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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

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	**39-3690783**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
256 E. Grand Avenue, Suite 104	
South San Francisco, CA	**94080**
(Address of principal executive offices)	**(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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 5, 2026, the Registrant had 80,251,267 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

BridgeBio Oncology Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except shares and per share data)

	September 30, 2026	December 31, 2025
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 76,479	$ 373,687
Short-term marketable securities	117,390	51,773
Receivables from related parties	155	386
Prepaid expenses and other current assets	14,302	6,550
Total current assets	208,326	432,396
Long-term marketable securities	121,462	—
Property and equipment, net	815	956
Operating lease right-of-use asset	1,987	2,330
Other non-current assets	13,502	12,567
Restricted cash	132	132
Total assets	$ 346,224	$ 448,381
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,261	$ 1,374
Accrued compensation and benefits	5,267	5,746
Accrued research and development liabilities	32,681	25,951
Accrued professional services	1,652	674
Payables to related parties	232	534
Operating lease liability, current	571	522
Other accrued liabilities	362	240
Total current liabilities	51,026	35,041
Operating lease liability, noncurrent	1,810	2,244
Total liabilities	52,836	37,285
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, $0.0001 par value; no shares authorized, issued and outstanding as of September 30, 2026 or December 31, 2025	—	—
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2026 and December 31, 2025; no shares issued or outstanding as of September 30, 2026 or December 31, 2025, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 80,234,557 and 79,991,768 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	8	8
Additional paid-in capital	784,378	767,639
Accumulated deficit	(489,303)	(356,567)
Accumulated other comprehensive income (loss)	(1,695)	16
Total stockholders' equity	293,388	411,096
Total liabilities, redeemable convertible preferred stock, and stockholders' equity	$ 346,224	$ 448,381

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

BridgeBio Oncology Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development[(1)]	$ 29,593	$ 35,052	$ 118,620	$ 83,125
General and administrative[(2)]	7,895	14,129	25,234	19,286
Total operating expenses	37,488	49,181	143,854	102,411
Loss from operations	(37,488)	(49,181)	(143,854)	(102,411)
Other income, net:				
Interest income	3,262	3,444	10,757	6,919
Income from transition services agreements	87	1,010	506	1,010
Change in fair value of participation right liability	—	—	—	(725)
Other expense	(37)	(30)	(145)	(40)
Total other income, net	3,312	4,424	11,118	7,164
Net loss	$ (34,176)	$ (44,757)	$ (132,736)	$ (95,247)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (1.03)	$ (1.66)	$ (6.49)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	80,184,540	43,491,085	80,110,047	14,684,990

(1) Research and development expenses include related party amounts of $3 and $153 for the three months ended September 30, 2026 and 2025, respectively, and $376 and $590 for the nine months ended September 30, 2026 and 2025, respectively.

(2) General and administrative expenses include related party amounts of $7 and $7,905 for the three months ended September 30, 2026 and 2025, respectively, and $85 and $8,274 for the nine months ended September 30, 2026 and 2025, respectively.

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

BridgeBio Oncology Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Comprehensive loss, net of tax:				
Net loss	$ (34,176)	$ (44,757)	$ (132,736)	$ (95,247)
Unrealized loss on marketable securities	(736)	(15)	(1,711)	(312)
Comprehensive loss	$ (34,912)	$ (44,772)	$ (134,447)	$ (95,559)

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

BridgeBio Oncology Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)
(In thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2025	—	$ —	79,991,768	$ 8	$ 767,639	$ (356,567)	$ 16	$ 411,096
Exercise of common stock options for cash	—	—	97,163	—	416	—	—	416
Stock-based compensation	—	—	—	—	3,871	—	—	3,871
Unrealized loss on marketable securities	—	—	—	—	—	—	(997)	(997)
Net loss	—	—	—	—	—	(42,106)	—	(42,106)
Balance as of March 31, 2026	—	$ —	80,088,931	$ 8	$ 771,926	$ (398,673)	$ (981)	$ 372,280
Exercise of common stock options for cash	—	—	8,719	—	37	—	—	37
Vesting of restricted stock units	—	—	17,352	—	—	—	—	—
Stock-based compensation	—	—	—	—	7,227	—	—	7,227
Unrealized gain on marketable securities	—	—	—	—	—	—	22	22
Net loss	—	—	—	—	—	(56,454)	—	(56,454)
Balance as of June 30, 2026	—	$ —	80,115,002	$ 8	$ 779,190	$ (455,127)	$ (959)	$ 323,112
Exercise of common stock options for cash	—	—	104,890	—	478	—	—	478
Vesting of restricted stock units net of shares withheld for taxes	—	—	14,665	—	(36)	—	—	(36)
Stock-based compensation	—	—	—	—	4,746	—	—	4,746
Unrealized loss on marketable securities	—	—	—	—	—	—	(736)	(736)
Net loss	—	—	—	—	—	(34,176)	—	(34,176)
Balance as of September 30, 2026	—	$ —	80,234,557	$ 8	$ 784,378	$ (489,303)	$ (1,695)	$ 293,388
Balance 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
Stock-based compensation	—	—	—	—	627	—	—	627
Unrealized loss on marketable securities	—	—	—	—	—	—	(157)	(157)
Net loss	—	—	—	—	—	(22,055)	—	(22,055)
Balance as of March 31, 2025	36,364,919	$ 323,169	50,198	$ —	$ 44,354	$ (244,578)	$ 191	$ (200,033)
Issuance of Series B redeemable convertible preferred stock for cash consideration and settlement of participation right liability	2,509,446	26,052	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	875	—	—	875
Unrealized loss on marketable securities	—	—	—	—	—	—	(140)	(140)
Net loss	—	—	—	—	—	(28,435)	—	(28,435)
Balance as of June 30, 2025	38,874,365	$ 349,221	50,198	$ —	$ 45,229	$ (273,013)	$ 51	$ (227,733)
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	360,786	—	—	360,790
Stock-based compensation	—	—	—	—	1,425	—	—	1,425
Fair value of common stock issuable to related party	—	—	—	—	7,769	—	—	7,769
Unrealized loss on marketable securities	—	—	—	—	—	—	(15)	(15)
Net loss	—	—	—	—	—	(44,757)	—	(44,757)
Balance as of September 30, 2025	—	$ —	79,196,710	$ 8	$ 764,426	$ (317,770)	$ 36	$ 446,700

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

BridgeBio Oncology Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Operating activities		
Net loss	$ (132,736)	$ (95,247)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	226	196
Stock-based compensation	15,844	2,927
Fair value of common stock issuable to related party	—	7,769
Change in fair value of participation right liability	—	725
Net amortization (accretion) of premiums and discounts on marketable securities	454	(1,171)
Amortization of right-of-use assets	343	220
Other non-cash adjustments, net	11	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(7,752)	(4,365)
Other non-current assets	(935)	(398)
Accounts payable	8,888	577
Accrued compensation and benefits	(479)	667
Accrued research and development liabilities	6,730	15,831
Accrued professional services	1,099	480
Operating lease liabilities	(386)	74
Other accrued liabilities	122	(7)
Balances due to and from related parties	(72)	62
Net cash used in operating activities	(108,643)	(71,660)
Investing activities		
Maturities and sales of marketable securities	146,874	128,976
Purchases of marketable securities	(336,129)	(62,881)
Purchases of property and equipment	(84)	(533)
Net cash (used in) provided by investing activities	(189,339)	65,562
Financing activities		
Proceeds from reverse recapitalization and PIPE Financing	—	373,457
Issuance of Series B redeemable convertible preferred stock, net of issuance costs	—	22,222
Payment of deferred transaction costs	(121)	(11,691)
Exercise of common stock options for cash	931	—
Repurchase of RSU shares to satisfy tax withholding	(36)	—
Net cash provided by financing activities	774	383,988
Net (decrease) increase in cash, cash equivalents, and restricted cash	(297,208)	377,890
Cash, cash equivalents, and restricted cash at beginning of period	373,819	30,983
Cash, cash equivalents, and restricted cash at end of period	$ 76,611	$ 408,873
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
Deferred de-SPAC transaction costs included in accrued professional services and other accrued liabilities	$ —	$ 976

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

BridgeBio Oncology Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

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 condensed 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 12, the Company had material related party transactions with BridgeBio Pharma during the periods presented in these condensed consolidated financial statements.

Basis of Presentation and Principles of Consolidation

These condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States ("US GAAP") for interim financial information. All costs, as well as assets and liabilities directly associated with the Company's business activity, are included in the condensed 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 condensed 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.

These condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair presentation of the Company's financial information. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of results to be expected for the year ending December 31, 2026 or for any other future annual or interim period.

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 condensed consolidated financial statements have been derived from BridgeBio Pharma's historical accounting records and are presented on a carve-out basis. The condensed 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 12. 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 condensed consolidated financial statements relates to Legacy BBOT on a standalone basis.

Liquidity

Since its inception through September 30, 2026, the Company has incurred net losses. As of September 30, 2026, the Company had an accumulated deficit of $489.3 million and incurred net losses of $34.2 million and $44.8 million during the three months ended September 30, 2026 and 2025, respectively, and $132.7 million and $95.2 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, the Company had a balance of cash, cash equivalents, and marketable securities of $315.3 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 condensed 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 nonclinical 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

The Company's significant accounting policies are disclosed in the Company's consolidated financial statements for the year ended December 31, 2025, and related notes. There have been no material changes to the Company's significant accounting policies as compared to the significant accounting policies described in the Company's consolidated financial statements for the year ended December 31, 2025 included in the Company's Annual Report on Form 10-K filed with the SEC on March 5, 2026 (the "Form 10-K").

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 through September 30, 2026.

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 condensed 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 condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed 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 share-based awards and participation right liability,
- Recoverability of deferred tax assets,
- Allocations of operating expenses, and
- The determination of the incremental borrowing rate used in lease-related calculations.

The Company bases its estimates on historical experience and various other reasonable assumptions. Actual results may differ from those estimates or assumptions.

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 September 30, 2026, cash and cash equivalents consisted of money market funds, commercial paper, and corporate debt securities. As of December 31, 2025, cash and cash equivalents consisted of money market funds and commercial paper. Restricted cash represented 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 balance included the following (in thousands):

	September 30, 2026	December 31, 2025
Cash	$ 459	$ 624
Cash equivalents	76,020	373,063
Restricted cash	132	132
Total cash, cash equivalents, and restricted cash	$ 76,611	$ 373,819

Marketable Securities

The Company generally invests its excess cash in money market funds and investment grade short to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents, short-term marketable securities or long-term marketable securities on the condensed consolidated balance sheets and are considered available-for-sale. The Company classifies investments in securities with remaining maturities of less than one year, or where its intent is to use the investments to fund current operations or to make them available for current operations, as short-term investments. The Company classifies investments in securities with remaining maturities of over one year as long-term investments, unless intended to fund current operations.

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 until realized. Realized gains and losses are calculated using the specific identification method and recorded as other income (expense) in the condensed consolidated statement of operations.

The Company reports the accrued interest receivable as a component of prepaid and other assets on its condensed 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 September 30, 2026 or December 31, 2025.

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the 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.

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 condensed 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 September 30, 2026, our lease population consisted primarily 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 purchased software with an estimated useful life of 3 years, 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 $0.1 million for the three months ended September 30, 2026 and 2025, respectively, and $0.2 million for the nine months ended September 30, 2026 and 2025, 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 three and nine months ended September 30, 2026 and 2025.

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 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):

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Research and development trials and consumables expenses	$ 20,139	$ 26,724	$ 86,515	$ 60,010
Payroll and personnel expenses	7,721	6,730	26,810	18,280
Facilities and other expenses	1,733	1,598	5,295	4,835
Total research and development	$ 29,593	$ 35,052	$ 118,620	$ 83,125

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 condensed 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 a review of 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 condensed consolidated balance sheets.

Receivables from and Payables to Related Parties

Receivables from and payables to related parties represent the amounts due from and to 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 condensed 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 are reported separately as current assets or liabilities in the condensed 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, costs associated with laboratory supplies, nonclinical 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 nonclinical 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 condensed consolidated balance sheets and within research and development expenses in the condensed 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:

- Fees paid to contract research organizations ("CROs") in connection with nonclinical 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 investigational 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 a related party (refer to Note 12), 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 September 30, 2026. 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.

Stock-based compensation includes expenses related to common stock options and restricted stock units 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.

Accrued Milestone Compensation Arrangements

Historically we have 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 as of September 30, 2026 or December 31, 2025.

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.

Participation Right Liability

The Company's 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 condensed consolidated statements of operations during the nine months ended September 30, 2025. 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.

Income Taxes

The Company is subject to U.S. federal and state income taxes as a corporation. The Company's tax provision and the resulting effective tax rate for interim periods is determined based upon its estimated annual effective tax rate adjusted for the effect of discrete items arising in that quarter. There was no provision for income tax for the three and nine months ended September 30, 2026 or 2025.

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 condensed 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 stockholders 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.

At the Closing, each outstanding share of Legacy BBOT common stock was exchanged for shares of BBOT common stock based on the Consideration Ratio of approximately 0.0889. For periods prior to the Closing, the reported share and per share information has been retroactively adjusted to reflect the Consideration Ratio (refer to Note 3).

Basic 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 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 equity outside of the stockholders' equity in the accompanying condensed 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 operates 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 condensed 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 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. Entities that elect the practical expedient and, if applicable, make the accounting policy election are required to apply the amendments prospectively. The amendments in ASU 2025-05 were effective for fiscal years beginning after December 15, 2025, including interim periods within those fiscal years. The Company has adopted this guidance effective January 1, 2026 and there was no material impact to the condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 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 condensed financial statements and related disclosures.

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 condensed financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software ("ASU 2025-06")*. This standard modernizes the accounting for software costs, including updating guidance on the recognition and measurement of costs incurred in connection with development and implementation activities related to internal-use software. The standard is effective for annual reporting periods beginning after December 15, 2027, including interim reporting periods within those fiscal years. The standard can be adopted retrospectively, prospectively or on a modified prospective basis, and early adoption is permitted as of the beginning of an annual reporting period, provided that the financial statements for that period have not yet been issued or made available for issuance. The Company is currently evaluating the impact of the standard on its condensed financial statements and related disclosures and will determine the appropriate transition method prior to adoption.

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 during the year ended December 31, 2025, all of which had been paid as of March 31, 2026. 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; and
- 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	79,196,710

The de-SPAC Transaction was accounted for as a reverse recapitalization under U.S. GAAP because Legacy BBOT was identified as the accounting acquirer and Helix as the accounting acquiree for financial reporting purposes. Accordingly, these condensed 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.

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):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 70,331	$ —	$ —	$ 70,331
Commercial paper	—	4,171	—	4,171
Corporate debt securities	—	1,518	—	1,518
Total cash equivalents	70,331	5,689	—	76,020
Short-term marketable securities:				
Commercial paper	—	23,057	—	23,057
Corporate debt securities	—	86,343	—	86,343
Certificates of deposit	—	7,990	—	7,990
Total short-term marketable securities	—	117,390	—	117,390
Long-term marketable securities:				
U.S. Treasury securities	—	2,856	—	2,856
Corporate debt securities	—	118,606	—	118,606
Total long-term marketable securities	—	121,462	—	121,462
Total marketable securities	—	238,852	—	238,852
Total assets	$ 70,331	$ 244,541	$ —	$ 314,872

	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
Short-term marketable securities:				
Commercial paper	—	7,313	—	7,313
Corporate debt securities	—	44,460	—	44,460
Total short-term marketable securities	—	51,773	—	51,773
Total assets	$ 366,348	$ 57,257	$ —	$ 423,605

Money market funds are highly liquid and actively traded marketable securities that generally transact at a stable $1.00 net asset value and are classified as Level 1. The Company's commercial paper, corporate debt securities, certificates of deposit, and U.S. Treasury securities are classified as Level 2, as their fair values are determined using 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.

The Company's participation right liability was settled in full in April 2025 and was no longer outstanding as of December 31, 2025.

