Audit Committee has the authority and power to provide specific oversight of cybersecurity matters.

Item 2. Properties

Our principal executive office is located in South San Francisco, California, where we lease approximately 11,000 square feet of combined office and lab space under a lease that terminates in April 2030. We believe that these existing facilities will be adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings

Except as discussed below, as of the date of this Form 10-K, we were not currently a party to any material legal proceedings. From time to time, in the ordinary course of business, we may become involved in legal proceedings. Regardless of the outcome, litigation could have a material adverse effect on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors, and there can be no assurances that favorable outcomes will be obtained.

In September 2016, BBOT entered into the UCSF License Agreement with The Regents of the University of California, San Francisco for an exclusive license to certain compounds. Although the UCSF License Agreement was terminated in June 2021, certain of its terms survived, including one calling for a payment that would become due to UCSF upon the occurrence of a change of control or an initial public offering of BBOT, as those events are contractually defined in the UCSF License Agreement (the “Indexed Milestone Payment”). In April 2025, UCSF sent an email to BBOT, followed by a letter dated June 16, 2025, stating that, in the future, the Indexed Milestone Payment in an amount less than \$5.0 million will become due on an unspecified date following the Closing Date of the Business Combination Agreement. BBOT disagrees with UCSF’s interpretation of the terminated UCSF License Agreement and believes that no such payment will be due now or in the future.

Item 4. Mine Safety Disclosures

Not applicable.

PART II—OTHER INFORMATION

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

Market Information

Our ticker symbol is “BBOT”, as traded and reported by The NASDAQ Global Market.

Holders of Common Stock

As of March 2, 2026, there were approximately 57 stockholders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in “street name” or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividends

We have never declared or paid any dividends on our capital or common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

On October 10, 2025, we issued 784,720 shares of our common stock to BridgeBio Pharma LLC pursuant to an amendment to the Transition Services Agreement, dated August 11, 2025, by and among TheRas, Inc., BridgeBio Services, Inc., BBOT and BridgeBio Pharma LLC, in exchange for additional financial and accounting support services provided by BridgeBio Services, Inc. to us through December 31, 2025.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the year ended December 31, 2025.

Item 6. [Reserved]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion and analysis of our financial condition and results of operations should be read together with the consolidated financial statements and related notes included in this Annual Report on Form 10-K ("Form 10-K"). This discussion may contain forward-looking statements including, but not limited to, our expectations or predictions of future financial or business performance or conditions. Forward-looking statements are inherently subject to risks, uncertainties, and assumptions. You should read the sections in this Form 10-K titled "Risk Factors" and "Special Note of Forward-Looking Statements" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by these forward-looking statements.

Overview

BBOT is a clinical-stage biopharmaceutical company advancing a next-generation pipeline of novel small-molecule therapeutics targeting RAS and Phosphoinositide 3-kinase ("PI3K"). BBOT is headquartered in South San Francisco, California. Our mission is to accelerate scientific and medical breakthroughs and deliver well-tolerated medicines with greater efficacy and safety to people with the deadliest cancers. We are advancing our next-generation RAS-pathway targeted small molecules with a focus on optimized target coverage for patients with tumors driven by RAS and PI3K α and a synergistic portfolio that is designed to enable targeted KRAS combinations.

Our business was established in August 2016 by BridgeBio Pharma Inc. ("BridgeBio Pharma"). We operated as part of BridgeBio Pharma through April 30, 2024. Since our inception, we devoted substantially all of our resources to raising capital, conducting discovery and research activities, and establishing arrangements with third parties. We are currently developing three lead product candidates:

- BBO-8520 is an orally bioavailable small molecule direct inhibitor targeting both the ON and OFF states of KRAS. OFF-only inhibitors cannot covalently modify the ON-state; hence they need to maintain high concentration levels to capture free cycling KRAS G12C. ON/OFF inhibitors overcome this shortcoming. Dual ON/OFF inhibition allows BBO-8520 to fully capture the covalent mechanism of action, resulting in sustained pathway inhibition even after systemic drug levels decline. We believe this should enable a more potent and safer combination with pembrolizumab in patients with KRAS G12C mutant NSCLC. BBO-8520 has been shown to drive strong anti-tumor activity with favorable durability in multiple preclinical models. Early data from Phase 1 dose escalation showed 60% confirmed overall response rate in KRAS G12C NSCLC patients. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to BBO-8520 for the treatment of adult patients with previously treated, KRAS G12C-mutated metastatic NSCLC. We are currently enrolling the Phase 1 ONKORAS-101 trial (NCT06343402) for patients with KRAS G12C mutant non-small cell lung cancer (NSCLC). ONKORAS-101 is an open-label, multi-center Phase 1a/1b study designed to evaluate the safety, tolerability, preliminary antitumor activity, and pharmacokinetics of BBO-8520 as a single agent and in combination with pembrolizumab in patients with KRASG12C mutant NSCLC. Updated clinical data are expected in the first quarter of 2026.
- BBO-10203 is an orally bioavailable small molecule with a novel mechanism of action designed to inhibit the physical interaction between RAS and PI3K α , inhibiting RAS-driven PI3K α -AKT signaling in tumors. BBO-10203 binds directly and covalently to the RAS-binding domain of PI3K α , preventing its activation by KRAS, HRAS and NRAS, reducing downstream signaling and tumor growth. It is a protein-protein inhibitor and not a kinase inhibitor, enabling inhibition of RAS-driven PI3K α -AKT signaling in tumors without the risk of hyperglycemia. Importantly, BBO-10203's ability to block RAS activation of PI3K α is agnostic to the mutational status of either RAS or PI3K α . In addition to a potentially differentiated safety profile, BBO-10203 could be combined with direct KRAS inhibitors, such as BBO-8520 and BBO-11818, or drugs that target HER2 or ER receptor. Preclinical data has demonstrated that BBO-10203 blocks RAS-mediated activation of PI3K α and strongly inhibits pAKT signaling in tumor cells without affecting glucose metabolism. In addition, robust monotherapy activity, as well as combination activity with KRAS inhibitors BBO-8520 and BBO-11818, HER2 inhibitors and ER antagonists, was observed at well-tolerated dose levels. The combination of a KRAS inhibitor with a PI3K α pathway inhibitor may maximize the response rate and reduce the development of adaptive resistance mechanisms due to full inhibition of both MAPK and PI3K α signaling. We are currently enrolling the Phase 1 BREAKER-101 trial (NCT06625775) for patients with locally advanced or metastatic HER2+ breast cancer, HR+/HER2-breast cancer, KRAS mutant colorectal cancer, and KRAS mutant non-small cell lung cancer. Initial Phase 1 clinical data are expected in the first half of 2026.

- BBO-11818 is an orally bioavailable small molecule pan-KRAS inhibitor that targets mutant KRAS in both the ON and OFF states. Similar to BBO-8520, the structure-based design was employed to target mutant KRAS in both the ON and the OFF states with strong affinity against KRAS G12D and KRAS G12V mutants. BBO-11818 has selectivity over HRAS and NRAS with the goal of achieving high levels of KRAS inhibition in human tumors. In addition, it has combination potential with BBO-10203 to mitigate the PI3Ka resistance pathway. Preclinical data has demonstrated suppression of MAPK signaling and viability in KRAS mutant cell lines, as well as anti-tumor activity across multiple KRAS G12D and KRAS G12V cell-derived xenograft (CDX) models. In addition, BBO-11818's selectivity for KRAS was demonstrated by its >1000-fold lower potency against NRAS, HRAS, and BRAF-mutant cell lines. The preclinical activity of the combination of BBO-11818 with BBO-10203 was driven by a robust decrease in tumor cell proliferation and increase in apoptosis; combination benefit also observed with cetuximab and anti-PD-1 treatment. We are currently enrolling the Phase 1 KONQUER-101 (NCT06917079) trial for patients with locally advanced or metastatic KRAS mutant solid tumors. Initial Phase 1 clinical data are expected in the second half of 2026.

We have no product candidates approved for sale and have not generated any revenue related to our product candidates.

Since inception, we have incurred significant operating losses. For the year ended December 31, 2025, we incurred a net loss of \$134.0 million and had an accumulated deficit of \$356.6 million as of December 31, 2025. For the year ended December 31, 2024, we incurred a net loss of \$74.3 million. Our ability to generate sufficient product revenue to achieve profitability will depend heavily on the development and eventual commercialization of our product candidates. We expect to continue to incur significant expenses, and our operating losses are expected to increase for the foreseeable future if and as we:

- Advance our existing and future research and development, including potential expansion into additional indications;
- Conduct future clinical studies for our product candidates;
- Pursue investigational new drug applications or comparable foreign applications that allow commencement of the planned clinical trials or future clinical trials for any programs we may develop;
- Hire research and development, clinical, manufacturing, and commercial personnel;
- Add operational, financial, and management information systems and personnel;
- Experience any delays, challenges, or other issues associated with the preclinical and clinical development of our product candidates, including with respect to our regulatory strategies;
- Develop, maintain, and enhance sustainable, scalable, reproducible, and transferable clinical and commercial-scale cGMP capabilities through a third party or our own manufacturing facility for the product candidates that we may develop;
- Seek, obtain, and maintain regulatory approvals for any product candidates for which we successfully complete clinical trials;
- Ultimately establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval;
- Generate revenue from commercial sales of product candidates for which we receive regulatory approval, if any;
- Maintain safety, tolerability, and efficacy profile of any product we may develop in additional indications following approval in one indication;
- Maintain, expand, enforce, defend, and protect our intellectual property portfolio and other intellectual property protection or regulatory exclusivity for any products we may develop and defend any intellectual property-related claims;
- Further acquire or in-license product candidates or programs, intellectual property, and technologies;
- Maintain our current licenses and establish and maintain any future collaborations, including making related development and sales milestone payments, royalties, or other required payments; and
- Incur additional costs of operating as a public company, including increased costs of audit, legal, regulatory, and tax-related services associated with maintaining compliance with an exchange listing and the SEC requirements, director and officer insurance premiums and investor and public relations costs.

Any changes in the outcomes of these variables could significantly affect the costs and timing associated with the development of our product candidates. For example, if the U.S. Food and Drug Administration ("FDA") or another comparable regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required to complete clinical development and obtain regulatory approval of one or more product candidates, or if we experience significant delays in our preclinical studies or

clinical trials, we would be required to expend significant additional financial resources and time to advance and complete clinical development. We may never obtain regulatory approval for any of our product candidates.

We will not generate revenue from product sales unless and until we successfully initiate and complete clinical development and obtain regulatory approval for any product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, and distribution.

As a result of the above factors, we expect to need substantial additional funding to support our continued operations and growth strategy. Until such a time as we can generate significant revenue from our product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including collaborations with other companies or other strategic transactions. We may not be able to raise additional funds or enter into such other agreements on favorable terms or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our programs.

Due to the numerous risks associated with product development, we cannot accurately predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or cannot sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

de-SPAC Transaction

On February 28, 2025, TheRas, Inc. (“Legacy BBOT”) entered into a definitive business combination agreement, amended on June 17, 2025 (“Business Combination Agreement”) with Helix Acquisition Corp. II (“Helix”), a publicly traded special purpose acquisition company listed on Nasdaq under the ticker symbol “HLXB.” Pursuant to the Business Combination Agreement closing, Helix II Merger Sub, Inc., a wholly owned subsidiary of Helix, merged with and into Legacy BBOT, with Legacy BBOT surviving the merger as a wholly-owned subsidiary of Helix (“Merger”). In connection with the Merger, Helix changed its name to BridgeBio Oncology Therapeutics, Inc. and redomiciled as a Delaware corporation (“de-SPAC Transaction”). The de-SPAC Transaction was consummated on August 11, 2025 (“Closing”), and BBOT’s common stock became listed on Nasdaq under the ticker symbol “BBOT”. Prior to the Closing, all references to BBOT are related to the balances and activity of Legacy BBOT. Upon the Closing, BBOT became the successor of Helix and the reporting entity, which consolidates the balances and activity of Legacy BBOT.

Concurrent with the execution of the Business Combination Agreement, Helix entered into subscription agreements with certain investors pursuant to which Helix agreed to issue and sell shares of its common stock to investors in a private placement financing (“PIPE Financing”) for an aggregate purchase price of approximately \$260.9 million, which was executed immediately prior to the Closing.

The de-SPAC Transaction was accounted for as a reverse recapitalization effective upon the Closing. Under this method of accounting, Helix was treated as the acquired company for accounting purposes, and BBOT was the deemed acquirer for accounting purposes. The consolidated financial statements of BBOT for periods prior to the Closing include the financial information of Legacy BBOT.

The number of shares and per share amounts for all periods presented were adjusted to reflect the capital structure of BBOT. For periods prior to the Closing, the share activity of BBOT was recast by multiplying the number of shares of Legacy BBOT held by each investor by a ratio of approximately 0.0889 (“Consideration Ratio”), established by the Business Combination Agreement, rounded down to the nearest whole share. The de-SPAC Transaction is presented as the issuance of common stock for the net assets of Helix and proceeds from the PIPE Financing, accompanied by a recapitalization and a change in the reporting entity. The net assets of Helix were recorded at historical cost as of the Closing date, with no goodwill or other intangible assets recognized.

As a result of the de-SPAC Transaction, we assumed the operations of Legacy BBOT upon the Closing, and we became subject to the regulatory and reporting requirements and customary practices applicable to public companies. The costs and administrative demands of operating as a public company, including hiring additional personnel and implementing certain procedures and processes, may materially impact our financial position and results of operations.

Material Related Party Transactions

BridgeBio Pharma is a commercial-stage biopharmaceutical company founded to discover, create, test, and deliver transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers. BridgeBio Pharma and its controlled entities are related parties of BBOT.

In August 2025, upon completion of the de-SPAC Transaction, we made a contractual promise to issue 784,720 shares of our common stock to BridgeBio Pharma (“TSA Shares”), which was not contingent on anything but the passage of time. We treated this transaction as a nonreciprocal transfer with a non-pro-rata distribution to related party. The contract was concluded to be equity-classified, and we recorded general and administrative expense of \$7.8 million equal to the fair value of the underlying shares as of the contract execution date. The TSA Shares were issued to BridgeBio Pharma in October 2025.

Emerging Growth Company Status

As an emerging growth company (“EGC”) under the Jumpstart Our Business Startups Act (the “JOBS Act”), we are eligible for certain regulatory relief, including reduced disclosure obligations and extended transition periods for adopting new or revised accounting standards. Our EGC status commenced upon the completion of Helix’s initial public offering in February 2024 and is expected to continue for up to five years from this date through February 2029, unless certain disqualifying events occur earlier, such as achieving large accelerated filer status.

Impact of General Economic Risk Factors on Our Operations

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including inflation, fluctuating interest rates, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics, particularly in the pharmaceutical and biotech spaces, bank failures, geopolitical factors, including the ongoing conflicts between Russia and Ukraine and in the Middle East and the responses thereto, and supply chain disruptions.

While we closely monitor the impact of the current macroeconomic and geopolitical conditions on all aspects of our business, including the impacts on participants in any future clinical trials and our employees, suppliers, vendors, business partners, and our future access to capital, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period. We will continue to evaluate the nature and extent of the potential impacts on our business, results of operations, liquidity, and capital resources.

Basis of Presentation and Principles of Consolidation

The consolidated financial statements of BBOT for the year ended December 31, 2025, included in Item 8 of this Form 10-K, are prepared in accordance with generally accepted accounting principles in the United States (“US GAAP”). All costs, assets, and liabilities directly associated with BBOT’s business activity are included in our consolidated financial statements. In connection with the de-SPAC Transaction, as the successor entity following the Closing, BBOT became the reporting entity and consolidates the balances and activity of Legacy BBOT. The financial information presented in these consolidated financial statements reflects the balances and results of operations of the combined entity post-Merger. Prior to the Closing, all references to BBOT or the Company are related to the balances and activity of Legacy BBOT. All intercompany balances have been eliminated in consolidation.

From its inception through the issuance of the Series B redeemable convertible preferred stock (“Series B”) on April 30, 2024 (“Legacy BBOT Series B Financing”), Legacy BBOT had been majority-owned and controlled by BridgeBio Pharma. Prior to April 30, 2024, we operated as part of BridgeBio Pharma and not as an independent entity. The consolidated financial statements of BBOT have been derived from BridgeBio Pharma’s historical accounting records and are presented on a carve-out basis. Before April 30, 2024, the consolidated financial statements include allocations of certain general and administrative expenses to Legacy BBOT from BridgeBio Pharma. The allocations have been determined on a reasonable basis; however, the amounts are not necessarily representative of the amounts that would have been reflected in the consolidated financial statements had BBOT been an entity that operated independently from BridgeBio Pharma. After April 30, 2024 and prior to the de-SPAC Transaction, the financial information in the consolidated financial statements relates to Legacy BBOT operating on a standalone basis.

Components of Results of Operations

Revenues

To date, we have not generated any revenue from product candidates under development and does not expect to generate any revenue in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue from product sales in the future. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- Employee-related expenses, including salaries, related benefits, stock-based compensation, and travel expenses for employees engaged in research and development functions;
- Expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with contract research organizations (“CROs”);
- The cost of consultants and contract manufacturing organizations (“CMOs”) that manufacture drug products for use in our preclinical studies and clinical trials;
- Facilities, depreciation, insurance, and other direct and allocated expenses incurred as a result of research and development activities; and
- Payments made under third-party licensing and asset acquisition agreements.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct research and development costs consist primarily of external costs, such as fees paid to consultants, contractors, CMOs, and CROs in connection with our preclinical and clinical development activities.

We are heavily dependent on the success of our product candidates, which are in early stages of development, and require a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical and preclinical development activities in the near term and in future reporting periods, as we conduct additional clinical trials for our product candidates. We currently track research and development expenses based on expense nature.

General and Administrative Expenses

Our general and administrative costs consist primarily of fair value of common stock issued to BridgeBio Pharma, employee-related costs, travel expenses, expenses for outside professional services, including legal, human resources, audit, accounting, and tax services, and allocated facilities-related costs. Employee-related costs include salaries, bonuses, related benefits, and stock-based compensation.

We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities, and other administrative and professional services. We also expect to increase the size of our administrative, finance, and legal functions to support the anticipated growth of our business.

Other Income (Expenses), Net

Interest Income

Other income consists of interest income earned on our cash equivalents and marketable securities.

Income Under Transition Services Agreement

In 2024, other income included income for services provided to BridgeBio Pharma subsequent to the Legacy BBOT Series B Financing under the transition services agreement with BridgeBio Pharma. In 2025, other income includes income for services provided to another party under a different transition services agreement.

Change in Fair Value of Participation Right Liability

Change in fair value of participation right liability represents the income or expense from the right to participate in the Legacy BBOT Series B Financing that we provided to the Regents of the University of California (“UCSF”), which was determined to be a freestanding financial instrument. This right was not exercised upon the initial issuance of the Series B in April 2024 and was subsequently extended through March 2025. UCSF elected to exercise the participation right in March 2025, and it was settled in full through the issuance of Series B shares in April 2025.

Results of Operations

Comparison of the years ended December 31, 2025 and 2024

The following table sets forth a summary of our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,			
	2025	2024	Change	Change, %
Operating expenses:				
Research and development	121,199	73,107	48,092	66%
General and administrative	24,620	7,756	16,864	217%
Total operating expenses	145,819	80,863	64,956	80%
Loss from operations	(145,819)	(80,863)	(64,956)	80%
Other income (expense), net:				
Interest income	11,343	6,377	4,966	78%
Income from transition services agreements	1,192	775	417	54%
Change in fair value of participation right liability	(725)	(564)	(161)	29%
Other income (expense)	(35)	—	(35)	100%
Total other income (expense), net	11,775	6,588	5,187	79%
Net loss	<u>\$ (134,044)</u>	<u>\$ (74,275)</u>	<u>\$ (59,769)</u>	81%

Research and Development Expenses

Research and development expenses consisted of the following components for the periods indicated (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Research and development trials and consumables expenses	\$ 84,578	\$ 36,680	\$ 47,898
Payroll and personnel expenses	26,616	24,077	2,539
Facilities and other expenses	10,005	12,350	(2,345)
Total research and development	<u>\$ 121,199</u>	<u>\$ 73,107</u>	<u>\$ 48,092</u>

Research and development expenses increased by \$48.1 million or 66%, from \$73.1 million for the year ended December 31, 2024, to \$121.2 million for the year ended December 31, 2025. The changes in research and development expenses include the following key drivers:

- a \$47.9 million increase primarily due to increase in clinical trial expenses and manufacturing expenses for BBO-8520, BBO-10203 and BBO-11818,
- a \$2.5 million increase in our payroll and personnel expenses primarily due to headcount expansion, and
- a \$2.3 million decrease primarily from reduced professional fees and consulting costs from related parties attributable to the winding down of activities under the transition services agreement with BridgeBio Pharma.

General and Administrative Expenses

General and administrative expenses increased by \$16.9 million or by 217%, from \$7.8 million for the year ended December 31, 2024, to \$24.6 million for the year ended December 31, 2025. The change was primarily driven by the following key drivers:

- a \$8.8 million increase related to personnel-related expenses and professional and consulting fees, which reflects the initiation of our standalone operations and the de-SPAC Transaction, and
- a \$7.8 million charge related to TSA Shares issued to BridgeBio Pharma.

Interest Income

Interest income increased by \$5.0 million, from \$6.4 million for the year ended December 31, 2024, to \$11.3 million for the year ended December 31, 2025. This increase was primarily driven by a full year of interest earnings on our marketable securities portfolio and interest earned on the proceeds from the de-SPAC Transaction and PIPE Financing completed in August 2025.

Income from Transition Services Agreements

Other income of \$0.8 million for the year ended December 31, 2024 was related to the transition services agreement with BridgeBio Pharma executed after the Legacy BBOT Series B Financing. Other income of \$1.2 million for the year ended December 31, 2025 was recognized in connection with a transition services agreement with a third party.

Change in Fair Value of Participation Right Liability

The changes in fair value of participation right liability of \$0.7 million for the year ended December 31, 2025 and \$0.6 million for the year ended December 31, 2024 were driven primarily by the increase in the estimated fair value per share of the underlying Legacy BBOT Series B redeemable convertible preferred stock relative to the fixed price per share granted to UCSF in connection with the participation right. The participation right was settled in full in April 2025, and there were no subsequent changes in fair value of the associated liability.

Liquidity, Going Concern, and Capital Resources

Sources of Liquidity

Since our inception, BBOT has incurred significant operating losses. For the year ended December 31, 2025, BBOT incurred a net loss of \$134.0 million and had an accumulated deficit of \$356.6 million as of December 31, 2025. For the year ended December 31, 2024, BBOT incurred a net loss of \$74.3 million.

In January 2017, we issued to BridgeBio Pharma 800,061 shares of Series Seed redeemable convertible preferred stock in a single closing at \$1.2508 per share for gross cash proceeds of \$1.0 million. Between May 2017 and April 2024, we issued to BridgeBio Pharma 10,929,005 shares of Series A redeemable convertible preferred stock ("Series A") at \$11.2467 per share for gross cash proceeds of \$122.9 million and 2,072,629 shares of the Series A at \$11.2467 per share in exchange for the settlement of related party payables of \$23.3 million. In April 2024, BBOT received \$175.0 million in gross cash proceeds from the issuance of 19,761,881 shares of Series B at \$8.8554 per share. In May 2024, BBOT received \$25.0 million in gross cash proceeds through the issuance of 2,823,126 shares of Series B at \$8.8554 per share. In March 2025, UCSF elected to exercise the Participation Right. BBOT settled the Participation Right in April 2025 through the issuance of 2,509,446 shares of the Series B for \$22.2 million of cash proceeds.

In August 2025, upon closing of the de-SPAC Transaction, the combined company received \$373.5 million from Helix, which included the proceeds from the PIPE Financing, the unredeemed cash held by Helix, and reflected payment of Helix's transaction costs. The proceeds from the PIPE Financing and reverse recapitalization are expected to advance our project pipeline and will be used for research and development, business development, working capital, and other general corporate purposes.

We estimate that the existing cash, cash equivalents, and marketable securities of BBOT of \$425.5 million as of December 31, 2025 will be sufficient to meet our cash requirements for at least twelve months from the issuance date of the consolidated financial statements for the year ended December 31, 2025 included in this Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and our operating plan may change due to many factors currently unknown to management. We could exhaust our available capital resources sooner than management expects.

In the future, we plan to access capital resources by public or private equity offerings, debt financings, potential collaborations, licensing agreements, and other sources. We have historically been able to raise capital through the issuance and sale of equity and equity-linked instruments, such as redeemable convertible preferred stock for Legacy BBOT and common stock for BBOT. However, no assurance can be provided that we will continue to be successful in doing so in the future. If sufficient funds on acceptable terms are not available when needed, we may be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact our ability to achieve our intended business objectives.

Cash Flows

Overview of BBOT Cash Flows

We have historically financed our operations primarily through the sale of equity securities. During the year ended December 31, 2024, we raised capital through our Series A financing from BridgeBio Pharma and the initial closing of the Legacy BBOT Series B Financing to external investors. During the year ended December 31, 2025, we received additional proceeds from the Legacy BBOT Series B financing. The de-SPAC Transaction completed in August 2025 represented a significant financing event, generating cash inflows from the reverse recapitalization and the associated PIPE Financing. We utilized the proceeds from these financing transactions to fund our operating activities during the years ended December 31, 2025 and 2024. We expect to continue using these available funds to facilitate the ongoing development of our product candidates. Subsequent to April 30, 2024, we began operating as a standalone entity and deployed available funds from the Legacy BBOT Series B Financing into marketable securities. The proceeds from the de-SPAC Transaction are currently held in cash equivalents and did not contribute materially to cash flows from investing activities for the year ended December 31, 2025.

The changes in our working capital structure and operating cash flows were notably impacted by the timing of cash disbursements related to our research and development activities. Specifically, we made significant prepayments under our agreements with contract research organizations and contract manufacturing organizations prior to the commencement of clinical trials and manufacturing activities. These upfront deposits increase our prepaid expenses and non-current assets and accelerate cash outflows in periods prior to the recognition of the associated research and development expenses, causing period-over-period fluctuations in our operating cash burn, especially as we ramp up the development of our product candidates.

Material Adjustments for Non-Cash Investing and Financing Activities

During the year ended December 31, 2025, we recognized \$3.8 million in settlement of participation right liability upon the issuance of the Series B redeemable convertible preferred stock, which resulted in a reclassification of the settlement date fair value of this liability to temporary equity. Additionally, we recognized a \$2.7 million right-of-use asset obtained in exchange for operating lease liability upon commencement of our office lease space in March 2025.

During the year ended December 31, 2024, we extinguished related party payables of \$19.7 million due to the conversion of these liabilities into Series A redeemable convertible preferred stock issued to BridgeBio Pharma. We also recorded \$2.5 million to reflect the initial fair value of the participation right liability, which was allocated from the proceeds of the Legacy BBOT Series B Financing. Additionally, at the time of the Legacy BBOT Series B Financing, we recognized \$3.7 million from the forgiveness of our related party payables to BridgeBio Pharma as a deemed contribution credited to additional paid-in capital.

Cash Flow Comparison for the years ended December 31, 2025 and 2024

The following table summarizes our cash flows during the periods indicated (in thousands):

	Year Ended December 31,		Change
	2025	2024	
Net cash used in operating activities	\$ (113,894)	\$ (55,027)	\$ (58,867)
Net cash provided by (used in) investing activities	73,328	(120,530)	193,858
Net cash provided by financing activities	383,402	206,290	177,112
Net increase in cash, cash equivalents, and restricted cash	<u>\$ 342,836</u>	<u>\$ 30,733</u>	<u>\$ 312,103</u>

Net Cash Flows from Operating Activities

Net cash used in our operating activities for the year ended December 31, 2025 was \$113.9 million. This amount consisted of our net loss of \$134.0 million, reduced to reflect net changes in operating assets and liabilities of \$6.4 million, and further reduced by non-cash charges of \$13.7 million. Our non-cash adjustments primarily consisted of \$7.8 million charge representing the fair value of shares issued to BridgeBio Pharma, \$5.9 million in stock-based compensation, \$0.7 million for losses from changes in the fair value of

the participation right liability prior to its settlement, \$0.3 million in depreciation of property and equipment, and \$0.3 million in amortization of right-of-use assets, partially offset by \$1.3 million in net accretion of premiums on marketable securities. The net change in operating assets and liabilities was primarily due to an increase in our liabilities, including \$17.7 million increase in accrued research and development liabilities, and \$1.9 million increase in accrued compensation and benefits. These changes were partially offset by a decrease of \$7.6 million in other non-current assets, a decrease of \$3.4 million in prepaid expenses, and a decrease of \$1.8 million in accounts payable.

Net cash used in operating activities for the year ended December 31, 2024 was \$55.0 million. This amount consisted of our net loss of \$74.3 million, reduced to reflect changes in operating assets and liabilities of \$15.6 million, and further reduced to reflect our non-cash charges of \$3.7 million. Our non-cash adjustments primarily included \$4.4 million in stock-based compensation, \$0.6 million in the fair value of the participation right liability, and \$0.2 million in depreciation of property and equipment, partially offset by \$1.5 million in net accretion of premiums on marketable securities. The net change in operating assets and liabilities was primarily due to an increase in our liabilities, including \$9.4 million from the net related party balances, \$4.9 million increase in accrued research and development liabilities, \$2.7 million increase in accrued compensation and benefits, a \$2.5 million increase in accounts payable, and a \$0.5 million increase in accrued professional services. These changes were partially offset by an increase of \$3.6 million in other non-current assets and \$1.0 million in prepaid expenses.

Net Cash Flows from Investing Activities

Net cash provided by investing activities for the year ended December 31, 2025 was \$73.3 million, which consisted of \$157.9 million in cash inflows from maturities of marketable securities, offset by \$83.9 million in cash outflows from purchases of marketable securities, and \$0.6 million in purchases of property and equipment.

Net cash used in investing activities for the year ended December 31, 2024, was \$120.5 million, which consisted of \$154.4 million in cash outflows from purchases of marketable securities offset by \$31.5 million in cash inflows from maturities of marketable securities, and \$2.4 million in cash inflows related to a cash pooling arrangement with BridgeBio Pharma.

Net Cash Flows from Financing Activities

Net cash provided by financing activities of \$383.4 million for the year ended December 31, 2025 included \$373.5 million in proceeds from the reverse recapitalization and PIPE Financing and \$22.2 million cash inflows from the issuance of Series B shares to UCSF, offset by \$12.3 million cash outflow related to the payment of de-SPAC Transaction costs.

Net cash provided by financing activities of \$206.3 million for the year ended December 31, 2024 included primarily the net proceeds from the Legacy BBOT Series B Financing from new investors of \$199.3 million, the net proceeds from the Series A financing from BridgeBio Pharma of \$5.9 million, and \$1.1 million for constructive cash inflows related to other contributions from BridgeBio Pharma.

Future Funding Requirements

We will not generate revenue from product sales unless we complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution.

Subsequent to the de-SPAC Transaction, we expect to incur additional costs associated with operating as a public company. In the future, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants that limit or restrict our ability to take specific actions, such as incurring debt, making capital expenditures, or declaring dividends. Furthermore, we may be unable to raise additional funds or enter into other agreements or arrangements on favorable terms or at all when needed. If we fail to raise capital or enter into such agreements, as and when needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our product candidates.

Due to the numerous risks and uncertainties associated with the research, development, and commercialization of pharmaceutical products, we are unable to accurately estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- The successful achievement of preclinical and clinical milestones;

- Continuing our research and drug discovery and development efforts;
- Conducting preclinical and clinical trials for our current product candidates and additional product candidates;
- Establishing a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval;
- Establishing and maintaining manufacturing and supply chain capacity sufficient to provide adequate supplies of our product candidates to support our ongoing and planned clinical trials and commercial quantities of any product candidates for which we may obtain marketing approval;
- Maintaining, expanding, and protecting our intellectual property portfolio;
- Acquiring or in-licensing other product candidates and technologies;
- Continuing to discover and develop additional product candidates;
- Hiring additional personnel to support our product candidate development efforts to obtain regulatory approval and securing additional facilities for operations; and
- Operating as a public company following the de-SPAC Transaction.

Due to the numerous risks and uncertainties associated with the development of our product candidates, we are unable to accurately predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at the planned levels and be forced to reduce or terminate our operations.

In-Licensing and Collaboration Agreements

The Regents of the University of California License Agreements

In September 2016, BBOT entered into a license agreement with UCSF and was granted certain worldwide exclusive licenses to use the licensed compounds (the “UCSF License”). The UCSF License was subsequently amended and was terminated in June 2021.

Under the UCSF License, UCSF received the right, but not the obligation, to purchase up to 10% of the securities in any offering on the same terms as other investors, which survived the termination of the UCSF License (“Participation Right”). Because UCSF was not notified of the Legacy BBOT Series B Financing at the time it was completed in 2024, the Participation Right was extended through March 29, 2025. As a result, UCSF received the right to purchase up to 2,509,446 shares of Series B at the original issue price of \$8.8554 per share. In April 2025, we settled the Participation Right in full by issuing of 2,509,446 Series B shares for cash proceeds of \$22.2 million, and it was no longer outstanding as of December 31, 2025.