The following tables summarize the amortized cost and fair value of the Company's marketable securities by major investment category for the periods indicated (in thousands):

	September 30, 2026			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:				
Commercial paper	$ 23,093	$ —	$ (36)	$ 23,057
Corporate debt securities	86,513	3	(173)	86,343
Certificates of deposit	8,004	1	(15)	7,990
Total short-term marketable securities	117,610	4	(224)	117,390
Long-term marketable securities:				
U.S. Treasury securities	2,942	—	(86)	2,856
Corporate debt securities	119,995	10	(1,399)	118,606
Total long-term marketable securities	122,937	10	(1,485)	121,462
Total marketable securities	$ 240,547	$ 14	$ (1,709)	$ 238,852

	December 31, 2025			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:				
Commercial paper	$ 7,311	$ 2	$ —	$ 7,313
Corporate debt securities	44,446	18	(4)	44,460
Total short-term marketable securities	$ 51,757	$ 20	$ (4)	$ 51,773

Unrealized gains or losses on cash equivalents were not material as of September 30, 2026 and December 31, 2025. As of September 30, 2026 and December 31, 2025, some of the Company's marketable securities were in an unrealized loss position, all of which had been in a continuous unrealized loss position for less than twelve months. The Company's investment portfolio consists primarily of investment-grade corporate debt securities, commercial paper, certificates of deposit, and U.S. Treasury securities. The Company does not intend to sell securities in an unrealized loss position, and it is not more likely than not that the Company will be required to sell them before recovery of their amortized cost basis. In evaluating whether unrealized losses resulted from credit losses, the Company monitors the credit quality of the portfolio on an ongoing basis and evaluates changes in issuer credit ratings, and other indicators of potential credit deterioration. When such indicators are identified, the Company performs a detailed evaluation of the issuer's financial condition and payment performance in assessing whether a credit loss exists. No allowance for credit losses was recorded as of September 30, 2026 and December 31, 2025.

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 The 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. In March 2025, UCSF elected to exercise the Participation Right, which was settled in full in April 2025 (refer to 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 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 Pan-KRAS 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 and introduce an additional $1.5 million in contribution funding payments. In September 2026, the Company executed an amendment to the Leidos CRADA, with an effective date of August 12, 2026, to extend the expiration date to March 2027 and provide an additional $1.0 million in funding contribution payments, of which $0.5 million was paid in September 2026 upon execution of the amendment. As of September 30, 2026, payments made under the Leidos CRADA exceeded the related research and development expense recognized, resulting in a prepaid balance of $0.4 million, which was included in prepaid expenses and other current assets in the condensed consolidated balance sheet.

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 September 30, 2026, 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 September 30, 2026 and December 31, 2025, the Company recorded a $0.5 million liability for milestones that had been achieved but remained unpaid, which was included in accrued research and development liabilities in the condensed consolidated balance sheets. During the three and nine months ended September 30, 2026, no further milestones had been achieved under the Leidos CRADA. The Company recognized research and development expenses of $0.6 million and nil for the three months ended September 30, 2026 and 2025, respectively, and $2.0 million and $2.2 million, for the nine months ended September 30, 2026 and 2025, 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 bring new knowledge and therapeutic 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. 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, the Company and LLNS executed three separate amendments to the 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. In January 2026, the Company and LLNS executed an amendment to extend the LLNS CRADA expiration date another twelve months until June 2027 and included additional estimated funding contributions of $5.0 million to be paid by the Company over the remaining term. As of September 30, 2026, payments made under the LLNS CRADA exceeded the related research and development expense recognized, resulting in a prepaid balance of $0.4 million, which was included in prepaid expenses and other current assets in the condensed consolidated balance sheet.

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 September 30, 2026, the Company is required to make contingent milestone payments totaling up to $21.8 million upon the achievement of certain clinical, regulatory, and sales milestones.

During the three and nine months ended September 30, 2026, no milestones had been achieved and therefore no liabilities associated with the LLNS Agreements were recorded as of September 30, 2026 or December 31, 2025 on the condensed consolidated balance sheets. The Company recognized research and development expenses of $0.1 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively, and $0.2 million and $0.6 million for the nine months ended September 30, 2026 and 2025, respectively, in connection with the LLNS Agreements.

6. Income from Transition Services Agreements

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. The Company recorded $0.1 million and $0.5 million for the three and nine months ended September 30, 2026, respectively, and $1.0 million for the three and nine months ended September 30, 2025, in connection with the TSA, which is presented separately as other income from transition services agreements in the condensed consolidated statements of operations.

7. Commitments and Contingencies

Other Research and Development Agreements

We may enter into contracts in the normal course of business with contract research organizations for clinical trials, contract manufacturing organizations for clinical supplies, and other vendors for nonclinical 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 three months ended September 30, 2025. There have been no other cash bonuses with performance conditions recorded or paid during the three and nine months ended September 30, 2026.

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 condensed 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, and therefore there were no redeemable convertible preferred stock shares authorized or outstanding as of September 30, 2026 or December 31, 2025.

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.

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 September 30, 2026.

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.

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:

	September 30, 2026	December 31, 2025
Common stock options issued and outstanding	12,222,399	9,035,498
Restricted Stock Units ("RSU"s) unvested and expected to vest	361,832	—
Shares available for issuance under the stock option and incentive plan	1,309,064	459,417
Shares available for issuance under the employee stock purchase plan	1,808,313	895,607
Shares available for issuance under the inducement plan	969,300	1,046,940
Total	16,670,908	11,437,462

Shelf Registration Statement and At-the-Market Offering Program

In September 2026, the Company filed with the SEC a shelf registration statement on Form S-3 (File No. 333-298697) (the "2026 Shelf") which was declared effective by the SEC on September 10, 2026. The registration statement included a base prospectus covering the offering and sale of the Company's common stock, preferred stock, debt securities, warrants and units or any combination thereof, in an aggregate amount of up to $500.0 million. The Company also concurrently entered into a Sales Agreement (the "2026 ATM Agreement") with Leerink Partners LLC and Cantor Fitzgerald & Co. (collectively, the "2026 ATM Sales Agents") with respect to an "at-the-market" offering program, under which the Company may sell from time to time at its sole discretion and pursuant to the sales agreement prospectus included in the 2026 Shelf, shares of common stock having an aggregate offering price of up to $200.0 million through the 2026 ATM Sales Agents. Under the 2026 ATM Agreement, the Company has agreed to pay the 2026 ATM Sales Agents a commission of up to 3.0% of the aggregate gross proceeds from sales of its common stock. As of September 30, 2026, the Company had not sold any shares pursuant to the 2026 ATM Agreement.

9. Leases

In November 2024, the Company entered into an operating lease for 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. As of September 30, 2026, the weighted average remaining lease term for the Company's lease was 3.6 years, and the discount rate used was 7.40%.

The following table presents the amortization of the Company's lease liabilities recorded in the condensed consolidated balance sheet as of September 30, 2026 (in thousands):

Fiscal year ended December 31:	
2026 (three months)	$ 178
2027	730
2028	755
2029	782
2030	263
Total lease payments	$ 2,708
Less: imputed interest	(327)
Total operating lease liabilities	$ 2,381

Operating lease costs, including immaterial short-term lease costs, were $0.2 million for each of the three months ended September 30, 2026 and 2025, and $0.6 million and $0.9 million for the nine months ended September 30, 2026 and 2025, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $0.5 million for the nine months ended September 30, 2026. No cash was paid for lease payments during the nine months ended September 30, 2025, and the Company received $0.2 million of lease incentives from the lessor during the nine months ended September 30, 2025.

10. Stock-Based Compensation

Stock-based compensation is included under the following expense categories presented in the condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 1,683	$ 927	$ 6,008	$ 1,979
General and administrative	3,063	498	9,836	948
Total	$ 4,746	$ 1,425	$ 15,844	$ 2,927

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 September 30, 2026, 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 September 30, 2026, there were 1,309,064 shares 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 BBOT'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 September 30, 2026, there were 1,808,313 shares available for future grants under the ESPP.

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 September 30, 2026, there were 969,300 shares available for future grants under the 2025 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, 2025	9,035,498	$ 7.79	9.0	$ 42,771
Granted	5,658,443	9.66		
Exercised	(210,772)	4.42		
Forfeited and cancelled	(2,260,770)	9.55		
Outstanding as of September 30, 2026	12,222,399	$ 8.39	8.8	$ 47
Exercisable as of September 30, 2026	3,607,360	$ 7.22	8.1	$ 47

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.

Outstanding equity awards held by executive officers and senior management generally provide for accelerated vesting if the holder is terminated without cause or resigns for good reason (each as defined in the 2016 and 2025 Plans or Executive Severance Plan) within twelve months following a qualified change in control of the Company. Outstanding equity awards held by non-employee directors generally vest immediately upon 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 in August 2025 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 nine months ended September 30, 2026 was $6.45 per share. The weighted-average grant-date fair value of common stock options vested and forfeited during the nine months

ended September 30, 2026 was $4.78 and $6.49 per share, respectively. As of September 30, 2026, there was $49.4 million of unrecognized stock-based compensation related to unvested common stock options, which is expected to be recognized over a weighted-average period of 2.9 years.

The fair value of stock options granted during the nine months ended September 30, 2026 and 2025 were estimated at the grant date using the Black-Scholes option pricing model based on the following assumptions:

	Nine Months Ended September 30,	
	2026	**2025**
Expected term, years	5.50 - 6.08	5.66 - 6.08
Expected volatility	70.3% - 74.0%	71.3% - 74.1%
Expected dividends	—	—
Risk-free interest rate	3.8% - 4.7%	3.8%

Extension of Exercise Period

In April 2026, the Company extended the post-termination exercise period of certain vested stock option awards held by former executives. The Company accounted for the extension as a modification of existing awards under ASC Topic 718 and determined the incremental fair value associated with the modification using a Black-Scholes option pricing model as of the modification date. The Company recognized incremental stock-based compensation expense of $2.0 million during the nine months ended September 30, 2026.

Restricted Stock Units

Activity under the 2025 Plan with respect to the Company's RSUs during the nine months ended September 30, 2026 was as follows:

	Number of Shares	**Weighted-Average Grant Date Fair Value**
Outstanding as of December 31, 2025	—	$ —
Granted	484,126	9.07
Vested and released	(42,381)	10.13
Forfeited and cancelled	(79,913)	10.19
Unvested and expected to vest at September 30, 2026	361,832	$ 8.70

As of September 30, 2026, there was $2.9 million of total unrecognized compensation cost related to RSUs that is expected to be recognized over a weighted average period of 2.7 years.

11. 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 September 30,	
	2026	**2025**
Common stock options issued and outstanding	12,222,399	8,228,828
Unvested RSUs of common stock	361,832	—
Total	12,584,231	8,228,828

12. Related Party Transactions

Transition Services Agreement with Related Party

In April 2024, Legacy BBOT entered into a transition services agreement with BridgeBio Pharma (as amended, the "BridgeBio TSA"), under which BridgeBio Pharma provides certain consulting services to the Company.

During the three and nine months ended September 30, 2026, the Company recognized nil and $0.4 million, in research and development expenses, and nil and $0.1 million in general and administrative expenses, respectively, for services provided by BridgeBio Pharma under the transition services agreement and related amendments.

During the three and nine months ended September 30, 2025, the Company recognized $0.2 million and $0.6 million, respectively, in research and development expenses, and $7.9 million and $8.3 million, respectively, in general and administrative expenses for the services provided by BridgeBio Pharma under the transition services agreement and related amendments. The amounts included in general and administrative expenses for the three and nine months ended September 30, 2025 include the fair value of the common stock issued to BridgeBio Pharma of $7.8 million discussed below.

No related party income from transition services agreements was recognized during the three and nine months ended September 30, 2026 or 2025.

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.

Redeemable Convertible Preferred Stock

All shares of the Series Seed redeemable convertible preferred stock and Series A redeemable convertible preferred stock of Legacy BBOT were issued to BridgeBio Pharma and became common stock of the Company upon the Closing of the de-SPAC Transaction.

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 three and nine months ended September 30, 2026, the Company recognized $0.2 million and $0.8 million, respectively, in connection with the RCA, which is included as a reduction to research and development expenses in the condensed consolidated statement of operations. For both the three and nine months ended September 30, 2025, the Company recognized $0.2 million as a reduction to research and development expenses in the condensed consolidated statement of operations in connection with the RCA.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion and analysis of our financial condition and results of operations of BridgeBio Oncology Therapeutics, Inc. ("BBOT" "we" "our" or "us") should be read together with the condensed consolidated financial statements for the three and nine months ended September 30, 2026 and 2025, and related notes included in this Quarterly Report on Form 10-Q ("Quarterly Report").

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. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" included in the Annual Report on Form 10-K (the "Form 10-K").

Overview

We are a clinical-stage biopharmaceutical company advancing a next-generation pipeline of novel small-molecule therapeutics targeting RAS and Phosphoinositide 3-kinase ("PI3K"), 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 PI3Kα and a synergistic portfolio that is designed to enable targeted KRAS combinations.

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 $KRAS^{G12C}$. 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 non-small cell lung cancer ("NSCLC"). We are currently enrolling the Phase 1 ONKORAS-101 trial (NCT06343402) for patients with $KRAS^{G12C}$ mutant 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 $KRAS^{G12C}$ mutant NSCLC. On January 7, 2026, we announced new clinical data from the ongoing Phase 1 trial. On September 8, 2026, we announced new clinical data for $KRAS^{G12C}$ inhibitor BBO-8520 and the strategic prioritization of BBO-8520 in combination with checkpoint inhibitor in 2L+ $KRAS^{G12C}$ inhibitor-experienced NSCLC patients. BBO-8520 in combination with pembrolizumab, at active dose levels, demonstrated promising efficacy data and a distinct safety profile, including a potentially differentiated liver toxicity profile. The expanded BBO-8520 plus pembrolizumab dataset in 2L+ $KRAS^{G12C}$ inhibitor-experienced NSCLC is expected in mid-2027.
- BBO-11818 is an orally bioavailable small molecule Pan-KRAS inhibitor that targets mutant KRAS in both the ON and OFF states. We are currently enrolling the Phase 1 KONQUER-101 (NCT06917079) trial for patients with locally advanced or metastatic KRAS mutant solid tumors. On April 20, 2026, we announced that BBOT was granted U.S. FDA Fast Track designation for BBO-11818 for the treatment of adult patients with advanced KRAS-mutant pancreatic ductal adenocarcinoma ("PDAC"). On September 8, 2026, we announced the strategic prioritization of BBO-11818 and BBO-10203 combinations in KRAS-mutant cancers. The BBO-11818 and BBO-10203 monotherapy data update is expected in the fourth quarter of 2026. Additionally, data from BBO-11818 and BBO-10203 internal and standard-of-care combination cohorts in colorectal cancer ("CRC") and PDAC is expected in mid-2027.
- BBO-10203 is an orally bioavailable small molecule with a novel mechanism of action designed to inhibit the physical interaction between RAS and PI3Kα, inhibiting RAS-driven PI3Kα-AKT signaling in tumors. We are currently enrolling the Phase 1 BREAKER-101 trial (NCT06625775) for patients with KRAS mutant CRC and PDAC. On September 8, 2026, we announced the strategic prioritization of BBO-11818 and BBO-10203 combinations in KRAS-mutant cancers. The BBO-11818 and BBO-10203 monotherapy data update is expected in the fourth quarter 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 three and nine months ended September 30, 2026, we incurred a net loss of $34.2 million and $132.7 million, respectively, and had an accumulated deficit of $489.3 million as of September 30, 2026. For the year ended December 31, 2025, we incurred a net loss of $134.0 million. Our ability to generate sufficient product revenue to achieve profitability will depend heavily on the development and eventual commercialization efforts related to 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 ongoing and future clinical trials for our product candidates;
- Pursue investigational new drug applications or comparable foreign applications that allow commencement of the planned clinical trials or additional 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 nonclinical 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 current good manufacturing practices ("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 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 nonclinical 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 Legacy BBOT was the deemed acquirer for accounting purposes. The 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 December 31, 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.

Components of Results of Operations

Revenues

To date, we have not generated any revenue from product candidates under development and do 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 nonclinical 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 nonclinical 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 nonclinical 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 nonclinical 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, Net

Interest Income

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

Income from Transition Services Agreements

Income from transition services agreements includes income for certain services provided to an unrelated party.

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 three months ended September 30, 2026 and 2025

The following table sets forth a summary of our results of operations for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,			
	2026	2025	Change	Change, %
Operating expenses:				
Research and development	$ 29,593	$ 35,052	$ (5,459)	(16)%
General and administrative	7,895	14,129	(6,234)	(44)%
Total operating expenses	37,488	49,181	(11,693)	(24)%
Loss from operations	(37,488)	(49,181)	11,693	(24)%
Other income, net:				
Interest income	3,262	3,444	(182)	(5)%
Income from transition services agreements	87	1,010	(923)	(91)%
Other expense	(37)	(30)	(7)	23%
Total other income, net	3,312	4,424	(1,112)	(25)%
Net loss	$ (34,176)	$ (44,757)	$ 10,581	(24)%

Research and Development Expenses

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

	Three Months Ended September 30,		
	2026	2025	Change
Research and development trials and consumables expenses	$ 20,139	$ 26,724	$ (6,585)
Payroll and personnel expenses	7,721	6,730	991
Facilities and other expenses	1,733	1,598	135
Total research and development	$ 29,593	$ 35,052	$ (5,459)

Research and development expenses decreased by $5.5 million or 16%, from $35.1 million for the three months ended September 30, 2025, to $29.6 million for the three months ended September 30, 2026. The changes in research and development expenses include the following key drivers:

- a $6.6 million decrease in research and development trials and consumables expenses pertaining to the strategic prioritization of our projects, and
- a $1.0 million increase in our payroll and personnel expenses primarily due to increased stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses decreased by $6.2 million or 44%, from $14.1 million for the three months ended September 30, 2025, to $7.9 million for the three months ended September 30, 2026. The changes in our general and administrative expenses were driven by the following key drivers:

- a $7.9 million decrease in payroll and personnel-related expenses primarily driven by a $7.8 million charge recognized in the third quarter of 2025 related to common stock issued to BridgeBio Pharma, and
- a $1.7 million increase in legal and other business expenses.

Interest Income

Interest income decreased by $0.2 million, from $3.4 million for the three months ended September 30, 2025, to $3.3 million for the three months ended September 30, 2026. Interest income was lower during the third quarter of 2026 due to less cash, cash equivalents, and marketable securities compared to the third quarter of 2025 as the de-SPAC Transaction and PIPE Financing had completed in August 2025.

Income from Transition Services Agreements

Other income of $0.1 million and $1.0 million for the three months ended September 30, 2026 and 2025, respectively, was related to a transition services agreement with an unrelated party.

Results of Operations

Comparison of the nine months ended September 30, 2026 and 2025

The following table sets forth a summary of our results of operations for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,			
	2026	2025	Change	Change, %
Operating expenses:				
Research and development	$ 118,620	$ 83,125	$ 35,495	43%
General and administrative	25,234	19,286	5,948	31%
Total operating expenses	143,854	102,411	41,443	40%
Loss from operations	(143,854)	(102,411)	(41,443)	40%
Other income, net:				
Interest income	10,757	6,919	3,838	55%
Income from transition services agreements	506	1,010	(504)	(50)%
Change in fair value of participation right liability	—	(725)	725	(100)%
Other expense	(145)	(40)	(105)	*
Total other income, net	11,118	7,164	3,954	55%
Net loss	$ (132,736)	$ (95,247)	$ (37,489)	39%

* Percentage is not meaningful

Research and Development Expenses

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

	Nine Months Ended September 30,		
	2026	2025	Change
Research and development trials and consumables expenses	$ 86,515	$ 60,010	$ 26,505
Payroll and personnel expenses	26,810	18,280	8,530
Facilities and other expenses	5,295	4,835	460
Total research and development	$ 118,620	$ 83,125	$ 35,495

Research and development expenses increased by $35.5 million or 43%, from $83.1 million for the nine months ended September 30, 2025, to $118.6 million for the nine months ended September 30, 2026. The changes in research and development expenses include the following key drivers:

- a $26.5 million increase in research and development trials and consumables expenses pertaining to increases in clinical trial expenses and manufacturing expenses for BBO-8520, BBO-10203 and BBO-11818, and
- an $8.5 million increase in our payroll and personnel expenses primarily due to increased headcount and stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses increased by $5.9 million or 31%, from $19.3 million for the nine months ended September 30, 2025, to $25.2 million for the nine months ended September 30, 2026. The changes in our general and administrative expenses were driven by the following key drivers:

- a $3.9 million increase in legal, facilities and other business expenses due to the growth and establishment of our operations as a public company as well as the filing of our shelf registration statement and establishment of our ATM offering program, and
- a $2.0 million increase in payroll and personnel-related expenses due to increased headcount in 2026 as a result of our standalone operations after the de-SPAC Transaction and stock-based compensation expense recorded as a result of certain modified equity awards and accrued severance costs for former executives during the second quarter of 2026. The increase in payroll and personnel-related expenses costs in 2026 was offset by the $7.8 million charge recognized in the third quarter of 2025 related to common stock issued to BridgeBio Pharma.

Interest Income

Interest income increased by $3.8 million, from $6.9 million for the nine months ended September 30, 2025, to $10.8 million for the nine months ended September 30, 2026. Interest income was higher during the nine months ended September 2026 due to interest earnings on our cash, cash equivalents, and marketable securities portfolio which includes the proceeds from the de-SPAC Transaction and PIPE Financing completed in August 2025 for the full nine month period in 2026.

Income from Transition Services Agreements

Other income of $0.5 million and $1.0 million for the nine months ended September 30, 2026 and 2025, respectively, was related to a transition services agreement with an unrelated party.

Change in Fair Value of Participation Right Liability

No change in fair value of participation right liability was recorded for the nine months ended September 30, 2026 because the participation right was settled in full in April 2025, and there were no subsequent changes in fair value of the associated liability. The change in fair value of participation right liability of $0.7 million for the nine months ended September 30, 2025 represented 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.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. For the nine months ended September 30, 2026, we incurred a net loss of $132.7 million and had an accumulated deficit of $489.3 million as of September 30, 2026. For the year ended December 31, 2025, we incurred a net loss of $134.0 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, we 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, we 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. We 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, we 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.

In September 2026, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-298697) (the "2026 Shelf") which was declared effective by the SEC on September 10, 2026. The registration statement included a base prospectus covering the offering and sale of our common stock, preferred stock, debt securities, warrants and units or any combination thereof, in an aggregate amount of up to $500.0 million. We also concurrently entered into a Sales Agreement (the "2026 ATM Agreement") with Leerink Partners LLC and Cantor Fitzgerald & Co. (collectively, the "2026 ATM Sales Agents") with respect to an "at-the-market" offering program, under which we may sell from time to time at our sole discretion and pursuant to the sales agreement prospectus included in the 2026 Shelf, shares of our common stock having an aggregate offering price of up to $200.0 million through the 2026 ATM Sales Agents. Under the 2026 ATM Agreement, we have agreed to pay the 2026 ATM Sales Agents a commission of up to 3.0% of the aggregate gross proceeds from sales of our common stock. As of September 30, 2026, we had not sold any shares pursuant to the 2026 ATM Agreement.

We estimate that the existing cash, cash equivalents, and marketable securities of $315.3 million as of September 30, 2026 will be sufficient to meet our cash requirements for at least twelve months from the issuance date of the condensed consolidated financial statements for the nine months ended September 30, 2026 included in this Quarterly Report. 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 Cash Flows

We have historically financed our operations primarily through the sale of equity securities. The de-SPAC Transaction executed in August 2025 represents a major financing event for our business generating cash inflows from the reverse recapitalization and the associated PIPE Financing. We utilized the proceeds from these financing transactions to finance our operations during the nine months ended September 30, 2026 and anticipate to continue doing so in the future to facilitate the development of our product candidates.

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.

Cash Flow Comparison for the nine months ended September 30, 2026 and 2025

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

	Nine Months Ended September 30,		
	2026	2025	Change
Net cash used in operating activities	$ (108,643)	$ (71,660)	$ (36,983)
Net cash (used in) provided by investing activities	(189,339)	65,562	(254,901)
Net cash provided by financing activities	774	383,988	(383,214)
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (297,208)	$ 377,890	$ (675,098)

Net Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $108.6 million. This amount consisted of our net loss of $132.7 million, adjusted for a change in net operating assets and liabilities of $7.2 million, and further offset by non-cash charges of $16.9 million. Our non-cash adjustments primarily consisted of $15.8 million in stock-based compensation, $0.2 million in depreciation, $0.3 million in amortization of right-of-use assets, and $0.5 million in net amortization (accretion) of premiums and

discounts on marketable securities. The net change in operating assets and liabilities was primarily due to increases in our liabilities, including $6.7 million in accrued research and development liabilities, $8.9 million in accounts payable, $1.1 million in accrued professional services, and $0.1 million in other accrued liabilities. These changes were partially offset by increases in assets of $7.8 million in prepaid expenses and other current assets and $0.9 million in other non-current assets, as well as decreases in liabilities of $0.5 million in accrued compensation and benefits, $0.4 million in operating lease liabilities, and $0.1 million in net balance due to and from related parties.

Net cash used in operating activities for the nine months ended September 30, 2025 was $71.7 million. This amount consisted of our net loss of $95.2 million, adjusted for a change in net operating assets and liabilities of $12.9 million, and further offset by non-cash charges of $10.7 million. Our non-cash adjustments primarily consisted of $7.8 million charge representing the fair value of shares issuable to BridgeBio Pharma, $2.9 million in stock-based compensation, $0.7 million for losses from changes in the fair value of the participation right liability, partially offset by $1.2 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 $15.8 million increase in accrued research and development liabilities, $0.7 million increase in accrued compensation and benefits, $0.6 million increase in accounts payable, and $0.5 million increase in accrued professional services. These changes were partially offset by an increase of $4.4 million in prepaid expenses and an increase of $0.4 million in other non-current assets.

Net Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2026 was $189.3 million, which consisted of $146.9 million in cash inflows from maturities and sales of marketable securities, offset by cash outflows of $336.1 million from purchases of marketable securities and $0.1 million in purchases of property and equipment. The proceeds from the de-SPAC Transaction were primarily invested in cash equivalents and short-term marketable securities as of December 31, 2025, but were reallocated to investments in short and long-term marketable securities as of September 30, 2026. This resulted in significant cash flows from investing activities for the nine months ended September 30, 2026 as a result of purchases of marketable securities.

Net cash provided by investing activities for the nine months ended September 30, 2025, was $65.6 million, which consisted of $129.0 million in cash inflows from maturities of marketable securities, offset by $62.9 million in cash outflows from purchases of marketable securities and $0.5 million in purchases of property and equipment.

Net Cash Flows from Financing Activities

Net cash provided by financing activities of $0.8 million for the nine months ended September 30, 2026 included $0.9 million in proceeds from option exercises, offset by $0.1 million in payments of deferred transaction costs and RSU share repurchase cost to satisfy tax withholding.

Net cash provided by financing activities of $384.0 million for the nine months ended September 30, 2025 included $373.5 million in proceeds from reverse recapitalization and PIPE Financing and $22.2 million cash inflows from the issuance of Series B shares to UCSF, offset by $11.7 million cash outflow related to the payment of deferred transaction costs.

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 nonclinical, clinical and regulatory milestones;
- Continuing our research and drug discovery and development efforts;
- Conducting nonclinical studies 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
- Continuing to operate 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, we entered into a license agreement with UCSF and were 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 an 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 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, we entered into a cooperative research and development agreement ("Leidos CRADA") with Leidos Biomedical Research, Inc. ("Leidos"). In December 2018, we entered into a license agreement ("Initial Leidos License"), under which we were 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. We subsequently entered into three additional license agreements with Leidos ("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 Pan-KRAS 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, we executed an amendment to extend the expiration date of the Leidos CRADA by nine months to September 2026. In December 2025, the Leidos Agreements were amended to introduce an additional $1.5 million in contribution funding payments. In September 2026, we executed the tenth amendment to the Leidos CRADA, with an effective date of August 12, 2026 to extend the expiration date to March 2027 and provide an additional $1.0 million in funding contribution payments, of which $0.5 million was paid in September 2026 upon execution of the amendment. As of September 30, 2026, payments made under the Leidos CRADA exceeded the related research and development expense recognized, resulting in a prepaid balance of $0.4 million, which was included in prepaid expenses and other current assets in the condensed consolidated balance sheet.

Under the Additional Leidos Licenses, we incurred initial upfront fees of $1.8 million and we are required to pay Leidos certain annual license maintenance fees and royalties on net sales for such licensed compounds. As of September 30, 2026, we are obligated to make contingent milestone payments totaling up to $25.9 million upon the achievement of certain clinical and regulatory milestones.

As of September 30, 2026 and December 31, 2025, we recorded a $0.5 million liability for milestones that had been achieved but remained unpaid, which was included in accrued research and development liabilities in the condensed consolidated balance sheets. In connection with our arrangements with Leidos, we recognized research and development expenses of $0.6 million and nil for the three months ended September 30, 2026 and 2025, respectively, and $2.0 million and $2.2 million for the nine months ended September 30, 2026 and 2025, respectively.

Lawrence Livermore National Security License and Cooperative Research and Development Agreements

In May 2018, we 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. We 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 PI3Kα 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, we 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, we executed three separate amendments to the 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, we executed an amendment to extend the LLNS CRADA expiration date by six months to June 2026. In January 2026, we executed an amendment with LLNS to extend the CRADA expiration date another twelve months until June 2027 and included additional estimated funding contributions of $5.0 million to be paid by us over the remaining term. As of September 30, 2026, payments made under the LLNS CRADA exceeded the related research and development expense recognized, resulting in a prepaid balance of $0.4 million, which was included in prepaid expenses and other current assets in the condensed consolidated balance sheet.

Upon execution of the LLNS Agreements, we paid an initial upfront cash fee of $0.2 million. In addition, under the terms of the LLNS Agreements, we are required to pay LLNS certain annual license maintenance fees and royalties to LLNS on net sales for such licensed compounds. As of September 30, 2026, we are required to make contingent milestone payments totaling up to $21.8 million upon the achievement of certain clinical, regulatory, and sales milestones.

As of September 30, 2026, no milestones had been achieved but not paid and therefore no liabilities associated with LLNS were recorded as of September 30, 2026 or December 31, 2025 on the condensed consolidated balance sheets. In connection with our arrangements with LLNS, we recognized research and development expenses of $0.1 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively, and $0.2 million and $0.6 million for the nine months ended September 30, 2026 and 2025, respectively.

As of September 30, 2026, 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 financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed 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 financial statements, as well as revenues, if any, and 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.

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC.

Recent Accounting Pronouncements

See Note 2, "Summary of significant accounting policies" to our condensed consolidated financial statements, which are included in this Quarterly Report, for more information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended ("Exchange Act"), and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Management's 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 (who serves as our principal executive officer), and our Chief Operating Officer (who serves as our principal financial officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026 and, based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2026.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Except as discussed below, as of the date of this Form 10-Q, we are 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, we 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, as those events are contractually defined in the UCSF License Agreement (the "Indexed Milestone Payment"). Since April 2025, we have received periodic communications from UCSF stating that, in the future, the Indexed Milestone Payment in an amount less than $5.0 million is or will become due on an unspecified date following the Closing Date of the Business Combination Agreement. We disagree with UCSF's interpretation of the terminated UCSF License Agreement and believe that no such payment is due now or will be due in the future.

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-Q, including our 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.

Summary of Risk Factors

- We have a limited operating history, have not completed any clinical trials, have no products approved for commercial sale 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.
- 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 nonclinical 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 nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, 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. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- 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 nonclinical 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 and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.
- 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 other jurisdictions.
- We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review in the U.S., and PRIME (priority medicines) in the EU, 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 and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.
- Our success is highly dependent on our ability to attract, hire and retain highly skilled executive officers and employees, and we may experience difficulties in managing the future growth of our organization.
- 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 ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.
- 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 nonclinical 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 in the past identified a material weakness in our internal controls over financial reporting. If we identify 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 our financial and operating reporting may be adversely affected, and confidence in our operations and disclosures may be lost.
- 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 changes in regulatory activities and economic policies and events related to the current U.S. presidential administration, ongoing military conflicts and geopolitical instability and inflation and interest rates.

Risks Related to our Financial Position and Need for Additional Capital

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

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

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

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

We have incurred significant net losses in each period since our inception, and expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through private placements of securities. Our net losses were $132.7 million and $95.2 million for the nine months ended September 30, 2026 and 2025, respectively, and $134.0 million for the year ended December 31, 2025. As of September 30, 2026, we had an accumulated deficit of $489.3 million. We have not yet completed any clinical trials. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant and increasing expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our 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 our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

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.

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

- successful and timely completion of nonclinical and clinical development of BBO-8520, BBO-10203, BBO-11818 and any future product candidates from our 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 our current or future discovery programs;

- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development and for any third-party product candidates for which our product candidates are designed to serve as a second-line therapy in the applicable patient populations;
- developing an efficient and scalable manufacturing process for our product candidates, including the production of finished products that are appropriately packaged for sale if our 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 our 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 our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third- party payors, including the willingness of physicians to use our 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 our 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 our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates, if approved;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

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

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.