Leidos Biomedical Research License and Cooperative Research and Development Agreements

In March 2017, BBOT entered into a cooperative research and development agreement (“Leidos CRADA”) with Leidos Biomedical Research, Inc. (“Leidos”). In December 2018, BBOT and Leidos entered into a license agreement (“Initial Leidos License”), under which BBOT was granted certain worldwide exclusive licenses to use the licensed compounds related to its drug discovery and development initiatives. The Initial Leidos License was terminated in 2021. BBOT and Leidos subsequently entered into three additional license agreements (“Additional Leidos Licenses”), including two related to KRAS G12C inhibitor and P13Ka breaker compounds that were executed in August 2022, and one related to the PanKRAS inhibitor executed in December 2023. The Leidos CRADA, the Initial Leidos License, and the Additional Leidos Licenses are referred to as the “Leidos Agreements.” In December 2025, BBOT and Leidos executed an amendment to extend the expiration date of the Leidos CRADA by nine months to September 2026. In December 2025, the Company and Leidos amended the Leidos Agreements to introduce an additional \$1.5 million in contingent development milestone payments.

Under the Additional Leidos Licenses, BBOT incurred initial upfront fees of \$1.8 million and BBOT is required to pay Leidos certain annual license maintenance fees and royalties on net sales for such licensed compounds. As of December 31, 2025, BBOT was obligated to make contingent milestone payments totaling up to \$25.9 million upon the achievement of certain clinical and regulatory milestones. As of December 31, 2025, BBOT recorded a \$0.5 million liability for milestones that had been achieved but remained unpaid, which is included in the accrued research and development liabilities in the consolidated balance sheet. In connection with our arrangements with Leidos, we recognized research and development expenses of \$3.0 million and \$3.6 million for the years ended December 31, 2025 and 2024, respectively.

In May 2018, BBOT entered into a cooperative research and development agreement (“LLNS CRADA”) with Lawrence Livermore National Security, LLC (“LLNS”) to bring new knowledge and therapeutic possibilities to KRAS drug discovery utilizing LLNS’ high-performance computing machines. BBOT and LLNS executed five subsequent amendments to the LLNS CRADA between December 2019 and November 2025 to clarify the scope and provide for term extensions. In July 2022, BBOT entered into an exclusive patent license agreement for KRAS G12C inhibitors and an exclusive patent license agreement for PI3K α breaker compounds. In December 2024, BBOT entered into an exclusive license agreement with LLNS for research and development of Pan KRAS inhibitor for oncology indications. In July 2025, BBOT entered into an exclusive license agreement with LLNS for research and development of Pan KRAS inhibitor for non-oncology indications. These four agreements are collectively referred to as the LLNS Agreements. In November 2025, BBOT and LLNS executed three separate amendments to the existing agreements for Pan KRAS inhibitors, PI3K α breakers, and KRAS G12C inhibitors. These amendments were made to include new patent applications within the scope of patent rights. In November 2025, BBOT and LLNS executed an amendment to extend the LLNS CRADA expiration date by six months to June 2026.

Upon execution of the LLNS Agreements, BBOT paid an initial upfront cash fee of \$0.2 million. In addition, under the terms of the LLNS Agreements, BBOT is required to pay LLNS certain annual license maintenance fees and royalties to LLNS on net sales for such licensed compounds. As of December 31, 2025, BBOT is required to make contingent milestone payments totaling up to \$21.1 million upon the achievement of certain clinical, regulatory, and sales milestones. In connection with our arrangements with LLNS, we recognized research and development expenses of \$0.8 million and \$2.1 million for the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, we did not have any off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with US GAAP. The preparation of consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements, as well as the expenses incurred during the reporting periods. Our estimates are based on our historical experience and various other factors that we believe are reasonable under the circumstances, which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in Note 2 to BBOT’s consolidated financial statements included in this Form 10-K. We believe that the following accounting policies and estimates are most critical to the judgments and used in the preparation of the consolidated financial statements.

Accrued Research and Development Liabilities

We record accruals for estimated costs of research and development activities performed by third-party service providers, including preclinical studies, clinical trials, and contract manufacturing. We record the estimated costs of research and development activities based on the estimated amount of services provided but not yet invoiced and include these costs in accrued research and development liabilities in the consolidated balance sheets and within research and development expenses in the consolidated statements of operations and comprehensive income. These costs are a significant component of our research and development expenses. Examples of estimated research and development expenses that we accrue include:

- Fees paid to CROs in connection with preclinical and toxicology studies and clinical trials;
- Fees paid to investigative sites in connection with clinical trials;
- Fees paid to contract manufacturing organizations in connection with the production of product and clinical trial materials; and
- Professional service fees for consulting and related services.

We base our expense accruals for clinical trials on estimates of services received and efforts expended under contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as patient enrollment and the completion of clinical trial milestones. Our service providers generally invoice us monthly in

arrears for services performed. In accruing service fees, we estimate the period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs we have already incurred, or if we underestimate or overestimate the level of services performed or the costs of those services, our actual expenses could differ from our estimates. We record advance payments to service providers as prepaid assets.

We record accruals for the estimated costs of third-party contract manufacturing activities. The financial terms of these agreements are negotiable, vary from contract to contract, and may result in uneven payment flows to our vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the completion of certain stages of the manufacturing process. To recognize an expense, we assess whether the production process is sufficiently defined to be the delivery of a good or a service, given that processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize the expense when the drug product is delivered, or we otherwise bear the risk of loss. If we consider the process to be the delivery of a service, we recognize expenses based on our best estimates of the contract manufacturer's progress through the contract stages. We base our estimates on the best information available at the time. However, additional information may become available to us, enabling us to make a more accurate estimate in future reporting periods. In this event, we may be required to record adjustments to research and development expenses in future reporting periods when the actual level of activity becomes more certain. Any increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the reporting period identified.

Allocated Operating Expenses and Related Party Transactions

Our operating expenses include significant amounts charged by or related to transactions with BridgeBio Pharma.

Prior to April 30, 2024, BBOT operated as part of BridgeBio Pharma. Costs and expenses directly attributable to BBOT's operations were recorded in the BBOT's ledger with a corresponding liability, based on their nature. BBOT also utilized certain general and administrative functions of BridgeBio Pharma that were not recorded in its ledger. These general and administrative expenses represent the costs of doing business that would have been incurred if BBOT were to operate on a standalone basis. These general and administrative expenses were recorded in these consolidated financial statements using the carve-out operating expense allocation methodology. The allocation process used a percentage of the operating expenses incurred by BBOT in each period compared to the total operating expenses incurred by all BridgeBio Pharma entities. This percentage was then applied to the applicable general and administrative expenses incurred by BridgeBio Pharma to calculate the amounts attributable to our operations.

We consider the allocation methodology used to be reasonable and to appropriately reflect the related expenses attributable to BBOT based on its activity in each period and for the purposes of consolidated financial statements for the year ended December 31, 2024. However, the allocated expenses reflected in consolidated financial statements for the year ended December 31, 2024, may not be indicative of the actual expenses that would have been incurred during the periods presented if BBOT had operated as a separate standalone entity. Additionally, the allocated expenses may not accurately reflect the expenses BBOT will incur in the future.

If we were not required to reimburse BridgeBio Pharma for the operating expenses, such amounts were presented as a deemed contribution from BridgeBio Pharma to BBOT and credited to stockholders' equity (deficit). If BBOT was required to reimburse BridgeBio Pharma for the operating expenses, such amounts were credited to liability. Subsequent to the Legacy BBOT Series B Financing, all outstanding amounts under the transition services agreement with BridgeBio Pharma are presented as assets and liabilities.

During the year ended December 31, 2025, BBOT recognized \$0.8 million in research and development expenses and \$8.4 million in general and administrative expenses for the services provided by BridgeBio Pharma under the transition services agreement. General and administrative expenses for the year ended December 31, 2025 include the grant date fair value of the TSA Shares issued to BridgeBio Pharma of \$7.8 million discussed in section "—Material Related Party Transactions" above.

During the year ended December 31, 2024, BBOT recognized \$8.9 million in research and development expenses and \$2.8 million in general and administrative expenses for the services provided by BridgeBio Pharma. For the year ended December 31, 2024, the allocated general and administrative expenses calculated using the carve-out methodology included \$1.1 million for other administrative expenses and \$0.9 million for stock-based compensation.

During the year ended December 31, 2024, BBOT recognized \$0.8 million in income from services rendered to BridgeBio Pharma under the transition services agreement executed after the Legacy BBOT Series B financing to facilitate BBOT's transition to standalone operations. No such related party income from transition services agreements was recognized during the year ended December 31, 2025.

Stock-based Compensation

Stock-based compensation is recorded in research and development expenses or general and administrative expenses based on the grantee's function. Prior to April 30, 2024, stock-based compensation recorded included the following components:

- Amounts related to equity and liability-classified awards issued by BridgeBio Pharma to non-employees of BBOT engaged in its research and development activities. These amounts were initially credited to liability and subsequently settled by BBOT through the issuance of Series A redeemable convertible preferred stock.
- Amounts related to stock-based awards issued by BridgeBio Pharma and allocated to BBOT based on the carve-out expense allocation methodology. These amounts were not expected or required to be settled in cash and were credited to stockholders' equity (deficit), within additional paid-in capital.

Subsequent to April 30, 2024, stock-based compensation includes expenses related to common stock options granted by BBOT. The associated stock-based compensation is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures of share-based awards are accounted for as they occur. The fair value of stock options is estimated on the grant date using the Black-Scholes option-pricing model, which requires certain assumptions further discussed below:

- **Fair Value of Common Stock:** Prior to the de-SPAC Transaction, the fair value of our common stock was determined by the board of directors with input from management and consideration of third-party valuation reports. In the absence of a public trading market, and as a clinical-stage company with no significant revenues, BBOT has concluded that it was appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. In addition, BBOT considered various objective and subjective factors, along with input from the independent third-party valuation firm. The factors included (1) the achievement of the development milestones by BBOT; (2) the significant risks associated with BBOT's stage of development; (3) capital market conditions for comparable, privately held, early-stage life science companies; (4) BBOT's available liquidity, financial condition, and results of operations; (5) the sales of BBOT's shares to third parties, such as the Legacy BBOT Series B Financing; and (6) the preferential rights of the redeemable convertible preferred stockholders. Following the de-SPAC Transaction, we became a public company and derive the fair value of our common stock from quoted prices on the Nasdaq.
- **Expected Dividend Yield:** BBOT has historically paid no dividends and does not anticipate paying dividends in the future.
- **Expected Equity Volatility:** BBOT does not have sufficient trading history for its common stock and has computed expected volatility based on the historical volatility of a representative group of public companies with similar characteristics to BBOT (e.g., public entities of similar size, complexity, stage of development, and industry focus). The historical volatility is commensurate with the expected term assumption.
- **Risk-Free Interest Rate:** The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of award grant for the expected term of the award.
- **Expected Term:** BBOT uses the simplified method to calculate the expected term for options granted to employees, as it does not have sufficient historical exercise data to provide a reasonable basis for estimating the expected term.

Participation Right Liability

The participation right liability represented the right granted to USCF to potentially participate in future Series B offerings at a fixed price of \$8.8554 per share. The participation right was a freestanding instrument substantially similar to a written call option on the Series B shares that may be redeemed outside of the Company's control. As such, the Company classified the participation right as a liability, remeasured at fair value, until the participation right was exercised. Changes in the fair value of the participation right liability are presented separately in the consolidated statements of operations. The participation right liability was subsequently settled in full in April 2025 as part of the issuance of the Series B shares, and its fair value represented the estimated intrinsic value per Series B share as of the settlement date.

As of the settlement date in April 2025, the fair value of the participation right liability was determined based on the intrinsic value of the underlying option to purchase each share of the Series B. The fair value per Series B share was estimated using the Probability-Weighted Expected Return Method ("PWERM"). Under the PWERM, we considered various liquidity events, including the de-SPAC Transaction, an initial public offering, and a sale of BBOT, assigned probability to each liquidity scenario, and estimated the fair value per Series B share using the following assumptions:

- **Probability of a Qualifying Liquidity Event:** This refers to the likelihood that a qualifying liquidity event will occur during the expected term of the liability.
- **Expected Term, Years:** This represents the estimated timeframe in years until a qualifying liquidity event is expected to occur.
- **Discount Rate:** The discount rate is applied to future cash flows to calculate their present value.

Recent Accounting Pronouncements

See Note 2, “Summary of significant accounting policies,” sections “—Recently Adopted Accounting Pronouncements” and “—Recently Issued Accounting Pronouncements” to our consolidated financial statements, which are included in Item 8 of this Form 10-K.

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

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended (“Exchange Act”), and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of BridgeBio Oncology Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BridgeBio Oncology Therapeutics, Inc. (the “Company”) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

San Francisco, CA
March 5, 2026

We have served as the Company's auditor since 2024.

BridgeBio Oncology Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except shares and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 373,687	\$ 30,851
Short-term marketable securities	51,773	124,780
Receivables from related parties	386	81
Prepaid expenses and other current assets	6,550	2,981
Total current assets	432,396	158,693
Property and equipment, net	956	490
Operating lease right-of-use asset	2,330	—
Other non-current assets	12,567	4,986
Restricted cash	132	132
Total assets	\$ 448,381	\$ 164,301
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,374	\$ 3,074
Accrued compensation and benefits	5,746	3,821
Accrued research and development liabilities	25,951	8,276
Accrued professional services	674	655
Payables to related parties	534	483
Operating lease liability, current	522	—
Other accrued liabilities	240	166
Participation right liability	—	3,105
Total current liabilities	35,041	19,580
Operating lease liability, noncurrent	2,244	—
Total liabilities	37,285	19,580
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued and outstanding as of December 31, 2025; 36,386,702 shares authorized, issued and outstanding as of December 31, 2024; liquidation preference of \$347,227 as of December 31, 2024	—	323,358
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized as of December 31, 2025; no shares issued and outstanding as of December 31, 2025; no shares authorized, issued and outstanding as of December 31, 2024	—	—
Common stock, \$0.0001 par value; 500,000,000 and 41,341,250 shares authorized as of December 31, 2025 and December 31, 2024, respectively; 79,991,768 and 28,415 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	8	—
Additional paid-in capital	767,639	43,538
Accumulated deficit	(356,567)	(222,523)
Accumulated other comprehensive income	16	348
Total stockholders' equity (deficit)	411,096	(178,637)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$ 448,381	\$ 164,301

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

BridgeBio Oncology Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except shares and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development ⁽¹⁾	\$ 121,199	\$ 73,107
General and administrative ⁽²⁾	24,620	7,756
Total operating expenses	<u>145,819</u>	<u>80,863</u>
Loss from operations	(145,819)	(80,863)
Other income (expense), net:		
Interest income	11,343	6,377
Income from transition services agreements ⁽³⁾	1,192	775
Change in fair value of participation right liability	(725)	(564)
Other income (expense)	<u>(35)</u>	<u>—</u>
Total other income (expense), net	11,775	6,588
Net loss	<u>\$ (134,044)</u>	<u>\$ (74,275)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (4.30)</u>	<u>\$ (5,756.41)</u>
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>31,144,775</u>	<u>12,903</u>

⁽¹⁾ Research and development expenses include related party amounts of \$849 and \$8,917 for the years ended December 31, 2025 and 2024, respectively.

⁽²⁾ General and administrative expenses include related party amounts of \$8,407 and \$2,779 for the years ended December 31, 2025 and 2024, respectively.

⁽³⁾ Income from transition services agreements includes related party amounts of \$0 and \$775 for the years ended December 31, 2025 and 2024, respectively.