Since inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate additional clinical trials of, and seek marketing approval for, our product candidates. Developing pharmaceutical products, including conducting nonclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Even if one or more of our product candidates or any future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory authorities to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our clinical trials, including our ongoing and planned clinical trials, are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of our product candidates or any future product candidates that we develop. We are currently conducting Phase 1 clinical trials of BBO-8520, BBO-10203 and BBO-11818. We are not permitted to market or promote any product candidate before it receives marketing approval from the FDA, EMA or any comparable foreign regulatory authorities. We are also incurring additional costs associated with operating as a public company. Accordingly, we may need to obtain additional funding in order to continue our operations.

We estimate that our existing cash, cash equivalents, short-term marketable securities, and long-term marketable securities as of the date of this report will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2029.

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

We 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 our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our 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 our cost of financing or restrict our access to potential sources of future liquidity. To the extent that we raise 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 our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

Risks Related to Our Product Development, Regulatory Approval and Commercialization

Our future prospects are substantially dependent on the advancement 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 are currently conducting Phase 1 clinical trials of BBO-8520, BBO-10203 and BBO-11818. Our ability to generate product revenue, which we do 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. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA, EMA or any comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on several factors, including the following:

- successful and timely completion of nonclinical 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 our 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 our 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 our 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 our product candidates that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;

- the timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- in the case of BBO-8520 as a potential second-line therapy for NSCLC patients whose disease progresses following treatment with a $KRAS^{G12C}$ inhibitor, the timely receipt by third parties of marketing approvals from applicable regulatory authorities for, and the successful commercialization of, $KRAS^{G12C}$ inhibitors that are currently in Phase 3 development;
- 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 our product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- the protection of our rights in our intellectual property portfolio;
- establishing sales, marketing and distribution capabilities and the successful launch of commercial sales of our 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 our product candidates, if approved, in lieu of (or in conjunction with) other approved therapies;
- Our ability to compete with other therapies; and
- Our ability to address any potential delays resulting from factors related to public health emergencies, natural disasters or geopolitical events.

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

Our nonclinical 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.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Nonclinical 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 nonclinical study and clinical trial processes, there is a high risk of failure, and we may never succeed in developing marketable products.

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

- failure of our product candidates in nonclinical studies or clinical trials to demonstrate safety and efficacy;
- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials or generate additional data beyond that which we expected to generate;
- negative or inconclusive clinical trial results that may require us 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 us in a timely manner, or at all;

- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable adverse events or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving our product candidates.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we are currently contemplating, if we are unable to successfully complete clinical trials of our 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, we may incur unplanned costs, be delayed in seeking and obtaining marketing approval, if we receive 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.

Our 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 we are 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 our 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 we believe, based on our nonclinical work and clinical trials to date, that our 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 our product candidates are limited to those with KRAS and PI3Kα mutations and HER2 amplification and may not be completely defined but are substantially smaller than the general treated cancer population, and we 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 we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and commercialize our product candidates and achieve profitability. In addition, the successful development and regulatory approval of BBO-8520 as a potential second-line therapy for NSCLC patients who have previously been treated with a $KRAS^{G12C}$ inhibitor is contingent on the regulatory approval and successful commercialization of $KRAS^{G12C}$ inhibitors that are presently in Phase 3 development by third parties, over which we have no control. We do not know if our approach of focusing on treating patients with RAS-dependent cancers will be successful, and if our approach is unsuccessful, our business will suffer.

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 to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials of any product candidate in any indication, we must submit the results of nonclinical 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 our proposed clinical trial protocol, as part of an IND or similar regulatory submission under which we must receive authorization to proceed with clinical development. The FDA, EMA or other comparable foreign regulatory authorities may require us to conduct additional nonclinical studies for any product candidate before they allow us to initiate clinical trials under any IND, CTA or comparable application which may lead to additional delays and increase the costs of our nonclinical 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, we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on nonclinical, clinical and quality data generated by our CROs and other third parties for regulatory submissions for our product candidates. While we have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. We are 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 our future product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, 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 our 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 we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs/IECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Certain of our current or future scientific advisors or consultants who receive compensation from us may become investigators for our future clinical trials. Under certain circumstances, we may be required to report some of these relationships to the FDA. Although we expect any such relationships to be within the FDA's guidelines, the FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates. If we experience 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 our ability to generate product revenue will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenue, which may harm our business, financial condition, results of operations and prospects significantly.

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

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

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

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through nonclinical 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 nonclinical 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, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical 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 nonclinical studies and clinical trials are never approved as products. The development of our product candidates and our stock price may also be impacted by inferences, whether correct or not, that are drawn between the success or failure of nonclinical studies or clinical trials of our competitors or other companies in the biopharmaceutical industry, in addition to our own nonclinical 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 our 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 our 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, our clinical trial outcomes.

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

We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

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

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize BBO-8520, BBO-10203 and BBO-11818 and future product candidates from our 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 nonclinical 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 we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of nonclinical 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 we successfully advance any research candidates into nonclinical and clinical development, their success will be subject to all of the nonclinical, clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, there can be no assurance that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates.

Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our approach to build a pipeline of product candidates with commercial value.

A key element of our strategy, which is unproven, is to use and expand our 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 our 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 we may develop may not be determined to be safe or effective as cancer therapeutics, and we may not be able to develop any other product candidates. For example, the potential product candidates that we have identified or may identify 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. Additionally, the successful development and commercialization of some of our product candidates are dependent on the receipt of marketing approvals for product candidates that are currently in clinical development by third parties, over which we have no control. If we do not successfully

develop and commercialize product candidates, we will not be able to generate product revenue in the future, which would result in significant harm to our financial position and adversely affect our business.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our 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. Leadership changes at the FDA in the current presidential administration may compound the uncertainty associated with obtaining regulatory approval. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional nonclinical, 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 we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product candidate's commercial potential. Even if approved, we may be required to conduct additional studies to or obtain, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

Applications for our 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 our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude us 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 we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical 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 our product candidates by the FDA, EMA or other comparable foreign regulatory authorities;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our 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 we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for our product candidates;
- We may not obtain or maintain adequate funding to complete our 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 our clinical data insufficient for approval.

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

We may not be able to submit INDs, CTAs or comparable applications to commence clinical trials on the timelines we expect, and even if we are able to, the FDA, EMA or any comparable foreign regulatory authority may not permit us to proceed.

Our research and development efforts to date have resulted in the initiation of clinical development of BBO-8520, BBO-10203 and BBO-11818. We may not be able to submit INDs for any future product candidates we may identify on the timelines we expect, or such submissions may not take effect on the timeline that we anticipate, or at all. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we 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 us 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, we cannot guarantee that the FDA will not change our requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to submit INDs, CTAs or comparable applications on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

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.

If our product candidates are associated with undesirable adverse events or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we 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 us from achieving or maintaining market acceptance of the affected product candidate and may harm our 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 our product candidates as is typically the case with oncology drugs. Results of our studies or trials could reveal a high and unacceptable severity and prevalence of these or other adverse events. In such an event, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our 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 our business, financial condition and prospects significantly.

In addition, our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory authorities. Our product candidates may be studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause adverse events that are unrelated to our product candidates but may still impact on the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, 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 our tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our 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. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

Interim, preliminary and topline data from our nonclinical studies and clinical trials that we announce 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.

We have disclosed interim preliminary or topline data from our clinical trials and expect to continue to make such disclosures 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, we 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. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, preliminary or topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data has 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, we 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 our business and prospects. Further, additional disclosure of interim, preliminary or topline data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose 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 we determine is the material or otherwise appropriate information to include in our public disclosures, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, preliminary or topline data that our report differs from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are 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. Our ability to enroll eligible patients may be limited or may result in slower enrollment than anticipated. We utilize profiling of patients' tumors to identify suitable patients for recruitment into our clinical trials. For these clinical trials, we seek patients who carry specific gene mutation or amplification that our product candidates are designed to precisely target. We cannot be certain (i) how many patients will have the requisite mutation or amplification that qualify for inclusion in our 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, we face competition, including from large pharmaceutical companies with significantly more resources than us, for enrollment of our targeted patient populations, which may impact our ability to successfully recruit patients for our clinical trials. If our strategies for patient identification and enrollment prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates.

Patient enrollment may be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our 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 our 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 we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our 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.

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

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

We are currently focusing our resources and efforts on our lead product candidates, BBO-8520, a KRAS inhibitor for $KRAS^{G12C}$ NSCLC; BBO-10203, a PI3Kα:RAS breaker for PIK3CAmut BC, HER2amp BC, KRASmut NSCLC, KRASmut PDAC, and KRASmut CRC; and BBO-11818, a Pan-KRAS inhibitor for $KRAS^{G12X\ NSCLC}$, $KRAS^{G12X\ PDAC}$, and $KRAS^{G12X\ CRC}$, and on advancing our discovery programs. As a result, because we have limited resources, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development activities for BBO-8520, BBO-10203 and BBO-11818 and our discovery programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for BBO-8520, BBO-10203 and BBO-11818 or any future product candidates identified through our discovery programs, we 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 us to retain sole development and commercialization rights. In addition, given the similar approaches being utilized by our lead product candidates, negative developments for one candidate in the pipeline may have negative implications for other candidates in the pipeline.

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

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities, particularly for later-stage trials. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our 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 our 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 our third-party suppliers (including suppliers of key active pharmaceutical ingredients, or API, drug product, and starting and intermediate materials) are currently our sole source of supplies and, as a result, an issue with one of these suppliers may more significantly impact or delay our development or commercial plans, as discussed further under the risk factor titled, "Some of the third parties upon whom we currently rely for the supply of the active pharmaceutical ingredients, drug product and starting materials used in our product candidates are our sole source of supply, and the loss of any of these suppliers could delay our development efforts and harm our business."

Our use of new third-party manufacturers or suppliers also increases the risk of delays in production or insufficient supplies of our product candidates (and the key API, drug product, and starting and intermediate materials for such product candidates) as we transfer our manufacturing technology to these manufacturers or suppliers and as they gain experience manufacturing or producing our 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 our product candidates (or the key API, drug product, and starting and intermediate materials for such product candidates), or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will supply or produce sufficient quantities of our 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. We may be delayed if we need to change the manufacturing process used by a third party. Further, if we change an approved manufacturing process, then we 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 nonclinical, 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 our 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 us.

While we have entered into master services agreements with our current suppliers under which work is performed on an as-needed basis pursuant to quotations or proposals, we do not currently have any agreements with third-party manufacturers for long-term commercial supply. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any of our product candidates, or may be unable to do so on acceptable terms. Even if we are 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. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, 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 our product candidates.

Our future product candidates and any products that we 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 us.

We are 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 our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition. For example, the United States government has proposed and, in certain cases, enacted legislation and policies intended to restrict or prohibit the use of biotechnology services or products provided by certain foreign entities

that are owned by, controlled by, or associated with the government of China or other foreign adversaries. Such measures include the "BIOSECURE Act", which was enacted on December 18, 2025, as well as related executive branch actions, which are intended to limit U.S. government funding or support for biotechnology activities involving specified foreign entities and to reduce perceived national security risks associated with reliance on such entities. Some of our sole source suppliers are companies in China, including some named in these bills, and it is possible some of our contractual counterparties could be impacted by the legislation described above. If applied to our third-party vendors, these laws or policies could restrict our ability, or the ability of our collaborators, contract research organizations, manufacturers, or other third-party vendors, to engage or continue to engage certain Chinese or Chinese-affiliated service providers, even where such providers are currently permitted to operate under applicable law. We could experience delays in finding suitable replacement service providers located outside China or not otherwise owned by or associated with Chinese companies, which could have a material adverse effect on our development activities and our business. In addition, alternative vendors may be more expensive, may have longer lead times, or may lack the same technical capabilities or capacity, which could increase our costs or delay our development timelines.

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

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

We face substantial competition which may result in others discovering, developing or commercializing products before or more successfully than we do.

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. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are currently attempting and may in the future attempt to develop product candidates. In addition, our product candidates may need to compete with drugs physicians use off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our product candidates.

In particular, there is intense competition in the field of oncology. We have 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. We also compete with these organizations to recruit and retain qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

For BBO-8520, there are currently two $KRAS^{G12C}$ inhibitors approved by the FDA for use in $KRAS^{G12C}$ mutant advanced or metastatic NSCLC.

For BBO-10203, there is one PI3Kα 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 $KRAS^{G12X}$ mutant lung, colorectal, or pancreatic cancers.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, nonclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than us. 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 us and may also have product candidates that have been approved or are in late stages of development, and collaborative arrangements in our 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 we develop 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, our programs. As a result of all of these factors, our 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 our field before we do.

Our 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 we 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, our products. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for our product candidates, which could result in competitors establishing a strong market position before we are able to enter the market, or make our development and marketing more complicated. Even if the product candidates we develop 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 our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of products we may develop, if approved, could be adversely affected.

Our 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 our 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 our 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 Risk Evaluation and Mitigation Strategy ("REMS"), if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our 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 our 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 our product candidates or similar approved products or product candidates of third parties; and
- the approval of other new therapies for the same indications.

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

The market opportunities for any product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate 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, we plan 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, we would potentially expect to seek approval ultimately as a first line therapy. There is no guarantee that our product candidates, even if approved for previously treated patients, would be approved for an earlier line of therapy, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk. Additionally, we are currently developing BBO-8520 as a potential second-line therapy in NSCLC patients who have previously been treated with a $KRAS^{G12C}$ inhibitor, and if $KRAS^{G12C}$ inhibitors that are presently in Phase 3 development by third parties do not receive marketing approval or otherwise do not become commercially available, we will not be able to obtain regulatory approval for or successfully commercialize BBO-8520 in this target patient population.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our 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 we are targeting, especially if new therapies that are approved while we advance our product candidates affect the treatment paradigm and/or the size of the target population. The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have 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 we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Any product candidates we develop 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 our 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, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Further, it is possible that a third-party payor may consider our 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 we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain 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 our 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 us to provide scientific and clinical support for the use of our 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, we cannot be sure that our 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 our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. For further discussion, see "- Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for our 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 we obtain for our 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. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

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 our 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 we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries have and will continue to put pressure on the pricing and usage of therapeutics such as our 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, we may be required to conduct a clinical trial that compares the cost-effectiveness of our 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 we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

If we are 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 we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us 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 our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our 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 our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability and other insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to advancing our product candidates into later stages of development or marketing any of our product candidates, if approved. Any insurance we have 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, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability or other claims or incidents, including data breach and incidents, that could have an adverse effect on our business and financial condition.

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

The manufacturing processes our third-party contract manufacturing organizations ("CMOs") use to produce our 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 our 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 our suppliers, including historical disruptions, which could reoccur in connection with any future global pandemic or health emergency.

Several of our 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. Our 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, our 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. We 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 us 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 we 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 us to delay clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

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

Any problems in our CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make us 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 our manufacturing process could also restrict our ability to meet potential future market demand for any products that may be approved.

Certain of our 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 us to abandon or limit our clinical development activities.

Patients in certain of our 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 we 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 our product candidates. While these side effects or AEs may be unrelated to our product candidates, they may still affect the success of our clinical trials. The inclusion of critically ill patients in our 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 us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our product candidates through clinical development may harm our business, financial condition, results of operations and prospects.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

Our 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 nonclinical 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. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We do 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. We 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 our 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 our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude us 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 we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our 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 we contract 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 our clinical data insufficient for approval.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we 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.

We are 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.

We plan to develop certain of our current product candidates and potentially future product candidates in combination with other therapies, which would expose us to additional risks.

We plan to develop certain of our 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, we reported positive preliminary safety and antitumor data across our three orally bioavailable, differentiated small molecule RAS and PI3Kα programs. The data updates included BBO-8520, a direct inhibitor targeting both the ON and OFF states of $KRAS^{G12C}$; BBO-11818, a Pan-KRAS inhibitor targeting mutant KRAS in both the ON and OFF states, and BBO-10203, a RAS-PI3Kα breaker with a novel mechanism of action designed to inhibit the physical interaction between RAS and PI3Kα. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we 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 our 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 our 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 our product candidates or our own products being removed from the market or being less successful commercially.

We are also evaluating and may in the future evaluate our product candidates in combination with, or as second-line therapies to, 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 our product candidates have obtained approval for marketing from any regulatory authority, and we plan to evaluate certain of our product candidates in combination with each other. We 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. In addition, we are currently developing certain of our product candidates as potential second-line therapies to product candidates currently in clinical development by third parties, and if such third-party product candidates fail to receive regulatory approval or achieve commercial success, we will not be able to obtain regulatory approval for our product candidates in the applicable target patient populations and may need to alter our clinical development strategies.

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 we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have conducted and intend to continue conducting certain of our clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We have conducted and intends to continue conducting certain of our 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. The FDA has signaled that foreign GCP inspections will be increasing alongside greater transparency of GCP inspection outcomes.

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 our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

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

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 other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we 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 nonclinical 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 we intend to charge for our 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 us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fails to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Further, we could face increased regulatory burden 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. Since January 1, 2025, under the Windsor Framework, the MHRA regulates medicines through UK-wide marketing authorizations, including for Northern Ireland. As a result, we will be required to obtain separate authorizations in order to market our 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 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 into EU law, and is not expected to become applicable before 2028. The revisions may however have a significant impact on the pharmaceutical industry and our 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 us to restrict or delay efforts to seek regulatory approval in the U.K. for our product candidates, which could significantly and materially harm our business. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the applicable regulatory requirements, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed, and our business, financial condition, results of operations and prospects could be harmed.

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

Any regulatory approvals that we may receive for our 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 our 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 our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our 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 current good manufacturing practices ("cGMP") and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, competent authorities of the EU Member States and other regulatory authorities for compliance with cGMP regulations and standards. If we 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 us, 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 us to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our 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 our product candidates. We 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 we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we 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 our 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 we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are 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 our product candidates or a group of therapeutic products, and we do not obtain or we face delays in obtaining clearance or approval of a diagnostic test, we may not be able to commercialize the product candidate and our ability to generate revenue may be materially impaired.

If we are 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 our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our 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 we may develop, which we expect 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 our product candidates, whether before, concurrently with approval, or post-approval of the product candidate, we 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 nonclinical 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 us 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 our related product candidates. Changes in policy or approach to regulation by the FDA, EMA and other regulatory authorities may impact our development of a companion diagnostic for our 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 our product candidates. We 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 our future approved product candidates' covered indications, we may no longer need to continue our companion diagnostic development plans or we need to alter those companion diagnostic development strategies, which could adversely impact our ability to generate revenue from the sale of our companion diagnostic test.

Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our 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 nonclinical 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. We and our future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our 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 we are unable to successfully develop companion diagnostics for our product candidates, or experiences delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We 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 our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the co-development or commercialization of our companion diagnostic and therapeutic product candidates.

Where appropriate, we plan to pursue approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval.

Where appropriate, we plan to pursue accelerated development strategies in areas of medical need. We may seek an accelerated approval pathway for one or more of our 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, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or 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, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide 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 us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our 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 our competitive position in the marketplace.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review in the U.S., and PRIME (priority medicines) in the EU, 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 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 our product candidates, or priority review for our marketing applications for our 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.

We may also seek Fast Track designation for one or more of our 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.

We may also seek a priority review designation for one or more of our 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 we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, such as the Fast Track designation we have received for BBO-8520 for the treatment of adult patients with previously treated, $KRAS^{G12C}$-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 our 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, we may seek support under the EMA's PRIME scheme for some of our 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 our 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. We may apply for support under the PRIME scheme for some of our product candidates and it may not be granted. Even if we receive PRIME designation for any of our 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.

We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, 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. our target indications may include diseases with large patient populations or may include orphan indications. There can be no assurances that we will be able to obtain orphan designation for our current product candidates or candidates we 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 we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have 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 we seek 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 we are unable to ensure that we 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 we obtain 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.

In February 2026, the Consolidated Appropriations Act of 2026 codified the FDA's longstanding interpretation of the scope of orphan drug exclusivity to apply to "the same drug for the same approved use or indication within such designated rare disease or condition." This change, which applies retroactively, authorizes the FDA to approve multiple versions of the same orphan drug for different sub-indications and subpopulations, such as adult and pediatric patients or multiple variations of the same disease that are caused by different genetic variants, and ties orphan exclusivity to the indication for which the orphan drug was ultimately approved. The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies.

Current and future legislative and regulatory reform measures and cost containment initiatives may increase the difficulty and cost for us to obtain adequate reimbursement for our 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 has developed, and may continue to develop, new payment and delivery models, including international reference-pricing initiatives such as GLOBE, GUARD, and GENEROUS, bundled payment models, or other drug pricing reforms. The current administration has imposed significant tariffs on certain imported patented pharmaceutical products and associated ingredients, effective beginning in July 2026, subject to exceptions and reduced rates for products of manufacturers that enter into qualifying pricing and onshoring arrangements with the administration, including most-favored-nation pricing arrangements intended to align U.S. drug prices with prices paid in other developed countries. 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 may continue to consider new legislative measures intended 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 our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect 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 we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our 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 we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used. We expect that the Patient Protection and Affordable Care Act, 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 us from being able to generate revenue, attain profitability or commercialize our 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 our 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, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our 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 our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the commercial launch of our products could be delayed, possibly for lengthy periods of time, we or our collaborators may not launch at all in a particular country, we may not be able to recoup our investment in one or more products, and there could be a material adverse effect on our business.

We are 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 us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

There are multiple privacy and data security laws that may impact our business activities in the U.S. and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our 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. We are not currently classified as a covered entity or business associate under HIPAA. Thus, we are not directly subject to HIPAA's requirements or penalties. The healthcare providers, including certain research institutions from which we 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, we could face criminal penalties if we knowingly receive 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, we may maintain sensitive personally identifiable information, including health and genetic information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement such programs. As such, in addition to risks and obligations related to HIPAA, we 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" in our annual report on Form 10-K for the fiscal year ended December 31, 2025, which is incorporated herein by reference, 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 our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Individuals from whom we or our collaborators may obtain health information, as well as the healthcare providers who may share this information with us, may have statutory or contractual rights that limit the ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

In addition to HIPAA, we are subject to other U.S. federal, state, and international privacy and data protection laws that may increase our compliance costs, restrict our use of personal information, or expose us to regulatory penalties or private litigation. For a detailed discussion of the risks associated with these laws and regulations, see "Other U.S. Regulatory Matters" in our annual report on Form 10-K for the fiscal year ended December 31, 2025, which discussion is incorporated herein by reference.

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 organizational 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 our ability to obtain regulatory approvals for our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

Disruptions at the FDA, the SEC and other government agencies or comparable regulatory authorities caused by funding shortages, leadership changes, 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 our business operations rely, including timely reviews, which could negatively impact our 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 leadership and 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 our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, 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 our 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 our regulatory submissions, which could materially adversely affect our 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 our regulatory submissions, which could have a material adverse effect on our business, including INDs placed on clinical holds or delayed new drug approvals. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Under the current U.S. presidential administration, 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 our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our 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 our ability to obtain guidance from the FDA on our 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 us 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 our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the current administration or otherwise, there could be a material adverse effect on us and our business.

If our product candidates are licensed for marketing and receive federal healthcare reimbursement, any relationships we may have with healthcare providers will be subject to applicable healthcare fraud and abuse laws and regulations, which could expose us 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 we are able to obtain marketing approval. Any arrangements we have with healthcare providers, third-party payors and customers will subject us 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 we conduct clinical research, markets, sells and distributes any products for which we obtain marketing approval. These include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or 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. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act ("FCA").
- federal civil and criminal false claims laws, including the FCA and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- HIPAA imposes criminal and civil liability for, among other things, executing, or attempting to execute, a scheme or making materially false statements in connection with the delivery of or payment for health care benefits regardless of the payor (e.g., public or private), items or services. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of

violating these statutes without actual knowledge of the statutes or specific intent to violate them in order to have committed a violation;

- 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.
- U.S. federal and state laws government price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives.

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. Our 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 we have with third parties and our business generally will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our 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 our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 our 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.

Our 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.

We are exposed to the risk that our 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 us. 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 our reputation. We have adopted a code of conduct and engage

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 we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Our 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 we operate, 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 our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. 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. Our 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 our employees, agents or contractors, or those of our 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 us, our officers or employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, brand, international activities, ability to attract and retain employees and business, prospects, operating results and financial condition.

In addition, our 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 our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect revenue. Compliance with applicable regulatory requirements regarding the conduct of clinical trials and export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our 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 we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges 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 our products by, or in our decreased ability to export our products to, existing or potential customers with international operations, in addition to adversely affecting cross-border operations and transactions. Any decreased use of our products or limitation on our ability to export or sell our products, or import materials for our products, would likely adversely affect our 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, our supply chain of materials and other imports needed for our 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 we are 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, our business, liquidity, financial condition, or operations would be materially and adversely affected.

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

We are 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste products. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our 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 our business, prospects, financial condition or results of operations.

Risks Related to our Business

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

We currently have a small team focused on research and development of RAS-pathway targeted small molecules. To succeed, we must recruit, hire, retain, manage and motivate qualified clinical, scientific, technical, financial and management personnel, and we face 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 us. Even if we are 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 our operating results.

We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel in these positions, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental if we cannot recruit suitable replacements in a timely manner. In April 2026, we announced certain changes to our management team, including the departures of our former President and Chief Executed Officer and our former Chief Financial Officer, and the appointments of Pedro J. Beltran as our President and Chief Executive Officer, Idan Elmelech as our Chief Operating Officer and principal financial officer, Marc Cobo as our principal accounting officer, and Neil Kumar as the Executive Chairman of our board of directors. Additionally, in November 2026, we announced the resignation of our Chief Medical and Development Officer, which will become effective in January 2027.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. 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 we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

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

In order to successfully implement our development and commercialization plans and strategies, and as we grow as a public company, we expect 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 our current and additional employees;
- managing our internal development efforts effectively, including the nonclinical, clinical, FDA, EMA and other comparable foreign regulatory authorities' review process for BBO-8520, BBO-10203 and BBO-11818 and our discovery programs, while complying with any contractual obligations to contractors and other third parties;
- managing increasing operational and managerial complexity; and
- improving our operational, financial and management controls, reporting systems and procedures.

We currently rely, 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 us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our nonclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval for any of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we 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 our discovery programs and, accordingly, may not achieve our research, development and commercialization goals.

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

As of September 30, 2026, we had 84 full-time employees, upon whom we rely for various administrative, research and development, and other services. The small size of our team may limit our ability to devote adequate personnel, time, and resources to support our operations or research and development activities, and the management of financial, accounting, and reporting matters. If our team fails to provide adequate administrative, research and development, or other services across our organization, our business, financial condition, and results of operations could be harmed.

Our internal computer systems, or those of any of our 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 our 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 our brand, material disruption of our operations, and potentially significant delays in our delivery to market.

Despite the implementation of security measures, our systems and the systems of our third-party CROs, other contractors (including sites performing our 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. We and the third parties upon which we rely face a variety of evolving threats, including from inadvertent or intentional actions by our 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 our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our 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 us and our 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 our employees are working remotely. As a result, we 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 we implement 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, we, and our 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, our data (including confidential information and personal data) or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage. Further, in such an event, the development and commercialization of our product candidates could be delayed. There can be no assurance that our 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, our data. Such events could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data, as well as claims or investigations from regulators or other third parties. Furthermore, significant disruptions of our 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 us. 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 our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to financial exposure related to the investigation of the security incident or data breach (including cost of forensic examinations), subject us to mandatory corrective action, and otherwise subject us 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 our business.

Notifications, follow-up actions, claims and investigations related to a security incident or data breach could impact our reputation and cause us 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 our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents and data breaches, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident or data breach. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our 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, our data (including personal data), or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations. Moreover, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with state, federal and/or international privacy and security laws.

Our 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 us from liabilities, damages, or claims related to our privacy and data security obligations. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure, security incident, or data breach of, our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of our merit, could be costly and divert management attention.

Our updating of our business systems could result in implementation issues and business disruptions

We have, and will continue to, update and consolidate systems and automate processes across many parts of our business, using a variety of systems, including the implementation of new enterprise resource planning ("ERP") software. Specifically, we implemented a new ERP system as of January 1, 2026. The expansion and ongoing implementation of operational systems may occur at a future date based on value to the business. In general, the process of planning and preparing for these types of integrated, wide-scale implementations is highly complex and success requires addressing a number of challenges, including information security assessment and remediation, data conversion, network and system cutover, user training, and integration with existing processes or systems. Incongruities in any of these areas could cause operational problems during implementation including inconsistent practices, delayed reporting, billing errors, and accounting errors.

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

We may use and integrate artificial intelligence into our business processes, and this innovation presents risks and challenges that could affect our adoption, and therefore our 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 our business.

The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our business processes 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 we enable or use models that contain actual or perceived biases, or otherwise draw controversy due to perceived or actual negative societal impact, we 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 and data privacy risks, including the disclosure or compromise of our 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, we expect 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 draft guidance on the use of artificial intelligence in regulatory decision-making for drug and biological products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating AI model outputs intended to support regulatory decision-making. If we develop or use AI systems that are governed by these laws or regulations, including as informed by regulatory guidance, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

Our 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 our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. The integration of AI systems, by us or by our vendors, may increase cybersecurity risk. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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

Our corporate headquarters are located in South San Francisco, California. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, fire, earthquake, power loss, telecommunications failure, terrorist activity, pandemic or other disasters and we do not have a recovery plan for such disasters. In addition, we do not carry sufficient

insurance to compensate for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our operations and financial condition and increase costs and expenses.

We have never commercialized a product candidate as a company before. If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We have never commercialized a product and currently do not have and have never had a significant marketing or sales team. In order to commercialize any product candidates, if approved, we 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 we may have approval to sell or market our product candidates. We 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 our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose 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 our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we 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 our own. If we are unable to enter into such arrangements when needed, on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

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

We may seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we expect that it will be subject to additional risks related to operating in foreign countries if we obtain 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 our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- the impact of pandemics or other public health emergencies, natural disasters and geopolitical events on our ability to produce our 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 our 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 our ability to attain or maintain profitable operations.

Changes in tax law could adversely affect our 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 us or holders of our 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 our business, cash flow, financial condition or results of operations.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our 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, our 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 our current year taxable income. As of December 31, 2025, we 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. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. There is also a risk that due to regulatory changes, such as suspensions on the use of NOL carryforwards, or other unforeseen reasons, our existing NOL carryforwards could expire or otherwise be unavailable to offset future income tax liabilities. Our ability to utilize our NOL carryforwards could have a material adverse effect on our cash flows and results of operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate 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 our 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 our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our 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
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we 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 our current or future product candidates and negatively affect our business.

The commercial success of our 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, our approach to targeting cancer cells carrying tumor causing mutations, including oncogenic RAS pathway mutations, is novel and unproven. Adverse events in clinical trials of our 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 we may develop. If public perception is influenced by claims that the use of cancer therapies is unsafe, whether related to our therapies or those of our competitors, our 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 our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our current or future product candidates.

Risks Related to our Intellectual Property

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us 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 us 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 our patents or patent applications or those of our future licensors. An unfavorable outcome may require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be adversely affected if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials and development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

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, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property rights we own (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 we develop). We seek to protect our proprietary position by filing patent applications in the U.S. and select other countries related to our technologies and product candidates that are important to our business and by in-licensing intellectual property related to such technologies and product candidates. We do not yet have issued patents for all of our most advanced product candidates in all markets in which we may commercialize them, but we continue to actively pursue patent protection for our technology and product candidates in certain jurisdictions around the world. However, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, or the methods of use or manufacture of those products. If we are unable to obtain and maintain meaningful patent protection in jurisdictions important to our business for our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, or other proprietary technologies, our business, financial condition, results of operations and prospects could be adversely affected.

The patent prosecution process is expensive, time-consuming and complex, and we 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 we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances involving technology that we may license from third parties, we 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 our business.

The patent rights of pharmaceutical and biotechnology companies, like us, 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 our 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 our 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. We cannot predict whether the patent applications we are currently pursuing will issue as patents that protect our 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 our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, affect the value or narrow the scope of our patent rights.

Further, third parties may have intellectual property rights relating to our product candidates of which we are unaware. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our 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 we nor our future licensors can know with certainty whether either we or our future licensors were the first to make the inventions claimed in the patent applications we own or any patents or patent applications we may own or in-license in the future, or that either we or any of our 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 our owned and future in-licensed patent rights are uncertain. For example, currently unpublished patent applications may later publish and limit our ability to obtain valid and enforceable patents.