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

BridgeBio Oncology Therapeutics, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,	
	2025	2024
Comprehensive loss, net of tax:		
Net loss	\$ (134,044)	\$ (74,275)
Unrealized gains (losses) on marketable securities	(332)	348
Comprehensive loss	<u>\$ (134,376)</u>	<u>\$ (73,927)</u>

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

BridgeBio Oncology Therapeutics, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock
and Stockholders' Equity (Deficit)
(In thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2023	129,580,878	\$ 104,808	124,726	\$ —	\$ 32,607	\$ (148,248)	\$ —	\$ (115,641)
Reverse recapitalization	(118,060,371)	—	(113,637)	—	—	—	—	—
Balances as of December 31, 2023	11,520,507	104,808	11,089	\$ —	\$ 32,607	\$ (148,248)	\$ —	\$ (115,641)
Issuance of Series A redeemable convertible preferred stock to BridgeBio Pharma for cash consideration	525,976	5,090	—	—	825	—	—	825
Issuance of Series B redeemable convertible preferred stock for cash consideration, net of issuance costs	22,585,007	196,720	—	—	—	—	—	—
Conversion of related party payables into Series A redeemable convertible preferred stock issued to BridgeBio Pharma	1,755,212	16,740	—	—	3,000	—	—	3,000
Deemed contribution from BridgeBio Pharma upon forgiveness of related party payables	—	—	—	—	3,698	—	—	3,698
Contribution from BridgeBio Pharma	—	—	—	—	1,062	—	—	1,062
Exercise of common stock options for cash	—	—	17,326	—	52	—	—	52
Stock-based compensation	—	—	—	—	2,294	—	—	2,294
Unrealized gain on marketable securities	—	—	—	—	—	—	348	348
Net loss	—	—	—	—	—	(74,275)	—	(74,275)
Balances as of December 31, 2024	36,386,702	\$ 323,358	28,415	\$ —	\$ 43,538	\$ (222,523)	\$ 348	\$ (178,637)
Conversion of Series B redeemable convertible preferred stock into common stock	(21,783)	(189)	21,783	—	189	—	—	189
Issuance of Series B redeemable convertible preferred stock for cash consideration and settlement of participation right liability	2,509,446	26,052	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock into common stock	(38,874,365)	(349,221)	38,874,365	4	349,217	—	—	349,221
Issuance of common stock in connection with reverse recapitalization and PIPE Financing, net of issuance costs	—	—	40,272,147	4	361,008	—	—	361,012
Common stock issued to related party	—	—	784,720	—	7,769	—	—	7,769
Exercise of common stock options for cash	—	—	10,338	—	45	—	—	45
Stock-based compensation	—	—	—	—	5,873	—	—	5,873
Unrealized losses on marketable securities	—	—	—	—	—	—	(332)	(332)
Net loss	—	—	—	—	—	(134,044)	—	(134,044)
Balances as of December 31, 2025	—	\$ —	79,991,768	\$ 8	\$ 767,639	\$ (356,567)	\$ 16	411,096

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

BridgeBio Oncology Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2025	2024
Operating activities		
Net loss	\$ (134,044)	\$ (74,275)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	280	208
Stock-based compensation	5,873	4,425
Fair value of common stock issued to related party	7,769	—
Change in fair value of participation right liability	725	564
Net accretion of premiums on marketable securities	(1,260)	(1,543)
Amortization of right-of-use assets	330	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,417)	(1,018)
Other non-current assets	(7,581)	(3,576)
Accounts payable	(1,840)	2,498
Accrued compensation and benefits	1,925	2,696
Accrued research and development liabilities	17,675	4,901
Accrued professional services	(102)	518
Operating lease liabilities	(47)	—
Other accrued liabilities	74	141
Balances due to and from related parties	(254)	9,434
Net cash used in operating activities	(113,894)	(55,027)
Investing activities		
Maturities of marketable securities	157,859	31,544
Purchases of marketable securities	(83,925)	(154,431)
Change in related party receivables related to cash pooling arrangement	—	2,406
Purchases of property and equipment	(606)	(49)
Net cash provided by (used in) investing activities	73,328	(120,530)
Financing activities		
Proceeds from reverse recapitalization and PIPE Financing	373,457	—
Payment of deferred transaction costs	(12,322)	—
Issuance of Series A redeemable convertible preferred stock	—	5,915
Issuance of Series B redeemable convertible preferred stock, net of issuance costs	22,222	199,261
Contribution from BridgeBio Pharma	—	1,062
Exercise of common stock options for cash	45	52
Net cash provided by financing activities	383,402	206,290
Net increase in cash, cash equivalents, and restricted cash	342,836	30,733
Cash, cash equivalents, and restricted cash at beginning of period	30,983	250
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 373,819</u>	<u>\$ 30,983</u>
Supplemental disclosures of non-cash investing and financing activities:		
Settlement of participation right liability upon issuance of Series B redeemable convertible preferred stock	\$ 3,830	\$ —
Right-of-use asset recognized in exchange for operating lease liabilities	\$ 2,706	\$ —
Unpaid property and equipment included in accounts payable	\$ 140	\$ —
Deferred de-SPAC transaction costs included in accrued professional services	\$ 123	\$ —
Conversion of related party payables into Series A redeemable convertible preferred stock issued to BridgeBio Pharma	\$ —	\$ 19,740
Deemed contribution from BridgeBio Pharma upon forgiveness of related party payables	\$ —	\$ 3,698
Initial recognition of participation right liability in connection with issuance of Series B redeemable convertible preferred stock	\$ —	\$ 2,541
Non-cash transfers of property and equipment from BridgeBio Pharma	\$ —	\$ 54

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

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

1. Organization

Description of the Business

BridgeBio Oncology Therapeutics, Inc. (“BBOT,” the “Company,” “we,” “our,” or “us”), formerly known as Helix Acquisition Corp. II (“Helix”), is a clinical-stage biopharmaceutical company advancing a next-generation pipeline of novel small molecule therapeutics targeting RAS and Phosphoinositide 3-kinase (“PI3K”) malignancies. BBOT is headquartered in South San Francisco, California.

de-SPAC Transaction

On February 28, 2025, TheRas Inc. (“Legacy BBOT”), a privately held Delaware corporation, entered into a definitive business combination agreement (“Business Combination Agreement”) with Helix, a publicly traded special purpose acquisition company (“SPAC”) listed on Nasdaq under the ticker symbol “HLXB.”

On August 11, 2025 (the “Closing”), Helix II Merger Sub, Inc., a wholly-owned subsidiary of Helix, merged with and into Legacy BBOT, with Legacy BBOT surviving the merger as a wholly-owned subsidiary of Helix (“Merger”). In connection with the Merger, Helix changed its name to BridgeBio Oncology Therapeutics, Inc., and the combined company became listed on Nasdaq under the new ticker symbol “BBOT” (“de-SPAC Transaction”). Immediately prior to the closing of the de-SPAC Transaction, Helix issued and sold shares of its common stock to investors in a private placement financing for an aggregate purchase price of \$260.9 million (“PIPE Financing”).

The de-SPAC Transaction was accounted for as a reverse recapitalization with Legacy BBOT being the accounting acquirer, and Helix identified as the acquired company for accounting purposes (see Note 3). Accordingly, prior to the Closing, all historical financial information presented in the consolidated financial statements represents the balances and activity of Legacy BBOT. At the Closing, each outstanding share of Legacy BBOT common stock was exchanged for shares of BBOT common stock based on a ratio of approximately 0.0889 (“Consideration Ratio”). For periods prior to the Closing, the reported share and per share information has been retroactively adjusted to reflect the Consideration Ratio.

Material Related Party Transactions

BridgeBio Pharma, Inc. is a commercial-stage biopharmaceutical company founded to discover, create, test, and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio Pharma, Inc. and its controlled entities (collectively, “BridgeBio Pharma”) were related parties of Legacy BBOT prior to the Closing and remained related parties of the Company after the Closing. As discussed in Note 13, the Company had material related party transactions with BridgeBio Pharma during the periods presented in these consolidated financial statements.

Basis of Presentation and Principles of Consolidation

These consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States (“US GAAP”). All costs, as well as assets and liabilities directly associated with the Company’s business activity, are included in the consolidated financial statements. In connection with the de-SPAC Transaction, as the successor entity following the Closing, BBOT became the reporting entity and consolidates the balances and activity of Legacy BBOT. The financial information presented in these consolidated financial statements reflects the balances and results of operations of the combined entity post-Merger. Prior to the Closing, all references to BBOT or the Company are related to the balances and activity of Legacy BBOT. All intercompany balances have been eliminated in consolidation.

From its inception through the issuance of the Series B on April 30, 2024, Legacy BBOT had been majority-owned and controlled by BridgeBio Pharma. Prior to April 30, 2024, the Company operated as part of BridgeBio Pharma. From inception through April 30, 2024, these consolidated financial statements have been derived from BridgeBio Pharma’s historical accounting records and are presented on a carve-out basis. The consolidated statement of operations includes allocations of certain general and administrative expenses to the Company from BridgeBio Pharma. The allocations have been determined on a reasonable basis. The related transactions are discussed further in Note 13. Following the Series B issuance, no individual investor or related party group held a controlling financial interest in the Company, and BBOT has operated independently from BridgeBio Pharma. Subsequent to April 30, 2024 and prior to the de-SPAC Transaction, the financial information included in these consolidated financial statements relates to Legacy BBOT on a standalone basis.

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

Liquidity

Since its inception through December 31, 2025, the Company has incurred net losses. As of December 31, 2025, the Company had an accumulated deficit of \$356.6 million and incurred net losses of \$134.0 million and \$74.3 million during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had a balance of cash, cash equivalents, and marketable securities of \$425.5 million. The Company believes that its existing cash, cash equivalents, and marketable securities will be sufficient to support operations for at least one year from the issuance date of these consolidated financial statements.

The Company expects to incur additional losses and negative cash flows for the foreseeable future as it continues its research and development efforts, advances its product candidates through preclinical and clinical development, enhances its approach and programs, expands its product pipeline, seeks regulatory approval, prepares for commercialization, hires additional personnel, protects its intellectual property, operates as a public company, and grows its business. The Company will need to raise additional capital to support its continuing operations and pursue its long-term business plan, including the development and commercialization of its product candidates if approved. Financing activities may include, but are not limited to, public or private equity offerings, debt financings, potential collaborations, licensing agreements, or other sources. Such activities are subject to significant risks and uncertainties.

2. Summary of Significant Accounting Policies

Concentration of Credit Risk and Other Risks and Uncertainties

Cash, cash equivalents, marketable securities, and restricted cash are financial instruments that subject us to significant concentrations of credit risk. These financial instruments are held in financial institutions in the United States. At times, the amounts on deposit may exceed federally insured limits. We believe that these financial institutions are financially sound, and, accordingly, minimal credit risk exists with respect to the amounts deposited. The Company has not experienced any credit losses associated with its balances in such accounts during the years ended December 31, 2025 and 2024.

We are subject to certain risks and uncertainties, and we believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to obtain future financing, regulatory approval and market acceptance of, and reimbursement for, product candidates, performance of third-party contract research organizations and manufacturers upon which we rely, protection of our intellectual property, litigation or claims against us based on intellectual property, patent, product, regulatory, clinical or other factors, and our ability to attract and retain employees necessary to support our growth.

We depend on third-party manufacturers to supply products for research and development activities in our programs. Specifically, we rely on and expect to continue relying on a small number of manufacturers to supply our requirements for active pharmaceutical ingredients and formulated drugs related to these programs. A significant interruption in the supply of active pharmaceutical ingredients and formulated drugs could adversely affect these programs.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and disclosure of contingent liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to:

- Accruals for research and development activities and contingent clinical, development, regulatory, and sales-based milestone payments in our in-licensing agreements,
- The fair value of redeemable convertible preferred stock and common stock prior to the de-SPAC Transaction,
- The fair value of share-based awards and participation right liability,
- Recoverability of deferred tax assets,
- Allocations of operating expenses, including stock-based compensation prior to April 30, 2024, and
- The determination of the incremental borrowing rate used in lease-related calculations.

We base our estimates on historical experience and various other reasonable assumptions. Actual results may differ from those estimates or assumptions.

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments purchased with a maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2025 and 2024, cash equivalents mainly consisted of money market funds, and restricted cash represents security deposits in the form of a letter of credit issued in connection with the Company's lease agreement. The cash, cash equivalents, and restricted cash included the following balances (in thousands):

	December 31, 2025	December 31, 2024
Cash	\$ 624	\$ 185
Cash equivalents	373,063	30,666
Restricted cash	132	132
Total cash, cash equivalents, and restricted cash	<u>\$ 373,819</u>	<u>\$ 30,983</u>

Marketable Securities

Marketable securities presented in these consolidated financial statements are classified as available-for-sale. Our available for-sale securities are carried at fair value with the unrealized gains and losses included in accumulated other comprehensive income as a component of stockholders' equity (deficit) until realized. Realized gains and losses are calculated using the specific identification method and recorded as interest income in the consolidated statement of operations.

The Company reports the accrued interest receivable as a component of prepaid and other assets on its consolidated balance sheet, which is presented separately from available-for-sale securities. The Company does not measure an allowance for credit losses on accrued interest receivable and instead writes it off if an issuer defaults or is expected to default on payments.

For available-for-sale securities in an unrealized loss position, the Company first assesses whether it intends to sell, or if 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 income or loss. For available-for-sale securities that do not meet the above criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, changes in interest rates, market conditions, 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 interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive income or loss. No allowance for credit losses has been recorded as of December 31, 2025 and 2024.

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based on the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- Level 1 — Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2 — Inputs, other than quoted prices included in Level 1, that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and
- Level 3 — Unobservable inputs supported by little or no market activity and significant to the fair value of the assets or liabilities.

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Due to their short-term nature, the carrying amounts of cash, cash equivalents, prepaid expenses and other current assets, accounts payable, and other accrued liabilities in the accompanying consolidated balance sheet approximate their fair values.

Leases

The Company determines if an arrangement contains a lease at inception and the classification of the lease on the commencement date. An arrangement contains a lease if there is an identified asset and if the Company controls the use of the identified asset throughout the period of use. The Company determines whether leases meet the classification criteria of a finance or operating lease considering: (1) whether the lease transfers ownership of the underlying asset to the lessee at the end of the lease term, (2) whether the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise, (3) whether the lease term is for a major part of the remaining economic life of the underlying asset, (4) whether the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset, and (5) whether the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of December 31, 2025, our lease population consisted of real estate operating leases. Lease right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of the future minimum lease payments over the lease term at the commencement date. Right-of-use assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less any lease incentives received. Lease incentives are included in the calculation of lease liability as of the commencement date to the extent it is probable that the Company will utilize them.

In determining the present value of its lease liabilities, the Company uses its incremental borrowing rate when the rate implicit in the lease is not readily determinable, based on information available as of the lease commencement date. The Company's incremental borrowing rate is based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment, and the determination of the rate requires the Company to make certain assumptions and judgments, including on its synthetic credit rating. Leases may include options to extend or early terminate the lease term. If the Company, using judgment, is reasonably certain that an option will be exercised, then the option will be included in the calculation of the lease term.

The Company elected to combine lease and non-lease components for office leases, and not to recognize right-of-use assets or lease liabilities for short-term leases. A short-term lease is a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise. Lease expense for operating leases is recognized on a straight-line basis over the lease term.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation of property and equipment is calculated using the straight-line method over the asset's estimated useful life. Our property and equipment consist of lab equipment with an estimated useful life of 5 years and leasehold improvements amortized over the shorter of 5 years or the remaining lease term. Maintenance and repairs that do not improve or extend the life of the assets are expensed when incurred. Depreciation expense for property and equipment was \$0.3 million and \$0.2 million during the years ended December 31, 2025 and 2024, respectively.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount of an asset group to the future net undiscounted cash flows the assets are expected to generate. If the carrying amount of an asset group exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. No impairment charges related to long-lived assets have been recorded during the years ended December 31, 2025 and 2024.

Segments

The Company operates in one operating and reportable segment within the United States, developing oncology therapies through various related development projects. All of the Company's assets are located in the United States. The single operating segment conclusion is further supported by the Company's organizational and management structure and other factors. The Company's chief operating decision-maker is its Chief Executive Officer, who manages operations, allocates resources, and evaluates financial performance using a top-down

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

approach and by setting and reviewing company-wide targets. Subsequent to the completion of the de-SPAC transaction, during the third fiscal quarter of 2025, the Company changed the segment information regularly provided to the chief operating decision maker to the below aggregated grouping of expense categories, which is the basis on which the chief operating decision-maker assesses segment performance and allocates resources. The prior period information has been recast to reflect this update. The chief operating decision-maker reviews research and development expenses by the following significant categories presented in the table below (in thousands):

	Year ended December 31,	
	2025	2024
Research and development trials and consumables expenses	\$ 84,578	\$ 36,680
Payroll and personnel expenses	26,616	24,077
Facilities and other expenses	10,005	12,350
Total research and development	<u>\$ 121,199</u>	<u>\$ 73,107</u>

Since the Company operates in a single operating and reportable segment represented by the entire entity, significant segment expenses are provided to the chief operating decision-maker using the same basis as presented in the consolidated statements of operations, including the research and development itemization above. Net loss is the key measure of segment profit and loss that the chief operating decision-maker uses to allocate resources, assess performance, monitor expenditures, and conduct budget versus-actual-analysis. The chief operating decision-maker does not review assets at a different level or category other than the amounts disclosed in the Company's consolidated balance sheets.

Receivables from and Payables to Related Parties

Receivables from and payables to related parties represent the amounts due to and from various BridgeBio Pharma entities, which are expected to be settled in cash within 12 months from the reporting date.

Prior to April 30, 2024, receivables from related parties represented receivables under the centralized cash management balances used by BridgeBio Pharma for cash management and to finance its operations. These arrangements may not reflect how the Company would have financed its operations had it been a separate, standalone entity during the applicable periods. Changes in related-party receivables arising from cash pooling arrangements are presented as investing activities in the consolidated statements of cash flows. Subsequent to April 30, 2024, receivables from related parties represent amounts due from various BridgeBio Pharma entities for services rendered by the Company under the transition services agreement. Payables to related parties represent the amounts due for various research and development and administrative services performed by BridgeBio Pharma to the Company. Prior to April 30, 2024, none of BridgeBio Pharma's third-party debt and related interest has been attributed to the Company because the Company is not the legal obligor of the debt, and the borrowings are not specifically identifiable to the Company.