Moreover, any issued patents we do obtain or in-license may be challenged, invalidated, or circumvented. We or our 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 our 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, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our products without infringing third-party patent rights. If the breadth or strength of protection provided by any patents we obtain and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Moreover, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents we may obtain. For these reasons and others, we may face competition with respect to our product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. Even if our owned and any future in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and any patents we do 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 our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Furthermore, our competitors may be able to circumvent any patents we obtain or in-licenses in the future by developing similar or alternative technologies or products in a non-infringing manner. For these reasons, even if we are successful in obtaining patents or in-licensing patents in the future, our patent portfolio may not provide us with sufficient rights to exclude others from using or commercializing technology and products similar or identical to any of our technology and product candidates for any period of time.

Patent terms may not protect our 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 our product candidates are obtained, once the patent life has expired, we 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 our ability to protect our 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 our owned and any future in-licensed patent applications and the maintenance, enforcement or defense of any issued patents we 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. We 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 our patents or patent applications and our ability to obtain patent protection in the future.

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.

Competitors and other third parties may infringe, misappropriate or otherwise violate patents or other intellectual property that we own or licenses. As a result, we or our future licensors may need to file infringement, misappropriation or other intellectual property claims, which can be expensive and time-consuming. Any claims we assert against others could provoke them to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on the extent to which we obtain and enforces patent claims that cover our 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 us or our 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 we are successful in obtaining patents or in-licensing patents, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our future licensing partners were unaware during prosecution.

An adverse result in any such proceeding could put one or more of the patents that we may own or in-license in the future at risk of being invalidated or interpreted narrowly, and could put any of our 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 we owned or in-licensed patents do not cover that technology. Furthermore, if the breadth or strength of

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

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our 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. We have 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 our 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 our competitors, exist in the fields in which we are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates may be subject to claims that they infringe the patent rights of third parties. Our competitors and others may have significantly larger and more mature patent portfolios than we have. 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 our future patents, if any, may provide little or no deterrence or protection. Competitors may also assert that our product candidates infringe their intellectual property rights as part of a business strategy to impede our 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 our product candidates near commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our 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 our 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 our product candidates or technologies. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe the intellectual property rights of third parties. Thus, we do not know with certainty that our technology and product candidates, or our 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 us may also obtain injunctive or other equitable relief. For example, if any third-party patents were held to cover the manufacturing process of our 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 our ability to commercialize such product candidates. In the event of a successful claim of infringement against us, we 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 our infringing products, which may not be possible or practical. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we may be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing and royalty payments.

Claims that we have misappropriated the confidential information, trade secrets or other intellectual property rights of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms, our business could be adversely affected.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we 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 we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to sell, assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, such as substantial licensing or royalty payments, our business could be materially and adversely affected. If we are unable to obtain a necessary license, the third parties owning such intellectual property rights could seek an injunction prohibiting our sales or we may be unable to otherwise develop or commercialize the affected product candidates, which could materially harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

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

If we fail to comply with our obligations in any future intellectual property licenses with third parties that we may enter into, or otherwise experiences disruptions to our business relationships with future licensors, we could lose intellectual property rights that are important to our business.

We 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 us. If we fail to comply with those obligations, our counterparties may have the right to terminate these agreements, in which event we 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 our counterparties may require us 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 our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in us having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our 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 our technology and processes infringe the intellectual property rights of the licensor that are not subject to the licensing agreement;
- whether our licensee or our licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement in the prosecution of licensed patents and our 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;
- our 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 our licensors and by us and our partners; and
- the priority of application of patented technology.

If we do not prevail in such disputes, we may lose any or all of our 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 we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Despite our efforts, our future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our 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 us. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and products 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 us, and our ability to successfully commercialize our technology and products will be impaired.

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

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

Third parties may attempt to develop and commercialize competitive products in foreign countries where we do not have any patent protection and/or where legal recourse may be limited. This may have a significant commercial impact on our 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, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling our inventions in such countries or importing products made using our inventions into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and, further, may export otherwise infringing products to territories where we do obtain patent protection or future licenses but enforcement is not as strong as that in the U.S. These products may compete with our products, and our 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 us to stop the infringement of any patents we do obtain or in-license or marketing of competing products in violation of our 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 our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we obtain at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We work with third-party contractors located in China to develop certain of our 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, we do not believe the Export Control Law applies to our product candidates, and we do not expect it to impact our business; however the Export Control Law could be amended in the future in a way that could adversely affect our 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 we do obtain or in-license patents and we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

Intellectual property rights do not necessarily address all potential threats.

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

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

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

We or our future licensors may be subject to claims that current or former employees, collaborators, CROs, universities or other third parties have an interest in our 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, we or our future licensors may have inventorship or ownership disputes that arise from conflicting obligations of employees, consultants, CROs or others who are involved in developing our 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 we or our licensors fail in defending any such claims, we may be required to pay monetary damages and we may also lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are 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 our patents and patent applications, we 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 our business, financial condition, results of operations and prospects.

We 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 our ability to develop and market our product candidates.

We are developing certain product candidates in highly competitive areas and cannot guarantee that any patent searches or analyses that we 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 we be certain that we have 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 our 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 our product candidates could have been or may be filed in the future by third parties without our 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 our product candidates or the manufacturing or use of our 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. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or pending patent application or that we are otherwise free to operate in relation to our product candidates. We 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 we consider relevant. Any failure by us to identify and correctly interpret relevant patents or pending patent applications may negatively impact our ability to develop and market our product candidates.

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

Inventions contained within our owned and in-licensed patents and patent applications have been, and we 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 us 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, we could be forced to license or sublicense intellectual property developed by us or that we may license on terms unfavorable to us, and there can be no assurance that we 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 us 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 our 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 our competitive position, business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our 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 we have misappropriated their intellectual property, or that they own what we regard as our own intellectual property.

Many of our employees, physician-scientist partners, consultants and contractors are or were previously employed at or engaged by universities or other pharmaceutical or biotechnology companies, including our 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 we try to ensure that the individuals who work for us do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we 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. We may also be subject to claims that we have 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 our ability to hire employees or engage consultants and contractors. A loss of key personnel or their work product could hamper or prevent us from developing and commercializing products and product candidates, which could harm our business.

In addition, while it is our policy to require our 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 us, we may be unsuccessful in obtaining such an agreement from each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our 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 our business, financial condition, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, we may be required to pay monetary damages, and we may also lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our 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 we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position would be adversely affected.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, unpublished

patent applications or other confidential research, and we 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 our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us.

Furthermore, we expect that, over time, our 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 our proprietary technology, we may be unable to prevent others from exploiting that technology, which could affect our ability to expand in domestic and international markets. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely affected.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our 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 we may not have adequate remedies for any breach.

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

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we 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 our size. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may determine another trademark is not infringing our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trademarks or trade names similar to ours, thereby impeding our 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 our trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our 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 our financial condition or results of operations.

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

If we do 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 our marketing exclusivity for any product candidates we may develop, our 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 our product candidates receive FDA approval, we expect 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 our assessment of whether such extensions should be granted and, even if granted, the length of such extensions. We may not be granted patent term extension either in the U.S. or in any foreign country, even where we obtain a patent that is eligible for patent term extension, if, for example, an applicable government authority determines that we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail 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 we request. If we obtain such an extension, it may be for a shorter period than we had sought. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially and adversely affected.

Furthermore, for any patents we may in-license in the future, we 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 we in-licenses in the future is eligible for patent term extension under the Hatch-Waxman Act, we 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. We may be unable to obtain or in-license patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we or our 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 our 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 us 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 our Dependence on Third Parties

We rely on third parties to conduct our nonclinical 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.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners (collectively, partners) to conduct and support our nonclinical studies and clinical trials under agreements with us and plans to continue to do so for future nonclinical studies and clinical trials. These third parties have had and will continue to have a significant role in the conduct of our nonclinical studies and clinical trials and the subsequent collection and analysis of data. For example, our partners contribute highly enabling technologies and services that include, among others: (i) clinical conduct support from CROs, (ii) support for our 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 our findings to the clinical setting.

These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our nonclinical studies or clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need 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 our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines.

Our heavy reliance on these third parties for such drug development activities reduces our control over these activities. As a result, we have less direct control over the conduct, timing and completion of nonclinical studies and clinical trials and the management of data developed through nonclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we remain responsible for ensuring that each of our clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us 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 us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial

sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations and require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our 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 our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Our 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 our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at a third party's facility or in any of our facilities, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are 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 our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our 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 our 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 our 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 our reputation and business.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our 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 we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, federal or foreign authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do 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 our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

If we decide to establish collaborations but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

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

We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration depends, among other things, upon our 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 nonclinical 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 our 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 us for our product candidate. Further, we may not be successful in our 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 we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

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

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

If we enter into any collaboration arrangements with any third parties for the development and commercialization of our product candidates, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, 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 our 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 our 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 ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that

could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our 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 us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates;
- collaborators may own or co-own intellectual property covering our products or product candidates that result from us collaborating with them, and in such cases, we 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 we currently rely for the supply of the active pharmaceutical ingredients, drug product and starting materials used in our product candidates are our sole source of supply, and the loss of any of these suppliers could delay our development efforts and harm our business.

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

We have qualified second-source suppliers for certain of our API, drug product, and starting materials, with manufacturing having commenced in 2026. In addition, we maintain safety stock of certain materials intended to mitigate the impact of short-term supply disruptions. We are continuing to assess our supply chain and may seek to qualify additional second sources in the coming years. Although we believe such second-source supply or other alternative second-source supplies could be made available to us on the timelines necessary to operate in accordance with our current business plans, if any of our current or planned third-party suppliers or manufacturers ceases 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 our needs, it could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

For all of our product candidates, we intend 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. We are not certain, however, that our single-source suppliers will be able to meet our demand for our products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for our products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and starting materials used in our product candidates, if required, may not be accomplished within the timeframes required to avoid delays in our development and commercialization efforts. When we find 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 we seek to maintain adequate inventory of the API, drug product and starting materials used in our product candidates, any interruption or delay in the supply of components or materials, or our 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 our development efforts, which could harm our 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 has been and may continue to be volatile, and investors could lose all or part of their investment.

The trading price of our common stock has been and is likely to continue 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. This risk is especially relevant given our recent stock price volatility following the announcement of our June 2026 BBO-8520 data and strategic prioritization of certain combinations for our product candidates.

Broad market and industry factors may also 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, nonclinical 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 business prospects relative to our competitors;
- regulatory or legal developments in the U.S. and other countries, including countries in which we conduct or plan to conduct nonclinical studies or clinical trials;
- 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 operational or strategic changes, including strategic prioritization of our product candidates, or 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 us, our business or our market, our 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 us, our business or our market. If any of the analysts who cover our issue adverse or misleading research or reports regarding us, our business model, intellectual property, stock performance or market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our common stock price or trading volume to decline.

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we 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 our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure 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 our Board, and recognizes the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our 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 our programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our 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 our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of nonclinical studies and clinical trials for BBO-8520, BBO-10203 and BBO-11818 and any product candidates from our 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 our discovery programs, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of BBO-8520, BBO-10203 and BBO-11818 or product candidates from any of our discovery programs;
- the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with BBO-8520, BBO-10203 and BBO-11818 or any of our discovery programs;
- our ability to commercialize BBO-8520, BBO-10203 and BBO-11818 or product candidates from any of our discovery programs, if approved, inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;

- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our 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 our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of future performance. This variability and unpredictability could also result in us failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we 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 our capital stock and our respective affiliates collectively beneficially own in excess of 50% of our outstanding common stock. In addition, several of our directors, including Frank McCormick, Neil Kumar, Raymond Kelleher and Bihua Chen are affiliated with certain of our large stockholders. Additionally, Dr. Kumar, the Chief Executive Officer of BridgeBio Pharma, was appointed as our Executive Chairman in April 2026. Our 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 our certificate of incorporation 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 our common stock that investors may feel are in their best interest as one of our 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 us or our stockholders in the public market could cause the market price for our common stock to decline.

The sale of our securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Shares of common stock reserved for future issuance under our 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. Our board of directors or the compensation committee thereof may determine the exact number of shares to be reserved for future issuance under our equity incentive plans at our discretion, subject to stockholder approval in the case of our 2025 Plan. We expect 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 our 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, we may also issue our securities in connection with investments or acquisitions. The number of shares of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. In particular, pursuant to a shelf registration statement on Form S-3 (File No. 333-298697) (the "2026 Shelf"), we have registered the offering and sale of our common

stock, preferred stock, debt securities, warrants and units or any combination thereof, in an aggregate amount of up to $500.0 million, which includes shares of common stock having an aggregate offering price of up to $200.0 million that we may sell from time to time under an "at-the-market" offering program pursuant to a Sales Agreement, dated September 1, 2026 with Leerink Partners LLC and Cantor Fitzgerald & Co. (the "2026 ATM Agreement"). Sales of our securities pursuant to the 2026 Shelf, including sales of our common stock under the 2026 ATM Agreement, or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline. Additionally, any incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through future strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

We have increased costs as a result of operating as a public company, and our management devotes substantial time to related compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are 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. We will have to hire additional accounting, finance, and other personnel in connection with becoming a public company. Our management and other personnel devote a substantial amount of time to these compliance initiatives and we cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

In addition, as a public company we are 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, we are required to maintain effective disclosure and financial controls and to make a formal assessment of the effectiveness of our internal control over financial reporting.

We have in the past identified a material weakness in our internal controls over financial reporting. If we identify additional material weaknesses in the future or otherwise fail to maintain effective internal controls over financial reporting and disclosure controls and procedures, the accuracy and timeliness of our financial and operating reporting may be adversely affected, and confidence in our operations and disclosures may be lost.

As a public company, we are 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 we evaluate and determine the effectiveness of our 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 our financial statements for the years ended December 31, 2024 and 2023, our management identified a material weakness in our internal control over financial reporting related to a lack of sufficient full-time personnel.

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

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

If we are not able to maintain effective internal control over financial reporting and disclosure controls and procedures, or if material weaknesses are discovered in future periods, we may be unable to accurately and timely report our 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 our business, reputation, results of operations, financial condition or liquidity. Our investors could lose confidence in our reported financial information, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

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

Our projections of both the number of people who have the diseases our 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 our 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 our 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 our products, or new patients may become increasingly difficult to identify or gain access to. Additionally, if certain product candidates currently under clinical development by third parties do not receive marketing approval or are not successfully commercialized for the applicable patient populations, the market for product candidates that we are presently developing as second-line therapies to these third-party product candidates may not develop or may be smaller than anticipated. We may not be successful in our efforts to identify additional product candidates. Assumptions made by management in connection with the preparation of our condensed consolidated financial statements could adversely affect our reported assets, liabilities or expenses if our estimates of the addressable patient populations and markets are incorrect.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file 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. We believe 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 our control system, misstatements due to error or fraud may occur and not be detected.

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

We have never declared or paid any cash dividends on our common stock. We currently anticipates that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

General Risk Factors

Anti-takeover provisions in our certificate of incorporation ("Charter") and bylaws ("Bylaws") and Delaware law might discourage, delay or prevent a change in control of us or changes in our management and, therefore, depress the market price of common stock.

Our Charter and Bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of the Company or changes in our management that our stockholders 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 our 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 our board of directors may be removed from office by our 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 our voting stock to amend any bylaws by stockholder action; and
- the authority of our Board to issue preferred stock on terms determined by our 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 our 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 our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for common stock.

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

Our Bylaws provide that, unless we consent 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 our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our 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 we consent 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 our 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 our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court 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, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the 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 us than our 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 our business. Trade disputes could also adversely impact supply chains which could now or in the future increase costs for us 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. We are continuing to monitor the trade disputes, inflation, interest rates and the military conflicts and the impacts to global capital markets to our 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.

In July 2026, the United States imposed significant tariffs ranging from 10% to 12.5% on virtually all imports to the United States and has also imposed significantly higher rates targeting certain imports in select industries, including certain pharmaceuticals. Imports from China continue to be assessed further elevated tariffs. In response, several countries have enacted retaliatory measures, and the situation remains unpredictable. 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 other components used in the development and manufacturing of our product candidates which may be subject to such tariffs.

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.

We are 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.

We are 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 condensed 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, we have determined we remain a smaller reporting company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is $250 million or more measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter.

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

None

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

During the three months ended September 30, 2026, the following directors and executive officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated the contracts, instructions or written plans 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), as set forth in the table below.