Subsequent to April 30, 2024, the Company continued its relationship with various BridgeBio Pharma entities, which remain related parties. While the nature of these interactions shifted from centralized cash management to services provided under the transition services agreement, the resulting receivables and payables reported separately as current assets or liabilities in the consolidated balance sheets.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of salaries, benefits, and other personnel-related costs, including stock-based compensation, laboratory supplies, preclinical studies, clinical trials, and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain research and development activities on our behalf, and allocated facility and other related costs. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

Accrued Research and Development Liabilities

We record accruals for estimated costs of research and development activities performed by third-party service providers, including preclinical studies, clinical trials, and contract manufacturing. We record the estimated costs of research and development activities based on the estimated amount of services provided but not yet invoiced and include these costs in accrued research and development liabilities in the consolidated balance sheets and within research and development expenses in the consolidated statements of operations and comprehensive loss. These costs are a significant component of our research and development expenses. Examples of estimated research and development expenses that we accrue include:

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

- Fees paid to contract research organizations (“CROs”) in connection with preclinical and toxicology studies and clinical trials;
- Fees paid to investigative sites in connection with clinical trials;
- Fees paid to contract manufacturing organizations in connection with the production of product and clinical trial materials; and
- Professional service fees for consulting and related services.

We base our expense accruals for clinical trials on estimates of services received and efforts expended under contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as patient enrollment and the completion of clinical trial milestones. Our service providers generally invoice us monthly in arrears for services performed. In accruing service fees, we estimate the period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs we have already incurred, or if we underestimate or overestimate the level of services performed or the costs of those services, our actual expenses could differ from our estimates. We record advance payments to service providers as prepaid assets.

We record accruals for the estimated costs of third-party contract manufacturing activities. The financial terms of these agreements are negotiable, vary from contract to contract, and may result in uneven payment flows to our vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the completion of certain stages of the manufacturing process. To recognize an expense, we assess whether the production process is sufficiently defined to be the delivery of a good or a service, given that processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize the expense when the drug product is delivered, or we otherwise bear the risk of loss. If we consider the process to be the delivery of a service, we recognize expenses based on our best estimates of the contract manufacturer’s progress through the contract stages. We base our estimates on the best information available at the time. However, additional information may become available to us, enabling us to make a more accurate estimate in future reporting periods. In this event, we may be required to record adjustments to research and development expenses in future reporting periods when the actual level of activity becomes more certain. Any increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the reporting period identified.

General and Administrative Expenses

General and administrative expenses represent salaries, benefits, and other personnel-related costs, including stock-based compensation, fair value of common stock issued to BridgeBio Pharma (Note 13), costs related to third-party service providers, and professional and legal fees.

Asset Acquisitions

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. The costs allocated to acquire in-process research and development (“IPR&D”) with no alternative future use are expensed as research and development as of the asset acquisition date. Contingent consideration payments for asset acquisitions include development, regulatory, and sales-based milestone payments due upon the occurrence of a specific event. Contingent payments are recognized when the milestone is met unless the contingent consideration meets the definition of a derivative, in which case the amount becomes part of the cost of the asset acquired. None of the contingent payments represented a derivative through December 31, 2025. Upon recognition of the contingent consideration payment, the amount is expensed as research and development expense if it relates to IPR&D with no alternative future use or capitalized if it relates to a developed product, which is generally when clinical trials have been completed and regulatory approval obtained.

Milestone Payments Under In-Licensing Agreements

Under our in-licensing agreements, the Company is required to pay development, regulatory, and sales-based milestone payments upon the achievement of certain substantive milestones. We recognize development milestones once they are achieved.

Stock-Based Compensation

Stock-based compensation is recorded in research and development expenses or general and administrative expenses based on the grantee's function.

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Prior to April 30, 2024, stock-based compensation recorded included the following components:

- Amounts related to equity and liability-classified awards issued by BridgeBio Pharma to non-employees of the Company engaged in its research and development activities. These amounts were initially credited to liability and subsequently settled by the Company through the conversion of related-party payables into the Series A redeemable convertible preferred stock ("Series A").
- Amounts related to equity-based awards issued by BridgeBio Pharma and allocated to the Company based on the carve-out expense allocation methodology (refer to Note 13). These amounts were not expected or required to be settled in cash and were credited to stockholders' equity (deficit), within additional paid-in capital.

Subsequent to April 30, 2024, stock-based compensation includes expenses related to common stock options granted by the Company. The associated stock-based compensation is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures of share-based awards are accounted for as they occur. The fair value of stock options is estimated on the grant date using the Black-Scholes option-pricing model, which requires certain assumptions further discussed below:

- **Fair Value of Common Stock** — Prior to the de-SPAC Transaction, the fair value of the Company's common stock was determined by the board of directors ("Board") with input from management and consideration of third-party valuation reports. In the absence of a public trading market, and as a clinical-stage company with no significant revenues, the Company believes that it was appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. In addition, the Company considered various objective and subjective factors, along with input from the independent third-party valuation firm. The factors included (1) the achievement of the development milestones by the Company; (2) the significant risks associated with the Company's stage of development; (3) capital market conditions for comparable, privately held, early-stage life science companies; (4) the Company's available liquidity, financial condition, and results of operations; (5) the sales of the Company's shares to third parties, such as the Series B financing; and (6) the preferential rights of the redeemable convertible preferred stockholders. Following the de-SPAC Transaction, the Company became a public entity and derives fair value of its common stock from quoted prices on the Nasdaq.
- **Expected Dividend Yield** — The Company has historically paid no dividends and does not anticipate paying dividends in the future.
- **Expected Equity Volatility** — The Company does not have sufficient trading history for its common stock and has computed expected volatility based on the historical volatility of a representative group of public companies with similar characteristics to the Company (e.g., public entities of similar size, complexity, stage of development, and industry focus). The historical volatility is commensurate with the expected term assumption.
- **Risk-Free Interest Rate** — The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of award grant for the expected term of the award.
- **Expected Term** — The Company uses the simplified method to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis for estimating the expected term.

Participation Right Liability

The participation right liability represented the right granted to a third party to potentially participate in future Series B offerings at a fixed price of \$8.8554 per share. The participation right was a freestanding instrument substantially similar to a written call option on the Series B shares that may be redeemed outside of the Company's control. As such, the Company classified the participation right as a liability, remeasured at fair value, until its full exercise and settlement, which occurred in April 2025. Changes in the fair value of the participation right liability are presented separately in the consolidated statements of operations. On the settlement date, in April 2025, the participation right liability was remeasured to the intrinsic value of the shares issued and reclassified to temporary equity.

Accrued Milestone Compensation Arrangements

During the year ended December 31, 2024, we had performance-based milestone compensation arrangements with certain employees and consultants, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled upon achievement of certain contingent milestones in the form of (1) cash, (2) equity of BridgeBio Pharma, or (3) cash or equity of BridgeBio Pharma or the Company at the issuer's sole election. No performance milestone awards that may be settled in the Company's shares or related liabilities were outstanding during the year ended December 31, 2025.

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For arrangements that involve settlement by cash or equity of BridgeBio Pharma or the Company at their sole election, the Company classifies the milestone compensation arrangements as liability-classified awards when they are assessed as probable of achievement due to the possible fixed monetary settlement outcomes. The arrangements could also result in a settlement with a variable number of shares based on the then-current stock price at the achievement date of each contingent milestone, should we elect to settle in equity.

We record accruals for the compensation expense arising from each development milestone when the specific contingent development milestone is probable of achievement, and such accruals are measured at each reporting period. We estimate the probability of achieving such milestones based on the progression and expected outcome of the related clinical programs. We base our estimates on the best available information at that time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to milestone compensation expenses in future periods. Any increases or decreases in such expenses are generally considered to be changes in estimates and will be reflected in the reporting period identified.

Income Taxes

Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the carrying amounts of existing assets and liabilities in the consolidated financial statements, their respective tax bases, and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are determined based on the difference between the carrying amounts under U.S. GAAP and the tax basis of assets and liabilities and are measured using the enacted tax rate expected to apply to taxable income in the years in which the differences are expected to be reversed. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We evaluate our deferred tax assets regularly to determine whether adjustments to the valuation allowance are appropriate due to changes in facts or circumstances, such as changes in expected future pre-tax earnings, tax law, interactions with taxing authorities, and developments in case law. In making this evaluation, we rely on our recent history of pre-tax earnings or losses. Our material assumptions include forecasts of future pre-tax earnings and the nature and timing of future deductions and income represented by deferred tax assets and liabilities, all of which involve judgment. Although we believe our estimates are reasonable, we are required to exercise significant judgment in determining the appropriate valuation allowance for deferred tax assets.

We recognize uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. Changes in recognition or measurement are reflected in the period in which judgment occurs. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of the provision for income taxes. To date, no interest or penalties have been recorded concerning unrecognized tax benefits.

Net Loss per Share Attributable to Common Stockholders

Prior to the Closing of the de-SPAC Transaction, the Company applied the two-class method to compute net loss per share, as it had issued redeemable convertible preferred stock that met the definition of participating securities. The two-class method required income available to common shareholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. Upon the de-SPAC Transaction, the outstanding redeemable convertible preferred stock was converted into common stock, and the two-class method is no longer applicable.

Basic net loss per share attributable to common shareholders is computed by dividing the net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding, adjusted for the effect of potentially dilutive common shares, including stock options and other equity-linked instruments. Potentially dilutive common shares are not assumed to be issued if their effect is anti-dilutive. As such, in periods in which the Company reported a net loss, diluted net loss per share attributable to common stockholders was the same as basic net loss per share attributable to common stockholders because the effects of potentially dilutive securities were anti-dilutive.

Redeemable Convertible Preferred Stock

The Company initially records redeemable convertible preferred stock at fair value on the dates of issuance, less issuance costs. Prior to the de-SPAC Transaction, the preferred stockholders, as a group, controlled the Company's Board and had the ability to initiate a deemed liquidation event, such as a change in control or transfer of substantially all of the Company's assets. Upon a deemed liquidation event, the preferred stockholders as a group could cause the redeemable convertible preferred stock to be redeemed for cash and other assets available for distribution. Based on these considerations, the redeemable convertible preferred stock was classified in temporary

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equity outside of the stockholders' equity (deficit) in the accompanying consolidated balance sheets. Subsequent adjustments to the carrying values of the redeemable convertible preferred stock classified in temporary equity are made only if it becomes probable that such liquidation events would occur, causing the shares to become redeemable. No such adjustments were made since the underlying events were not probable while the redeemable convertible preferred stock was outstanding.

The Company also evaluated the features of its redeemable convertible preferred stock to determine whether they required bifurcation from the underlying shares by assessing whether they were clearly and closely related to the underlying shares and whether they met the definition of a derivative. The Company concluded that no features of its outstanding redeemable convertible preferred stock required bifurcation and separate accounting.

In determining if an extinguishment or modification of changes to the temporary equity-classified preferred stock had occurred, the Company had elected a policy to evaluate if changes added, deleted, or significantly changed a substantive contractual term (e.g., one that was at least reasonably possible of being exercised), or fundamentally changed the nature of the redeemable convertible preferred stock. This evaluation considered both the expected economics and the business purpose of the amendment.

Other Comprehensive Income or Loss

Other comprehensive income or loss represents the change in the Company's stockholders' equity (deficit) from all sources other than investments by or distributions to stockholders. The Company's other comprehensive income or loss is the result of unrealized gains and losses on marketable securities.

Deferred de-SPAC Transaction Costs

The Company capitalized certain directly attributable legal, accounting, and other third-party fees associated with the de-SPAC Transaction as deferred transaction costs. Upon Closing of the de-SPAC Transaction, the associated costs capitalized by the Company were recorded to additional paid-in capital as a reduction of the proceeds from the de-SPAC Transaction.

Emerging Growth Company Status

The Company intends to operate as an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, EGCs can delay adopting new or revised accounting standards as of effective dates for private companies. The Company historically operated as part of BridgeBio Pharma and adopted new accounting pronouncements using the same timeline as BridgeBio Pharma. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of the effective dates for public companies.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state, and foreign taxes and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. The Company adopted the guidance using a retrospective approach in these annual consolidated financial statements for the year ending December 31, 2025. The adoption of this new guidance resulted in additional disclosures presented in Note 11 to these consolidated financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement — Reporting Comprehensive Income (Topic 220): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires public entities to provide disaggregated disclosures of certain expense captions presented on the face of the income statement into specific categories within the footnotes to the financial statements. ASU 2024-03 is effective for the Company's annual periods beginning on January 1, 2027, and interim periods beginning on January 1, 2028, with early adoption permitted. The ASU may be applied either on a prospective or retrospective basis. The Company is currently evaluating the impact of adopting this new accounting guidance on its consolidated financial statements and related disclosures.

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In May 2025, the FASB issued Accounting Standards Update No. 2025-03, *Business Combinations (Topic 805) and Consolidation (Topic 810): Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity* (“ASU 2025-03”). ASU 2025-03 changes how companies determine the accounting acquirer in certain business combinations involving variable interest entities. The new guidance requires considering the factors used for other acquisition transactions to assess which party is the accounting acquirer. ASU 2025-03 is effective for the Company’s annual reporting periods beginning on January 1, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting this new accounting guidance on its consolidated financial statements and related disclosures.

In May 2025, the FASB issued Accounting Standards Update No. 2025-04, *Compensation – Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Clarifications to Share-Based Consideration Payable to a Customer* (“ASU 2025-04”). ASU 2025-04 revises the definition of a performance condition, eliminates the forfeiture policy election for service conditions, and clarifies that the variable consideration constraint in Topic 606 does not apply to share-based consideration payable to customers. The new guidance requires entities to consistently account for share-based awards granted to customers by clarifying the treatment of vesting conditions and ensuring alignment with Topic 606 and Topic 718. ASU 2025-04 is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting this new accounting guidance on its consolidated financial statements and related disclosures.

In July 2025, the FASB issued ASU No. 2025-05, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets* (“ASU 2025-05”). ASU 2025-05 provides an optional practical expedient for estimating future credit losses based on current conditions as of the balance sheet date and assuming those conditions do not change over the remaining life of the accounts receivable. The amendments in ASU 2025-05 are effective for fiscal years beginning after December 15, 2025, including interim periods within those fiscal years. The Company is currently evaluating the impact of adopting this new accounting guidance on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606)* (“ASU 2025-07”). The guidance refines the scope of Topic 815 to clarify which contracts are subject to derivative accounting. The guidance also provides clarification under Topic 606 for share-based payments from a customer in a revenue contract. The amendments in ASU 2025-07 are effective for fiscal years beginning after December 15, 2026, and interim reporting periods, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2025-07 on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements* (“ASU 2025-12”). ASU 2025-12 provides for technical corrections, clarifications and other minor improvements to a variety of Topics. This guidance is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods and may be adopted on a prospective or retrospective basis on an issue-by-issue basis, except changes to Topic 260, *Earnings Per Share* are required to be applied retrospectively. Early adoption is permitted on an issue-by-issue basis. The Company is currently evaluating the impact of ASU 2025-12 on its consolidated financial statements and related disclosures.

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3. PIPE Financing and de-SPAC Transaction

Immediately prior to the de-SPAC Transaction described in Note 1, Helix issued and sold to investors in the PIPE Financing 24,343,711 shares of its common stock for gross proceeds of \$260.9 million. In connection with the de-SPAC Transaction, Helix redomiciled as a Delaware corporation and de-registered from the Register of Companies in the Cayman Islands, and Legacy BBOT became a wholly-owned subsidiary of Helix. As a result, BBOT, as the combined company, received \$112.3 million in net proceeds from the Trust account previously held by Helix. The Company incurred total transaction costs of \$12.4 million consisting of legal, accounting, and other professional fees, of which \$0.1 million remained unpaid as of December 31, 2025. The Company's total de-SPAC Transaction costs were recorded to additional paid-in capital as a reduction of the deemed proceeds from the PIPE Financing and the Trust Account.

Upon the Closing of the de-SPAC Transaction, the following occurred with respect to the equity of Legacy BBOT:

- Each outstanding share of Legacy BBOT redeemable convertible preferred stock issued and outstanding as of the Closing date was converted into Legacy BBOT common stock.
- The shares of Legacy BBOT common stock that were issued and outstanding immediately prior to the Closing were cancelled and converted into the right to receive 38,924,563 shares of the Company's common stock at the Consideration Ratio;
- All outstanding and unexercised Legacy BBOT common stock options were converted into an aggregate of 4,078,552 common stock options of the Company with the same terms and conditions, adjusted based on the Consideration Ratio.

Immediately after the Closing, the Company's outstanding common stock included the following components:

	Shares
Legacy BBOT common stock	38,924,563
Helix common stock subject to redemption prior to the Closing	18,400,000
Redemption of Helix common stock	(7,119,750)
Helix common stock held by the Sponsor	4,648,186
Common stock of Helix issued in the PIPE Financing	24,343,711
Total common stock issued and outstanding	<u>79,196,710</u>

The de-SPAC Transaction was accounted for as a reverse recapitalization under US GAAP because Legacy BBOT was identified as the accounting acquirer and Helix as the accounting acquiree for financial reporting purposes. Accordingly, these consolidated financial statements of the Company are presented as a continuation of the financial statements of Legacy BBOT. The de-SPAC Transaction is presented as the issuance of common stock by BBOT for the net assets of Helix and proceeds from the PIPE Financing, accompanied by a recapitalization and a change in the reporting entity. The net assets of Helix were recorded at historical cost as of the Closing date, with no goodwill or other intangible assets recognized.

Legacy BBOT was determined to be the accounting acquirer based on the following facts and circumstances as of the Closing date:

- Legacy BBOT stockholders comprised a relative majority of the voting power of BBOT;
- Legacy BBOT stockholders received the ability to influence decisions regarding the election and removal of members of BBOT's board of directors;
- Legacy BBOT stockholders received the right to appoint the majority of the BBOT board of directors;
- Legacy BBOT's operations prior to the de-SPAC Transaction comprised the only ongoing operations of BBOT;
- BBOT substantially assumed the Legacy BBOT name;
- Legacy BBOT's headquarters became BBOT's headquarters;
- Legacy BBOT's senior management comprised the senior management of BBOT; and
- Prior to the Closing, Helix did not meet the definition of a business.

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4. Fair Value Measurements and Disclosures

The following tables summarize the Company's assets and liabilities measured at fair value on a recurring basis by level within the valuation hierarchy (in thousands):

December 31, 2025				
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	\$ 366,348	\$ —	\$ —	\$ 366,348
Commercial paper	—	5,484	—	5,484
Total cash equivalents	\$ 366,348	\$ 5,484	\$ —	\$ 371,832
Marketable securities:				
Commercial paper	\$ —	7,313	\$ —	7,313
Corporate debt securities	—	44,460	—	44,460
Total marketable securities	\$ —	\$ 51,773	\$ —	\$ 51,773
Total assets	\$ 366,348	\$ 57,257	\$ —	\$ 423,605
December 31, 2024				
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	\$ 30,666	\$ —	\$ —	\$ 30,666
Total cash equivalents	\$ 30,666	\$ —	\$ —	\$ 30,666
Marketable securities:				
Treasury bills	\$ 30,932	\$ —	\$ —	\$ 30,932
Commercial paper	—	5,876	—	5,876
Corporate debt securities	—	87,972	—	87,972
Total marketable securities	\$ 30,932	\$ 93,848	\$ —	\$ 124,780
Total assets	\$ 61,598	\$ 93,848	\$ —	\$ 155,446
Liability				
Participation right liability	\$ —	\$ —	\$ 3,105	\$ 3,105
Total liabilities	\$ —	\$ —	\$ 3,105	\$ 3,105

Money market funds and treasury bills are highly liquid and actively traded marketable securities that generally transact at a stable \$1.00 net asset value, representing their estimated fair value. The fair value of marketable securities is based upon observable market inputs obtained from third-party pricing services. The pricing services use industry-standard valuation models and observable inputs, including reported trades, broker-dealer quotes, bids or offers on the same or similar securities issuer, credit spreads, benchmark securities, prepayment and default projections based on historical data, and other observable inputs. As of December 31, 2025 and 2024, the Company's marketable securities have maturities of less than one year and are classified as current assets.

The following table summarizes the activity of the Company's participation right liability, which was previously measured using unobservable inputs through its settlement in April 2025 (in thousands):

Balance as of December 31, 2024	\$ 3,105
Change in fair value of participation right liability	725
Settlement of participation right liability	(3,830)
Balance as of December 31, 2025	\$ —

As of the settlement date, the fair value of the participation right liability approximated the intrinsic value per Series B share issued. The fair value per Series B share was estimated using the Probability-Weighted Expected Return Method ("PWERM"). Under the PWERM, we considered various liquidity events, including the de-SPAC Transaction, an initial public offering, and a sale of the Company, assigned probability to each liquidity scenario, and estimated the fair value per Series B share using the following assumptions:

Probability of a qualifying liquidity event	15.0% – 50.0%
Expected term, years	0.29 – 1.67
Discount rate	20.0%

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The following tables summarize the amortized cost and fair value of the Company's cash equivalents and marketable securities by major investment category for the periods indicated (in thousands):

	December 31, 2025			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities:				
Commercial paper	\$ 7,311	\$ 2	\$ —	\$ 7,313
Corporate debt securities	44,446	18	(4)	44,460
Total marketable securities	<u>\$ 51,757</u>	<u>\$ 20</u>	<u>\$ (4)</u>	<u>\$ 51,773</u>

	December 31, 2024			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities:				
Treasury bills	\$ 30,825	\$ 107	\$ —	\$ 30,932
Commercial paper	5,857	19	—	5,876
Corporate debt securities	87,750	222	—	87,972
Total marketable securities	<u>\$ 124,432</u>	<u>\$ 348</u>	<u>\$ —</u>	<u>\$ 124,780</u>

There were no unrealized gains or losses on cash equivalents as of December 31, 2025, and December 31, 2024. There were no marketable securities in an unrealized loss position as of December 31, 2024. Unrealized losses on marketable securities were nominal as of December 31, 2025, and were attributable to changes in interest rates rather than credit deterioration. The Company does not intend to sell securities and it is not more likely than not that it will be required to sell them before recovery of amortized cost, the losses were considered temporary. No allowance for credit losses was recorded as of December 31, 2025 and December 31, 2024, the Company invests in high-quality short-term instruments, all of which have maturities under one year and no history of credit deterioration.

5. In-Licensing and Collaboration Agreements

From time to time, the Company enters into asset purchase and license agreements with third parties as a purchaser or licensee. These arrangements are generally accounted for as asset acquisitions, as the fair value of the consideration is concentrated in a single identifiable asset or group of similar identifiable assets. Given their stage of development, these assets typically have no alternative future use and are expensed as of the acquisition date.

The Regents of the University of California License Agreements

In September 2016, the Company entered into a license agreement with Regents of the University of California, San Francisco ("UCSF") and was granted certain worldwide exclusive licenses to use the licensed compounds (the "UCSF License"). The UCSF License was subsequently amended and terminated in June 2021. However, certain terms survived the termination of the UCSF License. Upon a change of control or an initial public offering, Legacy BBOT was required to make a payment to UCSF ("Indexed Milestone Payment"). The Company believes that no such payment will be due now or in the future.

Under the UCSF License, UCSF received a right but not an obligation to purchase up to 10% of securities in any offering on the same terms as other investors ("Participation Right"), which survived the termination of the UCSF License. Because UCSF was not notified of the Series B financing at the time it was completed in May 2024, the Participation Right was extended through March 29, 2025. As a result, UCSF received the right to purchase up to 2,509,446 shares of the Series B redeemable convertible preferred stock at the original issue price of \$8.8554 per share. As of December 31, 2024, the Company recognized a liability of \$22.2 million in connection with the Participation Right. In March 2025, UCSF elected to exercise the Participation Right in full. The Participation Right was settled in full in April 2025 (Note 8) and was no longer outstanding as of December 31, 2025.

Leidos Biomedical Research License and Cooperative Research and Development Agreements

In March 2017, the Company entered into a cooperative research and development agreement ("Leidos CRADA") with Leidos Biomedical Research, Inc. ("Leidos"). The Company and Leidos executed subsequent amendments to the Leidos CRADA between January 2018 and September 2025 to clarify the scope and provide for term extensions. In December 2018, the Company and Leidos entered into a license agreement ("Initial Leidos License"), under which the Company was granted certain worldwide exclusive licenses to use the licensed compounds for its drug discovery and development initiatives. The Initial Leidos License was terminated in 2021. The

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Company and Leidos subsequently entered into three additional license agreements (“Additional Leidos Licenses”), including two related to KRAS G12C inhibitor and PI3Kα breaker compounds that were executed in August 2022, and one related to the PanKRAS inhibitor executed in December 2023. The Leidos CRADA, Initial Leidos License, and Additional Leidos Licenses are referred to as the “Leidos Agreements.” In December 2025, the Company and Leidos executed an amendment to extend the expiration date of the Leidos CRADA by nine months to September 2026. In December 2025, the Company and Leidos amended the Leidos Agreements to introduce an additional \$1.5 million in contingent development milestone payments.

Under the Additional Leidos Licenses, the Company previously incurred initial upfront fees of \$1.8 million. The Company is required to pay Leidos annual license maintenance fees of \$0.5 million, as well as royalties on net sales for such licensed compounds calculated using low single-digit percentages of annual net sales of licensed products. The Company’s obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country. Leidos is also entitled to receive a low double-digit percentage of the sublicensing income received by the Company. As of December 31, 2025, the Company is obligated to make contingent milestone payments totaling up to \$25.9 million upon the achievement of certain clinical and regulatory milestones. As of December 31, 2025, the Company recorded a \$0.5 million liability for milestones that had been achieved but remained unpaid, which is included in the accrued research and development liabilities in the consolidated balance sheet. For the years ended December 31, 2025 and 2024, the Company recognized research and development expenses of \$3.0 million and \$3.6 million, respectively, in connection with the Leidos Agreements.

Lawrence Livermore National Security License and Cooperative Research and Development Agreements

In May 2018, the Company entered into a cooperative research and development agreement (“LLNS CRADA”) with Lawrence Livermore National Security, LLC (“LLNS”) to explore new knowledge therapeutics possibilities to KRAS drug discovery utilizing LLNS’s high-performance computing systems. The Company and LLNS executed subsequent amendments to the LLNS CRADA between December 2019 and November 2025 to clarify the scope and provide for term extensions. In July 2022, the Company entered into an exclusive patent license agreement for KRAS G12C inhibitors and an exclusive patent license agreement for PI3Kα breaker compounds. In December 2024, the Company entered into an exclusive license agreement with LLNS for research and development of a Pan KRAS inhibitor. These three agreements are collectively referred to as the LLNS Agreements. In July 2025, BBOT entered into an exclusive license agreement with LLNS for research and development of Pan KRAS inhibitor for non-oncology indications. In November 2025, the Company and LLNS executed three separate amendments to the existing agreements for Pan KRAS inhibitors, PI3Kα breakers, and KRAS G12C inhibitors. These amendments were made to include new patent applications within the scope of patent rights. In November 2025, the Company and LLNS executed an amendment to extend the LLNS CRADA expiration date by six months to June 2026.

Upon execution of the LLNS Agreements, the Company paid initial upfront cash fees of \$0.2 million. In addition, under the terms of the LLNS Agreements, the Company is required to pay LLNS certain annual license maintenance fees of \$0.1 million and royalties to LLNS on net sales for such licensed compounds. With respect to such royalty obligations, the Company agreed to pay LLNS low single-digit percentage tiered royalties on annual net sales of licensed products, with a minimum royalty requirement ranging between \$0.1 million and \$0.5 million, depending on the anniversary of the first commercial sale of the products. The Company’s obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country. LLNS is also entitled to receive half of the Company’s sublicensing income, capped at \$2.0 million per year for each indication. As of December 31, 2025, the Company is required to make contingent milestone payments totaling up to \$21.1 million upon the achievement of certain clinical, regulatory, and sales milestones. For the years ended December 31, 2025 and 2024, the Company recognized research and development expenses of \$0.8 million and \$2.1 million, respectively, in connection with the LLNS Agreements.

6. Income from Transition Services Agreement

In August 2025, we entered into a transition services agreement (“TSA”) with an unrelated party (“TSA Party”) to provide certain services unrelated to our principal operations, which represent the only performance obligation under this arrangement. For the year ended December 31, 2025, the Company recorded \$1.2 million in connection with the TSA, which is presented separately as other income from transition services agreements in the consolidated statements of operations. The corresponding amounts for the year ended December 31, 2024 represent income from a different transition services agreement with BridgeBio Pharma (Note 13).

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

7. Commitments and Contingencies

Other Research and Development Agreements

We may also enter into contracts in the normal course of business with contract research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies, supplies, and other services and products for operating purposes. These contracts generally provide for termination on notice with potential termination charges.

Cash Bonus with Performance Conditions

In May 2024, the Company committed to making a \$3.0 million cash payment to an executive contingent upon the consummation of an equity financing, a change-in-control transaction, an initial public offering, or a reverse merger with a SPAC. The Company recorded a \$3.0 million performance cash bonus payment to the executive upon closing of the de-SPAC Transaction, which was paid during the year ended December 31, 2025.

Indemnification

In the ordinary course of business, we may provide indemnifications of varying scope and terms to vendors, lessors, business partners, Board members, officers, and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by us, our negligence or willful misconduct, violations of law, or intellectual property infringement claims made by third parties. No material demands have been made upon us to provide indemnification under such agreements, and thus, there are no claims that we are aware of that could have a material effect on our consolidated financial statements.

Contingencies

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 is not currently involved in any legal actions that could have a material effect on the Company's financial position, results of operations, or liquidity.

8. Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

Redeemable Convertible Preferred Stock

In February 2025, one investor elected to voluntarily convert 21,783 shares of the Series B redeemable convertible preferred stock into common stock. In March 2025, UCSF elected to exercise the Participation Right, and the Company settled the Participation Right in full in April 2025 through the issuance of 2,509,446 Series B shares for cash proceeds of \$22.2 million, and the amount credited to redeemable convertible preferred stock included the settlement date fair value of the participation right liability of \$3.8 million.

In August 2025, the Company's outstanding redeemable convertible preferred stock was converted into common stock, immediately before the Closing of the de-SPAC Transaction discussed in Note 3. As of December 31, 2024, the redeemable convertible preferred stock consisted of the following balances (in thousands, except share and per share amounts):

As of December 31, 2024					
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Carrying Value	Aggregate Liquidation Preference
Series Seed	800,061	800,061	\$ 1.2508	\$ 1,001	\$ 1,001
Series A	13,001,634	13,001,634	\$ 11.2467	125,637	146,226
Series B	22,585,007	22,585,007	\$ 8.8554	196,720	200,000
Total	36,386,702	36,386,702		\$ 323,358	\$ 347,227

Prior to the August 2025 conversion, the holders of the redeemable convertible preferred stock were entitled to different rights, preferences, privileges, and restrictions regarding voting, dividends, liquidation, conversion, and redemption.

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

Voting Rights

Each share of the redeemable convertible preferred stock had voting rights equal to the number of shares of common stock into which it was convertible. The holders of redeemable convertible preferred stock voted together with the holders of common stock as a single class.

Dividends

The holders of the redeemable convertible preferred stock were entitled to receive noncumulative dividends at an annual rate of 8.0% of the original issuance price per share of the respective series when declared by the Company's Board prior and in preference to any dividends on common stock. The holders of the redeemable convertible preferred stock had priority and were entitled to participate in any distributions to the holders of common stock on an as-converted basis. No dividends have been declared or paid by the Company since its inception and through December 31, 2025.

Redemption

Shares of the redeemable convertible preferred stock were contingently redeemable upon the occurrence of certain change in control events that were outside the Company's control, including a sale, lease, transfer, or other disposition of all or substantially all of the Company's assets, merger with a special purpose acquisition company or with a public company ("Deemed Liquidation Event"). The following stockholders group were each required to vote to initiate or waive such redemption: (i) the holders of a majority of the then outstanding shares of the redeemable convertible preferred stock, voting together as a single class on an as-converted into common stock basis ("Requisite Holders"), and (ii) the holders of a majority of the then outstanding shares of the Series B, voting as a separate class ("Requisite Series B Holders"). Subsequent adjustments to the carrying values of the liquidation preferences were only required to be made if it became probable that such a liquidation event would occur. No subsequent measurement adjustments were recorded through August 2025.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, and upon a Deemed Liquidation Event, the holders of the redeemable convertible preferred stock were entitled to receive, with equal priority among them, prior and in preference to any distribution of any of the Company's assets to the holders of common stock, an amount equal to the greater of (a) the original issue price per share of redeemable convertible preferred stock of the respective series then outstanding, plus any declared or accrued but unpaid dividends, or (b) an amount payable on an as-converted into common stock basis. After payment of the preferential amounts to the holders of the redeemable convertible preferred stock, the remaining assets of the Company available for distribution were to be distributed among the holders of common stock in proportion to the number of shares then held.