Name	Position	Action	Date of Action	Duration of Trading Arrangement	Aggregate Number of Securities[1]	Description of Trading Arrangement
Pedro J. Beltran, Ph.D.	Chief Executive Officer	Adoption	8/19/2026	Until 10/31/2027, or such earlier date upon which all transactions are completed or expire without execution.	Up to 203,904 shares	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to terms of the trading plan
Marc Cobo	Principal Accounting Officer	Adoption	7/24/2026	Until 10/20/2027, or such earlier date upon which all transactions are completed or expire without execution.	Up to 610 shares	Sales of shares of the Company's common stock pursuant to terms of the trading plan

[1] Represents the maximum number of shares that may be sold pursuant to the 10b5-1 arrangement. The number of shares sold will be dependent on the satisfaction of certain conditions as set forth in the written plan and will be net of shares withheld to satisfy tax withholding obligations which is not yet determinable.

Immaterial Correction of Prior Period Financial Statements

Subsequent to the issuance of the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2026, the Company identified errors related to net loss per share and weighted average shares outstanding previously disclosed in each of the Quarterly Reports on Form 10-Q for the periods ended March 31, 2026 and June 30, 2026. The errors relate to the net loss per share amounts for

the quarters ended March 31, 2026 (unaudited) and June 30, 2026 (unaudited), and the six months ended June 30, 2026 (unaudited), due to incorrect inputs, including inappropriate use of shares in thousands as compared to actual shares, for the calculation of net loss per share.

The errors have no impact on the consolidated balance sheet, consolidated statements of operations (excluding the weighted average shares outstanding and net loss per share presentation), comprehensive loss, stockholders' equity, and cash flows. The Company has evaluated the quantitative and qualitative factors for these misstatements and has concluded it was not material, individually or in the aggregate, to the financial statements of prior periods.

The Company will prospectively correct the 2026 errors in the Condensed Consolidated Financial Statements that will be presented in its Quarterly Reports on Form 10-Q for the periods ending March 31, 2027 and June 30, 2027. The following tables reflect the correction on the affected line items in the Company's previously reported Condensed Consolidated Financial Statements for the periods ended March 31, 2026 and June 30, 2026:

Previously Reported	**Three Months Ended March 31, 2026**	**Three Months Ended June 30, 2026**	**Six Months Ended June 30, 2026**
Net loss per share attributable to common stockholders, basic and diluted	$ (526.11)	$ (705.20)	$ (1,230.89)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	80,032	80,054	80,072

As corrected	**Three Months Ended March 31, 2026**	**Three Months Ended June 30, 2026**	**Six Months Ended June 30, 2026**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.53)	$ (0.70)	$ (1.23)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	80,031,630	80,111,225	80,072,183

Item 6. Exhibits.

Exhibit 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 Exhibit 2.1 to the Registrant's Form 10-Q filed on May 12, 2026).
2.2	Amendment No. 1 to Business Combination Agreement, by and among Helix Acquisition Corp. II, TheRas, Inc. and Helix II Merger Sub, Inc., dated as of June 17, 2025 (incorporated by reference to Exhibit 2.2 to the Registrant's Form 10-Q filed on May 12, 2026).
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).
10.1*†	Cooperative Research and Development Agreement, dated March 3, 2017, between Frederick National Laboratory for Cancer Research (FNLCR) Operated by Leidos Biomedical Research, Inc. and the Registrant, as amended by Amendment No. 1 dated January 19, 2018, as further amended by Amendment No. 2 dated January 2, 2019, as further amended by Amendment No. 3 dated November 14, 2019, as further amended by Amendment No. 4 dated January 13, 2020, as further amended by Amendment No. 5 dated September 22, 2021, as further amended by Amendment No. 6 dated March 27, 2023, as further amended by Amendment No. 7 dated August 20, 2024, as further amended by Amendment No. 8 dated September 2, 2025, as further amended by Amendment No. 9 dated December 3, 2025, as further amended by Amendment No. 10 dated August 12, 2026.
10.2*†	Amendment No. 10 to Transition Services Agreement, by and among TheRas, Inc., BridgeBio Services, Inc., BridgeBio Oncology Therapeutics, Inc. and BridgeBio Pharma LLC as of September 15, 2026.
10.3^*	BridgeBio Oncology Therapeutics, Inc. Executive Severance Plan, as amended by Amendment No. 1 dated September 21, 2026
10.4	Sales Agreement by and among BridgeBio Oncology Therapeutics, Inc., Leerink Partners LLC and Cantor Fitzgerald & Co., dated as of September 1, 2026 (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-298697))
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.
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.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission because such information (i) is not material and (ii) is the type that the Registrant treats as private or confidential.

^ 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 the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned thereunto duly authorized.

BRIDGEBIO ONCOLOGY THERAPEUTICS, INC.

Date: November 10, 2026

By: /s/ Pedro J. Beltran
Pedro J. Beltran, Ph.D.
Chief Executive Officer

Date: November 10, 2026

By: /s/ Idan Elmelech
Idan Elmelech
Chief Operating and Principal Financial Officer

Exhibit 10.1

LEIDOS BIOMEDICAL

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Cooperative Research and Development Agreement ("CRADA" or "Agreement") has been adopted for use by the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) and a Federal Laboratory operated by Leidos Biomedical Research, Inc., under the Operations and Technical Support (OTS) Contractor.

This Cover Page identifies the Parties to this Agreement:

Frederick National Laboratory for Cancer Research (FNLCR)
Operated by Leidos Biomedical Research, Inc.
hereinafter referred to as "Leidos Biomedical",
having offices at 1050 Boyles Street, Frederick, Maryland 21702,
created and operating under the laws of Delaware

and

TheRas
hereinafter referred to as the "Collaborator",
having offices at 165 University Ave, Suite 5, Palo Alto, 94301,
created and operating under the laws of Delaware.

CRADA TITLE: Development and characterization of KRas targeting compounds

CRADA NUMBER: 10056-16

Article 1.Introduction

This Agreement is made under authority of the Federal Technology Transfer Act, 15 U.S.C. §3710a. This Agreement is governed by the terms of §3710a and consistent with the terms of the Operations and Technical Support (OTS) contract between Leidos Biomedical and the National Cancer Institute (NCI) in the National Institutes of Health (NIH).

The Agreement includes a cover page, the agreement terms, a signature page, a contacts page, a summary page, a joint work statement ("Joint Work Statement") attached as Appendix A, and the staffing, funding, and materials contributions of the Parties attached as Appendix B. The Parties are interested in collaborating on a joint project and in transferring research materials or confidential information between the Parties as described in the Joint Work Statement.

Article 2.Definitions

The terms listed in this Article will carry the meanings indicated throughout the Agreement. To the extent a definition of a term as provided in this Article is inconsistent with a corresponding definition in the applicable sections of either the United States Code (U.S.C.) or the Code of Federal Regulations (C.F.R.), the definition in the U.S.C. or C.F.R. will control.

2.1 **"Affiliate"** means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of the CRADA. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.

2.2 **"Background Invention"** means an invention conceived and first actually reduced to practice before the Effective Date.

2.3 **"Collaborator Materials"** means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by Collaborator and used in the performance of the Joint Work Statement, including certain materials licensed to Collaborator under the UCSF License Agreement.

2.4 **"Confidential Information"** of a Party means confidential scientific, business, or financial information disclosed by such Party to the other Party under this CRADA, provided that the information does not include:

(a) information that is publicly known or that is available from public sources, other than through the receiving Party's breach of the confidentiality obligations set forth herein;

(b) information that has been made available to the receiving Party by a third party without a confidentiality obligation;

(c) information that is already known by the receiving Party, or

(d) information that is independently created or compiled by the receiving Party without reference to or use of the provided information.

2.5 **"CRADA Data"** means all recorded information first produced in the performance of the Joint Work Statement.

2.6 **"CRADA Materials"** means all tangible materials first produced in the performance of the Joint Work Statement other than CRADA Data.

2.7 **"CRADA Subject Invention"** means any invention of either or both Parties, conceived or first actually reduced to practice in the performance of the Joint Work Statement.

2.8 **"Effective Date"** is the date which the agreement takes effect, which occurs on the date of the last signature of the Parties executing this Agreement.

2.9 **"Government"** means the Government of the United States of America.

2.10 **"Invention"** means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code.

2.11 **"Joint Work Statement"** means the description in Appendix A of the respective research and development commitments of the Parties.

2.12 **"Leidos Biomedical Materials"** means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by Leidos Biomedical and used in the performance of the Joint Work Statement.

2.13 **"Patent Application"** means an application for patent protection for a CRADA Subject Invention with the United States Patent and Trademark Office or the corresponding patent-issuing authority of another nation.

2.14 **"Patent"** means any issued United States patent, any international counterpart(s), and any corresponding grant(s) by a non-U. S. government in place of a patent.

2.15 **"Principal Investigator(s)"** or **"PI(s)"** means the person(s) designated by the Parties who will be responsible for the scientific and technical conduct under the Joint Work Statement and this Agreement.

2.16 **"Research Tools"** includes the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.

2.17 **"Research Tool Policy, NIH"** as stated in "NIH Principles and Guidelines for Sharing of Biomedical Resources — Final (December 1999)" provides guidance concerning appropriate terms for disseminating research tools developed with federal funds. The Research Tool Policy should be considered when disseminating, patenting, and licensing biomedical research resources.

2.18 **"UCSF License Agreement"** shall mean the agreement entered into between the Collaborator and the University of California, San Francisco (UCSF) for exclusive license rights to the technology entitled [***].

Article 3.Cooperative Research and Development

3.1 **Performance of Research and Development.** The Joint Work Statement will be performed solely by the Parties identified on the Cover Page unless specifically stated elsewhere in this Agreement. The interim research goals in the Joint Work Statement are good faith guidelines. If events occur that require modification of these goals, then by mutual agreement the Parties can modify the goals by amendment.

3.2 **Use and Disposition of Collaborator Materials and Leidos Biomedical Materials.** The Parties agree to use Collaborator Materials and Leidos Biomedical Materials and to transfer these materials to third parties only in accordance with this Agreement or as approved by the owning or providing Party. Upon expiration or termination of the CRADA, the Parties agree to dispose of these materials as directed by the owning or providing Party.

3.3 **Third-Party Rights in CRADA Subject Inventions.** If either Party wishes to conduct a portion of the Joint Work Statement through a third party (e.g., as a subcontractor of the Collaborator), then such Party agrees to notify the other Party and obtain the other Party's prior approval (not to be unreasonably withheld or delayed). The subcontracting Party shall ensure that any agreement between such Party and the third party will be consistent with such Party's obligations under this CRADA. In particular, to the extent any Invention the third party subcontractor may make would be a CRADA Subject Invention if it had been made by an employee of the subcontracting Party, then the subcontracting Party shall ensure that any Invention that is developed by a subcontractor based upon this Agreement complies with the terms and conditions of this Agreement. The subcontracting Party shall seek to secure a commitment from the third party subcontractor as necessary to ensure that any such Invention shall be treated as a CRADA Subject Invention in all respects. Without limiting the foregoing, Leidos Biomedical represents and warrants that its agreements with NIH and FNLCR are consistent with its obligations under this CRADA. Furthermore, Collaborator represents and warrants that its agreement with any subcontractors or any other Consulting Agreements entered into by the Collaborator related to the Joint Work Statement are consistent with its obligations under this CRADA.

Article 4.Reports

4.1 **Interim Research and Development Reports.** The Pls should exchange information regularly, in writing, through meeting minutes, annual reports, detailed correspondence, circulation of draft manuscripts, or by other means. Reports are exchanged [***] at a minimum.

4.2 **Final Research and Development Reports.** The Parties will exchange final reports of their results within [***] after the expiration or termination by mutual consent of this CRADA or [***] after Leidos

Biomedical ends work on the Joint Work Statement in case of unilateral termination by Collaborator. These reports will set forth the technical progress made, any publications arising from the research, and the existence of invention disclosures of potential CRADA Subject Inventions and/or any corresponding Patent Applications.

4.3 **Fiscal Reports.** If Collaborator provides funding to Leidos Biomedical under this CRADA, then concurrent with the exchange of the final research and development report, Leidos Biomedical will submit to Collaborator a statement of all costs incurred by Leidos Biomedical for the CRADA. If the CRADA has been terminated, Leidos Biomedical will specify any costs incurred before the date of termination for which Leidos Biomedical has not received funds from Collaborator, as well as for all reasonable termination costs including the cost of returning Collaborator property or removal of abandoned Collaborator property, for which Collaborator will be responsible.

Article 5.Staffing, Financial, and Materials Obligations

5.1 **Leidos Biomedical and Collaborator Contributions.** The contributions of any staff, funds, materials, and equipment by the Parties are set forth in Appendix B. Under §3710a(d)(l), Leidos Biomedical is prohibited from providing funds to the Collaborator for activities performed under this Agreement.

5.2 **Collaborator Funding.** If Collaborator has agreed to provide funds to Leidos Biomedical, Collaborator will make payments according to the schedule in Appendix B. If Collaborator fails to make any scheduled payment, Leidos Biomedical will not be obligated to perform any research and development activities specified herein or to take any other action required by this Agreement until the funds are received. Leidos Biomedical will use these funds exclusively for the purposes of this CRADA. Leidos Biomedical will maintain separate and distinct current accounts, records, and other evidence of the payments received under this CRADA and, upon written request, will provide Collaborator a Fiscal Report according to Paragraph 4.3, which delineates all payments made and all obligated expenses, along with the Final Research Report described in Paragraph 4.2. Any unused funds at the conclusion of the performance of the Joint Work Statement will be returned to the Collaborator.

5.3 **Capital Equipment.** Collaborator's commitment, if any, to provide Leidos Biomedical with capital equipment to enable the research and development activities under the Joint Work Statement appears in Appendix B. If Collaborator transfers to Leidos Biomedical the capital equipment or provides funds for Leidos Biomedical to purchase it, then Leidos Biomedical shall be the custodian of the equipment on behalf of the FFRDC and shall dispose of the equipment as directed by the Government and in accordance with the terms of the OTS contract at the conclusion of the CRADA. If Collaborator loans capital equipment to Leidos Biomedical for use during the CRADA, Collaborator will be responsible for paying all costs and fees associated with the transport, installation, maintenance, repair, removal, or disposal of the equipment, and Leidos Biomedical will not be liable for any damage to the equipment.

5.4 **Non-Solicitation.** Collaborator agrees that during the term of this Agreement and for [***] thereafter, it shall not, either directly or indirectly solicit, induce, encourage, or participate in soliciting, inducing or encouraging any person known to Collaborator to be an employee of Leidos Biomedical to terminate his or her relationship with Leidos Biomedical for the purposes of rendering services to Collaborator or to any other person or entity working on behalf of Collaborator. For clarity, the foregoing shall not be construed as preventing Collaborator from posting general advertisements for job openings.

Article 6.Intellectual Property

6.1 **Ownership of Background Inventions, CRADA Subject Inventions, CRADA Data, and CRADA Materials.** Subject to the terms of this Agreement, each Party will retain sole ownership of and title to all Background Inventions of such Party (including Collaborator Materials and Leidos Biomedical Materials, as applicable). Each Party shall solely own all CRADA Subject Inventions solely invented by such Party or its subcontractors and all copies of CRADA Data and all CRADA Materials developed solely by such Party or its subcontractors. The Parties will ensure that any CRADA Subject Inventions created solely by its subcontractors or consultants are subject to the terms and conditions of this Agreement. The Parties will own jointly all CRADA Subject Inventions invented jointly and all copies of CRADA Data and all CRADA Materials developed jointly. The Parties acknowledge that additional rights to Background Inventions, CRADA Subject Inventions, CRADA Data and CRADA Materials may exist under the terms and conditions of the UCSF License Agreement.

6.2 **Reporting.** Upon completion of the activities in the Joint Work Statement, Leidos Biomedical shall provide a comprehensive report of activities and a final CRADA Subject Invention Report. This report will provide a description of any CRADA Subject Inventions and any Patent Applications filed thereon, resulting from the research and development activities conducted under this Agreement. Collaborator shall promptly review the CRADA Subject Invention Report and provide any additional information necessary

to enable evaluation for potential patent filing and in sufficient detail to determine inventorship in accordance with U.S. patent law.