Conversion Rights

At the option of the holder, each share of the redeemable convertible preferred stock was convertible at any time into such number of shares of common stock as determined by dividing the original issue price per share of the respective series by the applicable conversion price. The initial conversion price per share was equal to the original issue price per share of the respective series. The conversion price of the redeemable convertible preferred stock was subject to adjustments for recapitalizations and under anti-dilution provisions contained in the Company's amended and restated certificate of incorporation.

All outstanding shares of the redeemable convertible preferred stock were subject to automatic conversion into shares of common stock, at the applicable conversion price, upon either of the following: (a) the closing of the sale of shares of common stock at a price per share of at least \$17.7109, as adjusted to reflect the Consideration Ratio, in a firm-commitment underwritten public offering under the Securities Act of 1933, as amended, resulting in at least \$100.0 million of proceeds to the Company, net of the underwriting discount and commissions, and on a qualified stock exchange, or (b) the date and time, or the occurrence of an event, specified by the Requisite Holders and the Requisite Series B Holders, voting or consenting as two separate groups.

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

Common Stock

Amendment to Certificate of Incorporation

In April 2025, the Company amended and restated its certificate of incorporation to increase the authorized redeemable convertible preferred stock from 36,386,702 to 38,896,148 shares and the authorized common stock from 41,341,250 to 44,008,427 shares.

In August 2025, in connection with the de-SPAC Transaction, the Company filed a new certificate of incorporation that authorized the issuance of up to 510,000,000 shares with a par value of \$0.0001 per share, including 500,000,000 shares of common stock, and 10,000,000 shares of undesignated preferred stock.

Shares Reserved for Issuance

The Company had the following shares reserved for issuance:

	December 31, 2025	December 31, 2024
Common stock options issued and outstanding	9,035,498	3,641,671
Redeemable convertible preferred stock on an as-converted into common stock basis	—	36,386,702
Shares available for issuance under the stock option and incentive plan	459,417	474,374
Shares available for issuance under the employee stock purchase plan	895,607	—
Shares available for issuance under the inducement plan	1,046,940	—
Shares issuable under the participation right	—	2,509,446
Total	11,437,462	43,012,193

9. Leases

In November 2024, the Company entered into an agreement for the lease of approximately 10,934 square feet of office space in South San Francisco, California, for 61 months. The Company has the option to renew for an additional four-year term. The renewal option was not reasonably certain to be exercised by the Company and was excluded from the lease term. The lease commenced in March 2025 and will expire in April 2030. The associated lease costs were not material during the year ended December 31, 2025. As of December 31, 2025, the weighted-average remaining lease term for the Company's lease was 4.3 years, and the discount rate used was 7.40%.

The following table presents the amortization of the Company's lease liabilities (in thousands):

Fiscal year ended December 31:	
2026	705
2027	730
2028	755
2029	782
2030	263
Total lease payments	\$ 3,235
Less: imputed interest	(469)
Total operating lease liabilities	\$ 2,766

Short-term lease costs were \$1.1 million and \$1.5 million for the years ended December 31, 2025 and 2024, respectively.

10. Stock-Based Compensation

Stock-based compensation is included under the following expense categories presented in the consolidated statements of operations (in thousands):

	Year ended December 31,	
	2025	2024
Research and development	\$ 3,551	\$ 3,073
General and administrative	2,322	1,352
Total	\$ 5,873	\$ 4,425

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

Stock-based compensation is comprised of the following components, as further described below (in thousands):

	Year ended December 31,	
	2025	2024
Common stock options issued by the Company	\$ 5,873	\$ 1,355
Performance-based milestone awards	—	1,125
Equity awards issued by BridgeBio Pharma	—	1,006
Amounts recognized under the carve-out methodology	—	939
Total	<u>\$ 5,873</u>	<u>\$ 4,425</u>

Common Stock Options Issued and Other Equity-Based Awards Issued by the Company

2016 Equity Incentive Plan

In January 2017, the Company adopted the 2016 Equity Incentive Plan (“2016 Plan”). The 2016 Plan provides for the grant of stock-based incentive awards, including common stock options and other forms of stock-based compensation. Any cancelled or forfeited awards under the 2016 Plan become available for future issuances. As of December 31, 2025, no shares were reserved for future issuance under the 2016 Plan.

2025 Stock Option and Incentive Plan

In August 2025, the Company adopted the 2025 Stock Option and Incentive Plan (“2025 Plan”). The 2025 Plan provides for the grant of equity and equity-based incentive awards, such as stock options and other forms of stock-based compensation, to officers, employees, directors, and consultants. Any cancelled or forfeited awards under the 2025 Plan become available for future issuances. As of December 31, 2025, 459,417 shares were available for future grants under the 2025 Plan.

2025 Employee Stock Purchase Plan

In August 2025, the Company adopted the 2025 Employee Stock Purchase Plan (“ESPP”). Under the ESPP, eligible employees may purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the fair market value of the common stock on the offering date or the exercise date, whichever is less. As of December 31, 2025, 895,607 shares were available for future grants under the ESPP, and no offering periods had started.

2025 Inducement Plan

In October 2025, the Company adopted the 2025 Inducement Plan (“2025 Inducement Plan”) to be used for grants of equity-based awards to individuals who were not previously its employees or directors as an inducement for entry into employment. Any cancelled or forfeited awards under the 2025 Inducement Plan become available for future issuances. As of December 31, 2025, 1,046,940 shares were available for future grants under the Inducement Plan.

Outstanding Common Stock Options

The Company had the following common stock options outstanding:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding as of December 31, 2024	3,641,671	\$ 4.24	9.5	\$ 3,437
Granted	5,751,509	9.90		
Exercised	(10,338)	4.39		
Forfeited and cancelled	(347,344)	5.54		
Outstanding as of December 31, 2025	<u>9,035,498</u>	\$ 7.79	9.0	\$ 42,771
Exercisable as of December 31, 2025	<u>1,680,981</u>	\$ 5.25	8.0	\$ 12,228

BridgeBio Oncology Therapeutics, Inc.
Notes to Consolidated Financial Statements

The aggregate intrinsic value in the above table is calculated as the difference between the estimated fair value of the Company's common stock and the exercise price of the underlying stock options as of each reporting date.

As of December 31, 2025, a total of 1,730,153 common stock options included provisions for accelerated vesting in connection with a qualified change in control of the Company. These instruments included 1,507,214 options, with vesting if the grantee is terminated without cause, as defined in the 2016 Plan, or for good reason, as defined in the grant terms, within 12 months following such a transaction. The remaining 222,939 options vest immediately upon the occurrence of a qualified change in control, excluding events such as an initial public offering or other bona fide financing transactions. The closing of the de-SPAC Transaction described in Note 1 did not constitute a qualified change in control event under these definitions.

The weighted-average grant-date fair value of common stock options granted during the year ended December 31, 2025 was \$6.70 per share. The weighted-average grant-date fair value of common stock options vested and forfeited during the year ended December 31, 2025 was \$3.38 per share and \$3.69 per share, respectively. As of December 31, 2025, there was \$41.2 million of unrecognized stock-based compensation related to unvested common stock options, which is expected to be recognized over a weighted-average period of 3.3 years.

The weighted-average grant-date fair value of common stock options granted during the year ended December 31, 2024 was \$2.81 per share. The weighted-average grant-date fair value of common stock options vested and forfeited during the year ended December 31, 2024 was, in each case, \$2.70 per share.

The fair value of stock options granted during the years ended December 31, 2025 and 2024 was estimated at the grant date using the Black-Scholes option pricing model based on the following assumptions:

	Year ended December 31,	
	2025	2024
Expected term, years	5.66 - 6.08	6.02 - 6.08
Expected volatility	71.3% - 74.1%	70.2% - 70.9%
Expected dividends	—	—
Risk-free interest rate	3.7% - 3.8%	3.6% - 4.5%

Performance-Based Milestone Awards of the Company

In May 2024, the Company granted a performance award of \$1.1 million to an executive. This award could be settled in the form of cash or equity at the Company's sole discretion, and the associated amount is classified as stock-based compensation within research and development expenses. The underlying milestone was achieved, and this award was settled in cash during the year ended December 31, 2024. No performance milestone awards that may be settled in the Company's shares or related liabilities were outstanding during the year ended December 31, 2025.

Equity Awards Issued by BridgeBio Pharma

Prior to April 30, 2024, the Company operated as part of BridgeBio Pharma, and certain non-employees received restricted stock units of BridgeBio Pharma as compensation for research and development services related to the Company's operations. The Company recognized the grant date fair value of these awards as expenses over the applicable vesting term, with a corresponding credit to related party liability. The Company subsequently reimbursed BridgeBio Pharma for these charges through the conversion of these amounts into shares of Series A redeemable convertible preferred stock.

Amounts Recognized under the Carve-Out Methodology

The amounts recognized under the carve-out methodology represent allocated stock-based compensation for certain management and administrative services provided by BridgeBio Pharma (Note 13).

11. Income Taxes

The Company accounts for income taxes in accordance with authoritative guidance, which requires the use of the asset and liability method. Under this method, deferred income tax assets and liabilities are determined based upon the difference between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities and are measured using the enacted tax rate expected to apply to taxable income in the years in which the differences are expected to be reversed.

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Notes to Consolidated Financial Statements

The Company's net losses for the years ended December 31, 2025 and 2024 have been derived in the United States. No current or deferred income taxes were recorded, and no material income tax payments were made during the years ended December 31, 2025 and 2024.

The following table presents a reconciliation of the statutory federal rate and our effective tax rate (in thousands, except percentages):

	Year Ended December 31, 2025		Year Ended December 31, 2024	
	Amounts	Percentages	Amounts	Percentages
Income tax benefit at statutory rate	\$ (28,149)	21.0%	\$ (15,598)	21.0%
Changes in valuation allowance	29,126	(21.7)%	13,748	(18.5)%
Tax credits	(2,499)	1.9%	(2,777)	3.7%
Change in unrecognized tax benefits	625	(0.5)%	694	(0.9)%
Nontaxable and nondeductible items	1,181	(0.9)%	136	(0.2)%
Initiation of standalone operations	—	—	3,797	(5.1)%
Other adjustments	(284)	0.2%	—	—
Income tax benefit at effective rate	<u>\$ —</u>	<u>— %</u>	<u>\$ —</u>	<u>— %</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The following table presents the significant components of the Company's deferred tax assets and liabilities for the periods presented (in thousands):

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating loss carryforwards	\$ 42,732	\$ 13,699
Property and equipment	49	—
Accruals and reserves	1,525	557
Amortization of intangibles not recognized under GAAP	2,515	1,081
Stock-based compensation	1,509	274
Capitalized research and experimental expenditures	32,237	25,641
Tax credits	6,490	3,939
Other	825	—
Gross deferred tax assets	87,882	45,191
Valuation allowance	(87,182)	(45,180)
Deferred tax assets, net of valuation allowance	700	11
Deferred tax liabilities:		
Property and equipment	—	(11)
Other	(700)	—
Deferred tax liabilities	(700)	(11)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2025, the Company has federal net operating loss carryforwards of approximately \$148.8 million, to reduce future taxable income. The federal net operating losses generated prior to 2018 amounting to \$4.9 million will begin to expire in 2036, losses generated after 2018 amounting to \$143.9 million will carry over indefinitely and would be subject to an 80% taxable income limitation in the year utilized. As of December 31, 2025, the Company has state net operating loss carryforwards of approximately \$129.8 million, to reduce future taxable income. State net operating losses will generally begin to expire in 2036.

As of December 31, 2025, the Company has federal research and development credit carryforwards of approximately \$6.7 million, to offset future tax liability. The credit carryforwards will begin to expire in 2039. As of December 31, 2025, the Company has state research and development credit carryforwards of approximately \$1.9 million, to offset future tax liability. The credit carryforwards are not subject to expiration.

A valuation allowance is provided for deferred tax assets where the recoverability of the assets is uncertain. The determination to provide a valuation allowance is dependent upon the assessment of whether it is more likely than not that sufficient future taxable income will be generated to utilize the deferred tax assets. Based on the weight of the available evidence, which includes the Company's historical operating losses and forecast of future losses, the Company provided a full valuation allowance against the Company's deferred tax assets resulting from the tax loss and credits carried forward.

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Utilization of the Company's net operating loss and credit carryforwards may be subject to a substantial annual limitation due to an ownership change limitations as provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. In the event that the Company had a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning balance at December 31, 2024	\$ 1,313	\$ 442
Reductions of prior year positions	(4)	(13)
Additions based on tax positions related to current year	855	884
Ending balance at December 31, 2025	<u>\$ 2,164</u>	<u>\$ 1,313</u>

As of December 31, 2025 and 2024, the Company has not recorded interest and penalties associated with its unrecognized tax benefits. If recognized, the unrecognized gross tax benefits would not reduce the annual effective tax rate because the Company has recorded a valuation allowance on its deferred tax assets. The Company currently has no federal or state tax examinations in progress, and all years are open for examination by federal and state authorities due to the losses carrying over.

12. Net Loss Per Share Attributable to Common Stockholders

The following common stock equivalents were excluded from the computation of diluted net loss per share as their impact would have been anti-dilutive:

	As of December 31,	
	2025	2024
Common stock options issued and outstanding	9,035,498	3,641,671
Redeemable convertible preferred stock on an as-converted into common stock basis	—	36,386,702
Shares issuable under the participation right	—	2,509,446
Total	<u>9,035,498</u>	<u>42,537,819</u>

13. Related Party Transactions

Redeemable Convertible Preferred Stock

All shares of the Series Seed redeemable convertible preferred stock and Series A redeemable convertible preferred stock were issued to BridgeBio Pharma and became common stock of the Company upon the Closing of the de-SPAC Transaction.

Common Stock Issued to BridgeBio Pharma

In August 2025, the Company executed an amendment to the transition services agreement with BridgeBio Pharma ("TSA Amendment"). Under the TSA Amendment, BBOT agreed to issue 784,720 shares of the Company's common stock to BridgeBio Pharma by October 31, 2025 ("TSA Shares") as a one-time charge related to the Closing of the de-SPAC Transaction. The promise to issue the TSA Shares represented a nonreciprocal transfer since the Company did not receive a commensurate value in exchange for the TSA Shares and was treated as a non-pro-rata distribution to a related party. During the year ended December 31, 2025, the Company recorded \$7.8 million, included in general and administrative expenses in the consolidated statements of operations using the closing price of its common stock as of the TSA Amendment date. The promise to issue the TSA Shares was concluded to be equity-classified, and the corresponding credit was recorded to additional paid-in capital. The TSA Shares were issued and became outstanding in October 2025. Under the TSA Amendment, the issuance of the TSA Shares was not contingent on any condition other than the passage of time, and these shares are treated as outstanding for basic and diluted net loss per share calculation purposes from the TSA Amendment date.

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Collaborative Arrangement with Related Party

In July 2025, the Company executed a research and collaboration agreement (“RCA”) with a related party (“RCA Party”) to grant a license over its intellectual property with respect to the new indication being developed by the RCA Party (“RCA License”) and perform certain research and development activities (“RCA Service”) intended to achieve an acceptance of an investigational new drug application that will be owned and further developed by the RCA Party. During the year ended December 31, 2025, the Company recognized \$0.6 million in connection with the RCA, which is included as a reduction to research and development expenses in the consolidated statements of operations.

Related Party Income and Expenses

During the year ended December 31, 2025, the Company recognized \$0.8 million in research and development expenses and \$8.4 million in general and administrative expenses for the services provided by BridgeBio Pharma under the transition services agreement and related amendments. General and administrative expenses for the year ended December 31, 2025 include the grant date fair value of the TSA Shares issued to BridgeBio Pharma of \$7.8 million.

During the year ended December 31, 2024, the Company recognized \$8.9 million in research and development expenses and \$2.8 million in general and administrative expenses for the services provided by BridgeBio Pharma.

During the year ended December 31, 2024, the Company recognized \$0.8 million in income from services rendered to BridgeBio Pharma under the transition services agreement executed after the Series B financing to facilitate the Company’s transition to standalone operations. No such related party income from transition services agreements was recognized during the year ended December 31, 2025.

Allocated Operating Expenses

Prior to April 30, 2024, the Company operated as part of BridgeBio Pharma. Costs and expenses directly attributable to the Company’s operations were recorded in the Company’s ledger with a corresponding liability, based on their nature. The Company also utilized certain general and administrative functions of BridgeBio Pharma that were not recorded in its ledger. These general and administrative expenses represent the costs of doing business that would have been incurred if the Company were to operate on a standalone basis. These general and administrative expenses were recorded in these consolidated financial statements using the carve-out operating expense allocation methodology. The allocation process used a percentage of the operating expenses incurred by the Company in each period compared to the total operating expenses incurred by all BridgeBio Pharma entities. This percentage was then applied to the applicable general and administrative expenses incurred by BridgeBio Pharma to calculate the amounts attributable to the Company’s operations.

The Company is not contractually required to reimburse BridgeBio Pharma or its controlled entities for the allocated operating expenses, including stock-based compensation. As such, the allocated operating expenses are presented as a deemed contribution from BridgeBio Pharma to the Company and were credited to additional paid-in capital. The corresponding amounts are presented as constructive cash inflows from financing activities in the consolidated statements of cash flows.

For the year ended December 31, 2024, the allocated general and administrative expenses calculated using the carve-out methodology included \$1.1 million for other administrative expenses and \$0.9 million for stock-based compensation. These allocated expenses were recorded only through April 30, 2024.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, as of December 31, 2025. Based on the evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework (2013). Based on our evaluation under the COSO framework, we believe that our internal controls over financial reporting were effective as of December 31, 2025.

Attestation Report of the Registered Public Accounting Firm

Our independent registered accounting firm is not required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 of Sarbanes-Oxley Act of 2002 until we are no longer either an "emerging growth company" as defined in the JOBS Act or a smaller reporting company as defined by Rule 12b-2 of the Exchange Act that does not otherwise also qualify as an "accelerated filer" or "large accelerated filer" for SEC reporting purposes.

Changes in Internal Control over Financial Reporting

Except for the changes to remediate the previous material weakness described below, there have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Material Weakness Remediation

As previously reported, management identified a material weakness in BBOT's internal control over financial reporting for the years ended December 31, 2024 and 2023, related to BBOT not having sufficient full-time accounting personnel, (i) to enable appropriate reviews over the financial close and reporting process, (ii) to allow for an appropriate segregation of duties, (iii) to perform an effective risk assessment process, and (iv) with the requisite experience and technical accounting knowledge to identify, review and resolve complex accounting issues under U.S. GAAP.

In order to remediate the material weakness, management implemented measures to ensure that control deficiencies contributing to the material weakness were remediated, such that these controls were designed, implemented and operating effectively. The remediation actions included:

- Hired additional accounting personnel to ensure segregation of duties and appropriate review over the financial close and reporting process,
- Engaged third-party consultants and specialists, as needed, for complex accounting issues,
- Developed enhanced risk assessment procedures to identify and address financial reporting risks,
- Revised and implemented new controls, including updating documentation,
- Provided training to appropriate personnel relating to the importance and execution of controls,
- Engaged internal and external resources to assist with remediation and monitor remediation progress.

As a result of these efforts, management determined that the previously identified material weakness was remediated as of December 31, 2025.

Item 9B. Other Information

During the fourth quarter ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

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, controller or persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, located at <https://investors.bbotx.com/corporate-governance/documents-charters>. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025, except as to information disclosed therein pursuant to Item 402(v) of Regulation S-K relating to pay versus performance.

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

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

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

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is Deloitte & Touche, LLP, San Francisco, CA, PCAOB Auditor ID 34.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

Item 15. Exhibits and Financial Statement Schedules**1. Financial Statements**

Information in this response to this Item 15 is included in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules are omitted because the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15 (b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

Not applicable.

EXHIBIT INDEX

Number	Description
2.1	Business Combination Agreement, by and among Helix Acquisition Corp. II, TheRas, Inc. and Helix II Merger Sub, Inc., dated as of February 28, 2025 (incorporated by reference to Annex A in the Registrant's proxy statement/prospectus filed on July 9, 2025).
2.2	Amendment No. 1 to Business Combination Agreement, by and among Helix Acquisition Corp. II, TheRas, Inc. and Helix Merger Sub, Inc., dated as of June 17, 2025 (incorporated by reference to Annex A in the Registrant's proxy statement/prospectus filed on July 9, 2025).
3.1	BridgeBio Oncology Therapeutics, Inc. Certificate of Incorporation (incorporated by reference to Exhibit 3.1 the Registrant's Current Report on Form 8-K filed on August 12, 2025).
3.2	BridgeBio Oncology Therapeutics, Inc. Bylaws (incorporated by reference to Exhibit 3.2 the Registrant's Current Report on Form 8-K filed on August 12, 2025).
4.1	Specimen Common Stock Certificate of BridgeBio Oncology Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 in the Registrant's proxy statement/prospectus filed on July 9, 2025).
4.2*	Description of Securities.
10.1	Amended and Restated Registration Rights Agreement dated as of August 11, 2025 (incorporated by reference to Exhibit 10.1 the Registrant's Current Report on Form 8-K filed on August 12, 2025).
10.2	Form of Subscription Agreement, dated February 28, 2025, by and between Helix Acquisition Corp. II and each PIPE Investor (incorporated by reference to Annex E in the Registrant's proxy statement/prospectus filed on July 9, 2025).
10.3	Lock-Up Agreement, dated as of August 11, 2025, by and between Helix Acquisition Corp. II, Helix Holdings II, LLC, certain investment vehicles of Cormorant Asset Management, LP, certain existing shareholders of the Company, and other persons and entities (incorporated by reference to Exhibit 10.3 the Registrant's Current Report on Form 8-K filed on August 12, 2025).
10.4#	Transition Services Agreement, by and between TheRas, Inc. and BridgeBio Services, Inc., as of April 30, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2025).
10.5#	Amendment No. 1 to Transition Services Agreement, by and between TheRas, Inc. and BridgeBio Services, Inc., as of August 27, 2024 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2025).
10.6#	Amendment No. 2 to Transition Services Agreement, by and between TheRas, Inc. and BridgeBio Services, Inc., as of October 1, 2024 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2025).
10.7#	Amendment No. 3 to Transition Services Agreement, by and between TheRas, Inc. and BridgeBio Services, Inc., as of January 1, 2025 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2025).
10.8#	Amendment No. 4 to Transition Services Agreement, by and between TheRas, Inc. and BridgeBio Services, Inc., as of April 1, 2025 (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2025).
10.9#	Amendment No. 5 to Transition Services Agreement, by and among TheRas, Inc., BridgeBio Services, Inc., BridgeBio Oncology Therapeutics, Inc. and BridgeBio Pharma LLC as of August 11, 2025 (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2025).
10.10#	Amendment No. 6 to Transition Services Agreement, by and among TheRas, Inc., BridgeBio Services, Inc., BridgeBio Oncology Therapeutics, Inc. and BridgeBio Pharma LLC as of August 29, 2025 (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2025).
10.11*#	Amendment No. 7 to Transition Services Agreement, by and among TheRas, Inc., BridgeBio Services, Inc., BridgeBio Oncology Therapeutics, Inc. and BridgeBio Pharma LLC as of October 1, 2025.
10.12^	Employee Offer Letter, dated April 30, 2024, by and between TheRas, Inc. and Eli Wallace (incorporated by reference to Exhibit 10.12 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
10.13^	Amendment to Employee Offer Letter, dated September 30, 2024, by and between TheRas, Inc. and Eli Wallace (incorporated by reference to Exhibit 10.13 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
10.14^	Employee Offer Letter, dated April 30, 2024, by and between TheRas, Inc. and Pedro Beltran (incorporated by reference to Exhibit 10.14 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
10.15^	Employee Offer Letter, dated August 12, 2024, by and between TheRas, Inc. and Yong Ben (incorporated by reference to Exhibit 10.15 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
10.16^	Employment Agreement, dated August 11, 2025, by and between the Registrant and Eli Wallace (incorporated by reference to Exhibit 10.16 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).

- 10.17^ Employment Agreement, dated August 11, 2025, by and between the Registrant and Pedro Beltran (incorporated by reference to Exhibit 10.17 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.18^ Employment Agreement, dated August 11, 2025, by and between the Registrant and Yong Ben (incorporated by reference to Exhibit 10.18 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.19^ Employment Agreement, dated August 11, 2025, by and between the Registrant and Uneek Mehra (incorporated by reference to Exhibit 10.19 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.20^ TheRas, Inc. 2016 Equity Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.20 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.21^ BridgeBio Oncology Therapeutics, Inc. 2025 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (No. 333-289940) filed on August 29, 2025).
- 10.22^ BridgeBio Oncology Therapeutics, Inc. 2025 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.22 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.23^ BridgeBio Oncology Therapeutics, Inc. Executive Severance Plan (incorporated by reference to Exhibit 10.23 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.24^ BridgeBio Oncology Therapeutics, Inc. Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.24 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.25*^ BridgeBio Oncology Therapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy.
- 10.26 Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.26 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.27 Form of Officer Indemnification Agreement (incorporated by reference to Exhibit 10.27 to the Registrant's Current Report on Form 8-K filed on August 12, 2025).
- 10.28# Stevenson-Wydler (15 USC 3710a) Cooperative Research and Development Agreement, dated as of May 22, 2018, by and between Lawrence Livermore National Security, LLC (the "LLNS") and BBOT, as amended by that certain Amendment No. 1 to the Cooperative Research and Development Agreement, dated as of December 2, 2019, by and between LLNS and BBOT, as further amended by that certain Amendment No. 2 to the Cooperative Research and Development Agreement, dated as of May 21, 2021, by and between LLNS and BBOT, as further amended by that certain Amendment No. 3 to the Cooperative Research and Development Agreement, dated as of June 22, 2022, by and between LLNS and BBOT, as further amended by that certain Amendment No. 4 to the Cooperative Research and Development Agreement, dated as of December 21, 2023, by and between LLNS and BBOT, as further amended by that certain Amendment No. 5 to the Cooperative Research and Development Agreement, dated as of May 20, 2025, by and between LLNS and BBOT (incorporated by reference to Exhibit 10.14 in the Registrant's proxy statement/prospectus filed on July 9, 2025).
- 10.29# Limited Exclusive Patent License Agreement, dated as of July 7, 2022, by and between BBOT and LLNS (incorporated by reference to Exhibit 10.15 in the Registrant's proxy statement/prospectus filed on July 9, 2025).
- 10.30# Limited Exclusive Patent License Agreement, dated as of July 7, 2022, by and between BBOT and LLNS (incorporated by reference to Exhibit 10.16 in the Registrant's proxy statement/prospectus filed on July 9, 2025).
- 10.31# Limited Exclusive Patent License Agreement, dated as of December 20, 2024, by and between BBOT and LLNS (incorporated by reference to Exhibit 10.17 in the Registrant's proxy statement/prospectus filed on July 9, 2025).
- 10.32# Patent License Agreement, dated as of August 5, 2022, by and between BBOT and The Frederick National Laboratory for Cancer Research, operated by Leidos Biomedical Research, Inc. (incorporated by reference to Exhibit 10.18 in the Registrant's proxy statement/prospectus filed on July 9, 2025).
- 10.33# Patent License Agreement, dated as of August 5, 2022, by and between BBOT and The Frederick National Laboratory for Cancer Research, operated by Leidos Biomedical Research, Inc. (incorporated by reference to Exhibit 10.19 in the Registrant's proxy statement/prospectus filed on July 9, 2025).
- 10.34# Patent License Agreement, dated as of December 20, 2023, by and between BBOT and The Frederick National Laboratory for Cancer Research, operated by Leidos Biomedical Research, Inc. (incorporated by reference to Exhibit 10.20 in the Registrant's proxy statement/prospectus filed on July 9, 2025).

10.35#	Cooperative Research and Development Agreement (“Agreement”), dated March 3, 2017, between Frederick National Laboratory for Cancer Research (FNLCR) Operated by Leidos Biomedical Research, Inc. (“Leidos”) and BBOT, as amended by Amendment No. 1 to Agreement dated January 19, 2018, by and between Leidos and BBOT, as further amended by Amendment No. 2 to Agreement dated January 2, 2019, by and between Leidos and BBOT, as further amended by Amendment No. 3 to Agreement dated November 14, 2019, by and between Leidos and BBOT, as further amended by Amendment No. 4 to Agreement dated January 13, 2020, by and between Leidos and BBOT, as further amended by Amendment No. 5 to Agreement dated September 22, 2021, by and between Leidos and BBOT, as further amended by Amendment No. 6 to Agreement dated March 27, 2023, by and between Leidos and BBOT, as further amended by Amendment No. 7 to Agreement dated August 20, 2024, by and between Leidos and BBOT (incorporated by reference to Exhibit 10.21 in the Registrant’s proxy statement/prospectus filed on July 9, 2025), as further amended by Amendment No. 8 to Agreement dated September 2, 2025, by and between Leidos and BBOT, as further amended by Amendment No. 9 to Agreement dated December 3, 2025, by and between Leidos and BBOT.
10.36*#	Amendment No. 1 to Patent License Agreement for PI3Ka Breakers, by and between TheRas, Inc. and Lawrence Livermore National Security, LLC, as of November 18, 2025
10.37*#	Amendment No. 1 to Patent License Agreement for PAN-Kras Inhibitors, by and between TheRas, Inc. and Lawrence Livermore National Security, LLC, as of November 18, 2025
10.38*#	Amendment No. 1 to Patent License Agreement for KRAS G12C Inhibitors, by and between TheRas, Inc. and Lawrence Livermore National Security, LLC, as of November 18, 2025
10.39*#	Amendment No. 1 to Patent License Agreement – Exclusive License Number 0401, by and between TheRas, Inc. and Leidos, dated as of December 23, 2025.
10.40*#	Amendment No. 1 to Patent License Agreement – Exclusive License Number 0421, by and between TheRas, Inc. and Leidos, dated as of December 23, 2025.
10.41*#	Amendment No. 1 to Patent License Agreement – Exclusive License Number 0486, by and between TheRas, Inc. and Leidos, dated as of December 23, 2025.
14.1*	Code of Business Conduct and Ethics.
19.1*	Insider Trading Policy.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant’s Current Report on Form 8-K filed on August 12, 2025).
23.1*	Consent of Deloitte & Touche, LLP as an independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page to this Annual Report).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Compensation Recovery Policy.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in Exhibit 101)

* Filed herewith.

Portions of this exhibit have been omitted because they are both (i) not material and (ii) the type of information that the registrant treats as private or confidential.

† Certain schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Commission upon request.

^ Indicates management contract or compensatory plan.

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

SIGNATURES

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

BRIDGEBIO ONCOLOGY THERAPEUTICS, INC.

Date: March 5, 2026

By: /s/ Eli Wallace
Eli Wallace
Chief Executive Officer

Date: March 5, 2026

By: /s/ Uneek Mehra
Uneek Mehra
Chief Financial Officer

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

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL BY THESE PRESENT, that each individual whose signature appears below hereby constitutes and appoints each of Eli Wallace and Uneek Mehra, as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Form 10-K, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following person in the capacities and on the date indicated.

NAME	TITLE	DATE
<u>/s/ Eli Wallace</u>	Chief Executive Officer and Director	March 5, 2026
<u>/s/ Uneek Mehra</u>	Chief Financial Officer	March 5, 2026
<u>/s/ Jake Bauer</u>	Director	March 5, 2026
<u>/s/ Bihua Chen</u>	Director	March 5, 2026
<u>/s/ Michelle Doig</u>	Director	March 5, 2026
<u>/s/ Raymond Kelleher</u>	Director	March 5, 2026
<u>/s/ Neil Kumar</u>	Director	March 5, 2026
<u>/s/ Frank P. McCormick</u>	Director	March 5, 2026
<u>/s/ Praveen Tipirneni</u>	Director	March 5, 2026

EXECUTIVE OFFICERS

Pedro J. Beltran

Director, President and Chief Executive Officer

Yong Ben, M.D., M.B.A.

Chief Medical and Development Officer

Idan Elmelech

Chief Operating Officer

BOARD OF DIRECTORS

Pedro J. Beltran

President and Chief Executive Officer, BridgeBio Oncology Therapeutics, Inc.

Jake Bauer

Chairman of the Board, BridgeBio Oncology Therapeutics, Inc.; Venture Partner, ARCH Venture Partners; Venture Partner, SR One Capital Management

Bihua Chen, M.B.A.

Founder and Managing Member, Cormorant Asset Management, LP

Michelle Doig

Partner and the Head of Corporate Development, Omega Funds

Raymond Kelleher, M.D., Ph.D.

Managing Director, Cormorant Asset Management, LP

Neil Kumar, Ph.D.

Executive Chairman of the Board¹, BridgeBio Oncology Therapeutics, Inc.; Director and Chief Executive Officer, BridgeBio Pharma, Inc.

Peter Lebowtiz, M.D., Ph.D.

Chief Executive Officer and Chief Medical Officer, Third Arc Bio

Frank P. McCormick, Ph.D., F.R.S., D.Sc

Director and Chairman of Oncology, BridgeBio Pharma, Inc.; Professor, University of California, San Francisco

Praveen Tipirneni, M.D., M.B.A.

Chief Executive Officer, Caldera Therapeutics, Inc.; Director, Tectonic Therapeutic Inc.

CORPORATE INFORMATION

Corporate Headquarters

256 E. Grand Avenue, Suite 104
South San Francisco, CA

Independent Registered Public Accounting Firm

Deloitte and Touche, LLP

Transfer Agent

Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004-1571

Investor Relations

Investors@bbotx.com

¹ Executive officer within the meaning of Rule 3b-7 under the Securities Exchange Act of 1934, as amended.

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