6.3 **Filing of Patent Applications.** Each Party will make timely decisions regarding the filing of Patent Applications on the CRADA Subject Inventions made solely by its employee(s), and will notify the other Party in advance of filing. Collaborator will have the first opportunity to file a Patent Application on all CRADA Subject Inventions that are not Research Tools (as defined in this Agreement) and to which the exclusive option identified in 7.4 applies. Collaborator will notify Leidos Biomedical of its decision within [***] after an invention is reported or [***]. If Collaborator fails to notify Leidos Biomedical of its decision within that time period or notifies Leidos Biomedical of its decision not to file a Patent Application then Leidos Biomedical has the right to file a Patent Application on such CRADA Subject Invention. Neither Party will be obligated to file a Patent Application. Collaborator will place the following statement in any Patent Application it files on a CRADA Subject Invention: "This invention was created in the performance of a Cooperative Research and Development Agreement with Leidos Biomedical, Inc., the Operations and Technical Support contractor for the Frederick National Laboratory for Cancer Research, an FFRDC in the Department of Health and Human Services. The Government of the United States has certain rights in this invention." If either Party files a Patent Application on a joint CRADA Subject Invention, then the filing Party will include a statement within the Patent Application that clearly identifies the Parties and states that the joint CRADA Subject Invention was made under this Agreement.

6.4 **Patent Expenses.** Unless agreed otherwise, the Party or assignee filing a Patent Application will pay all preparation and filing expenses, prosecution fees, issuance fees, post issuance fees, patent maintenance fees, annuities, interference expenses, and attorneys' fees for that Patent Application and any resulting Patent(s). If an exclusive license to any CRADA Subject Invention is granted to Collaborator, then Collaborator is responsible for all expenses and fees, past and future, in connection with the preparation, filing, prosecution, and maintenance of any Patent Applications and Patents claiming exclusively-licensed CRADA Subject Inventions.

6.5 **Prosecution of Patent Applications.** The Party filing a Patent Application will provide the non-filing Party with a copy of any official communication relating to prosecution of the Patent Application within [***] of transmission of the communication. Each Party will also provide the other Party with the power to inspect and make copies of all documents retained in the applicable Patent Application or Patent file. The Parties agree to consult with each other regarding the prosecution of Patent Applications directed to joint CRADA Subject Inventions. If Leidos Biomedical elects to file and prosecute Patent Applications on CRADA Subject Inventions after Collaborator decides not to file such Patent Application, then Leidos Biomedical agrees to use the United States Patent and Trademark Office (USPTO) Customer Number Practice and/or grant Collaborator a power(s) of attorney (or equivalent) necessary to assure access to its intellectual property rights in these Patent Applications. Leidos Biomedical and Collaborator will cooperate with each other to obtain necessary signatures on Patent Applications, assignments, or other documents.

Article 7.Licensing

7.1 **Background Inventions.** Unless specifically stated in this Agreement or as outlined in the UCSF License Agreement, no grant to any rights in a Party's Background Invention(s) to the other Party will be construed, except to the extent necessary for the performance of the Joint Work Statement.

7.2 **Government License in CRADA Subject Inventions.** To the extent required by applicable laws, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes. In the exercise of this license, the Government will not publicly disclose trade secrets or commercial or financial information

that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered privileged or confidential if it had been obtained from a non-federal party. Notwithstanding the preceding sentence, Collaborator acknowledges the applicability of the Government requirements as outlined in the UCSF License Agreement. For clarity, any inventions made by Subcontractors or consultants engaged by Collaborator, either solely or jointly with Collaborator, that are outside of the scope of this Joint Work Statement shall not be deemed CRADA Subject Inventions and shall be solely and exclusively owned by Collaborator without being subject to any of the licenses to Leidos' retained rights under Section 7.3 or any license to the US Government under this Section 7.2.

7.3 **Leidos Biomedical Retained License in CRADA Subject Inventions.** Leidos Biomedical shall retain the right to utilize CRADA Subject Inventions that constitute an improvement to Collaborator Materials developed under this Agreement for use as a Research Tool as defined herein solely for internal, non-profit, pre-clinical research purposes, and to any CRADA Subject Invention included within the scope of the retained rights in the UCSF License Agreement pursuant to the applicable terms and conditions therein.

7.4 **Collaborator's Exclusive License Option to CRADA Subject Inventions.** For any CRADA Subject Invention made solely by a Leidos Biomedical employee(s) or Leidos subcontractor(s) or made jointly by a Leidos Biomedical employee(s) or Leidos subcontractor(s) and a Collaborator employee(s) or Collaborator subcontractor(s), Leidos Biomedical grants to Collaborator an exclusive option to negotiate for reasonable compensation an exclusive or nonexclusive commercialization license for a field of use that does not to exceed the scope of the Joint Work Statement. The license will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, and other factors as appropriate.

7.5 **Exercise of Collaborator's Exclusive License Option.** To exercise the exclusive license option, Collaborator has [***] after the Collaborator receives a copy of the CRADA Subject Invention Report, to submit a written request to Leidos Biomedical to negotiate an exclusive license. Collaborator has [***] after submitting the license request to negotiate and execute the exclusive license with Leidos Biomedical. In the absence of Collaborator's exercise of the license option, or upon election of a non-exclusive license, Leidos Biomedical may license the CRADA Subject Invention solely owned by Leidos Biomedical to others. These time periods may be extended upon good cause shown in writing by Collaborator.

7.6 **Joint CRADA Subject Inventions Not Exclusively Licensed by Collaborator.** If Collaborator does not acquire an exclusive commercialization license in a joint CRADA Subject Invention in all fields of use then, for those fields of use [***], each Party will have the right to use the joint CRADA Subject Invention and to license its use to others. Each Party will cooperate with the other, as necessary, to fulfill international licensing requirements. The Parties may agree to a joint licensing approach for any remaining fields of use.

Article 8.Rights of Access and Publication

8.1 **Right of Access to CRADA Data and CRADA Materials.** Leidos Biomedical and Collaborator agree to exchange all CRADA Data and to share all CRADA Materials, including data generated and developed by Collaborator's Subcontractors and consultants performing activities related to the Joint Work Statement. If this Agreement is terminated, both Parties agree to provide CRADA Materials in quantities needed to complete the Joint Work Statement. Such provision will occur before the termination date of the Agreement or sooner, if required by the Joint Work Statement.

8.2 **Use of CRADA Data and CRADA Materials.** The Parties will be free to use CRADA Data and CRADA Materials for the purposes of performing their obligations or exercising their rights under this Agreement. The Parties may share CRADA Data or CRADA Materials with the Government, Affiliates, agents or contractors for such purposes provided the obligations of this Article are simultaneously conveyed. Leidos Biomedical retains the right to use CRADA Data and CRADA Materials for internal research purposes.

(a) CRADA Data. Collaborator and Leidos Biomedical will use reasonable efforts to keep CRADA Data confidential until published or until corresponding Patent Applications are filed. To the extent permitted by law and necessary to perform its obligations or to exercise its rights hereunder, each Party will have the right to use any and all CRADA Data in and for any regulatory filing by or on behalf of the Party.

(b) CRADA Materials. Collaborator and Leidos Biomedical will use reasonable efforts to keep descriptions of CRADA Materials confidential until published or until corresponding Patent Applications are filed.

(c) Collaborator acknowledges that the basic research mission of NIH and Leidos Biomedical includes sharing with third parties for further research those research tools made in whole or in part with NIH funding. Consistent with this mission, following publication Leidos Biomedical may make available to third parties for further research those CRADA Materials made by Leidos Biomedical (either alone or jointly with Collaborator). Notwithstanding the above, if those CRADA Materials are the subject of a pending Patent Application or a Patent and licensed exclusively by Collaborator, such distribution shall be subject to Collaborator's consent (not to be unreasonably withheld). The Parties agree that compounds and any derivatives licensed by Collaborator under the UCSF License Agreement or otherwise provided by or on behalf of Collaborator to Leidos Biomedical that constitute Collaborator Materials are not subject to this Section 8.2(c), and Leidos Biomedical may distribute those CRADA Materials made solely by Collaborator only upon written consent from Collaborator.

8.3 **Confidential Information.** Each Party agrees to limit its disclosure of Confidential Information to the amount necessary to carry out the Joint Work Statement, and will place a confidentiality notice on all such information. A Party orally disclosing Confidential Information to the other Party will summarize the disclosure in writing and provide it to the other Party within [***] of the disclosure. Each Party receiving Confidential Information agrees to use it only for the purposes described in the Joint Work Statement. Either Party may object to the designation of information as Confidential Information by the other Party in accordance with the exceptions set forth in Section 2.4.

8.4 **Government Access to Confidential Information.** Leidos Biomedical may disclose Confidential Information to NCI and other Government users of the OTS contract as necessary to carry out the Joint Work Statement or as part of the OTS contract oversight. The Government recipients will keep all such information confidential according to policy and to the extent permitted by law.

8.5 **Protection of Confidential Information.** Confidential Information will not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning or providing Party except as required by a court or administrative body of competent jurisdiction, or federal law or regulation. Each Party agrees to use reasonable efforts to maintain the confidentiality of Confidential Information, which will in no instance be less effort than the Party uses to protect its own Confidential Information. Each Party agrees that a Party receiving Confidential Information will not be liable for the disclosure of that portion of the Confidential Information which, after notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld, provided the disclosing Party has been given a reasonable opportunity to seek a court order to enjoin disclosure.

8.6 **Duration of Confidentiality Obligation.** The obligation to maintain the confidentiality of Confidential Information will expire at the earlier of the date when the information is no longer Confidential Information or [***] after the expiration or termination date of this Agreement. Collaborator may request an extension to this term when necessary to protect Confidential Information relating to products not yet commercialized.

8.7 **Publication.** The Parties are encouraged to make publicly available the results of their research and development activities. If a publication results from the work to be performed in the Joint Work Statement, the determination of authorship shall be in keeping with generally accepted standards in the research field for determining authorship. Before either Party submits a publication or otherwise intends to publicly disclose information about a CRADA Subject Invention, CRADA Data or CRADA Materials, the Parties agree to provide a copy of the proposed paper or poster [***] in advance of submission for publication review to ensure that Confidential Information is protected. If the proposed disclosure is an abstract, the Parties agree to provide a copy of the abstract [***] in advance of submission to ensure the protection of Confidential Information. Either Party may request in writing that the proposed publication or other disclosure be delayed for up to [***] as necessary to file a Patent Application.

Article 9.Representations

9.1 Both Parties hereby represent to the other that they have the requisite power and authority to enter into this Agreement and to perform according to its terms, and that officials signing this Agreement have authority to do so.

9.2 If and to the extent Collaborator has agreed to provide funding under Appendix B, Collaborator is financially able to satisfy these obligations in a timely manner.

Article 10.Duration Term and Termination

10.1 **Duration Term.** The duration term of this Agreement is stated on the Summary Page. The term may be extended only by written amendment.

10.2 **Termination by Mutual Consent.** Leidos Biomedical and Collaborator may terminate this Agreement at any time by mutual written consent.

10.3 **Unilateral Termination.** Either Leidos Biomedical or Collaborator may unilaterally terminate this Agreement at any time by providing written notice at least [***] before the desired termination date. Leidos Biomedical may, at its option, retain funds transferred to Leidos Biomedical before unilateral termination by Collaborator for use in completing the Joint Work Statement. The Parties acknowledge and agree that this Agreement shall automatically terminate in the event of termination of the [***].

10.4 **Funding for Leidos Biomedical Personnel.** If Collaborator has agreed to provide funding for Leidos Biomedical personnel and this Agreement is mutually or unilaterally terminated by Collaborator before its expiration, then Collaborator agrees that funds for that purpose will be available to Leidos Biomedical for a period of [***] after the termination date or until the expiration date of the Agreement, whichever occurs sooner. If there are insufficient funds to cover this expense, Collaborator agrees to pay the difference.

10.5 **New Commitments.** Neither Party will incur new expenses related to this Agreement after expiration, mutual termination, or a notice of a unilateral termination and will, to the extent feasible, cancel all outstanding commitments and contracts by the termination date. Collaborator acknowledges that Leidos Biomedical will have the authority to retain and expend any funds for up to [***] subsequent to the termination date to cover any unpaid costs obligated during the term of the Agreement in undertaking the research and development activities set forth in the Joint Work Statement.

Article 11.Disputes

11.1 **Settlement.** Any dispute arising under this Agreement which is not disposed of by agreement of the Principal Investigators will be submitted jointly to the signatories of this Agreement. The signatories, or their designees, will work jointly to resolve the dispute within [***] after notification of an ongoing dispute from the Principal Investigators. Nothing in this Paragraph will prevent either Party from pursuing

any administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

11.2 **Continuation of Work.** Pending the resolution of any dispute or claim pursuant to this Article 11, the Parties agree that performance of all obligations will be pursued diligently.

Article 12.Liability

12.1 **NO WARRANTIES.** EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR MATERIAL, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER OR OUTSIDE THE SCOPE OF THIS CRADA, OR THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR MATERIAL, OR THAT A TECHNOLOGY UTILIZED BY A PARTY IN THE PERFORMANCE OF THE JOINT WORK STATEMENT DOES NOT INFRINGE ANY THIRD-PARTY PATENT RIGHTS.

12.2 **Indemnification and Liability.** Collaborator agrees to indemnify and to hold the Government and Leidos Biomedical harmless for all third party damages, costs, and expenses, including attorneys' fees, arising from the commercialization or use of any Intellectual Property transferred by the Government or Leidos Biomedical, including, but not limited to, the making, using, selling, or exporting of products, processes, or services derived from the transferred technology, except to the extent resulting from Leidos Biomedical's negligence, willful misconduct or breach of this Agreement. Each Party otherwise will be liable for any claims or damages it incurs in connection with this Agreement.

12.3 ***Force Majeure.*** Neither Party will be liable for any unforeseeable event (including, without limitation, fire, explosion, earthquake, storm, flood, strike, lockout, labor difficulties, war, insurrection, riot, act of God or the public enemy, or any law, act, regulation or government or court order) beyond its reasonable control and not caused by its own fault or negligence, which causes the Party to be unable to perform its obligations under this Agreement, and which it has been unable to overcome by the exercise of due diligence. If a ***force majeure*** event occurs, the Party unable to perform will promptly notify the other Party. It will use its best efforts to resume performance as quickly as possible and will suspend performance only for such period of time as is necessary as a result of the ***force majeure*** event.

Article 13.Miscellaneous

13.1 **Governing Law.** The construction, validity, performance and effect of this Agreement will be governed in accordance with the laws of the State of Maryland and Federal law, as appropriate.

13.2 **Compliance with Law.** Leidos Biomedical and Collaborator agree that they will comply with, and advise their contractors and agents to comply with all applicable statutes, Executive Orders, regulations, and NIH policies relating to research, in particular those governing the use of human subjects and human source materials/data in research and t the appropriate care and use of laboratory animals (45 C.F.R. Part 46; 7 U.S.C. §§2131 ***et seq.;*** 9 C.F.R. Part 1, Subchapter A).

13.3 **Waivers.** None of the provisions of this Agreement will be considered waived by either Party unless a waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, will not be deemed a waiver of any rights of any Party.

13.4 **Headings.** Titles and headings of the articles and paragraphs of this Agreement are for convenient reference only, do not form a part of this Agreement, and will in no way affect its interpretation.

13.5 **Severability.** The illegality or invalidity of any provisions of this Agreement will not impair, affect, or invalidate the other provisions of this Agreement.

13.6 **Amendments.** Minor modifications to the Joint Work Statement may be made by the mutual written consent of the Principal Investigators. Substantial changes to the Agreement or extensions of the term will become effective only upon a written amendment signed by the signatories to this Agreement or by their representatives duly authorized to execute an amendment. A change will be considered substantial if it directly expands the range of the potential CRADA Subject Inventions, alters the scope or field of any license option governed by Article 7, extends the duration, or requires any increase in the contribution of resources by either Party.

13.7 **Assignment.** Neither this Agreement nor any rights or obligations of either Party hereunder will be assigned or otherwise transferred by either Party without the prior written consent of the other Party, except that in the event the prime contract of Leidos Biomedical with the National Cancer Institute is succeeded by a successor contractor selected by the National Cancer Institute, this Agreement may be assigned to the successor contractor. This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties hereto.

13.8 **Notices.** All notices pertaining to or required by this Agreement will be in writing, signed by an authorized representative of the notifying Party, and delivered by first class, registered, or certified mail, by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the contacts page, or to any other address designated in writing by the other Party. Alternatively notices may be made by electronic mail, if agreed to by both Parties, and receipt must be confirmed by the intended recipient. Notices regarding the exercise of license options will be made pursuant to Paragraph 7.4. Either Party may change its address by notice given to the other Party in the manner set forth above.

13.9 **Independent Contractors.** The relationship of the Parties to this Agreement is that of independent contractors and not agents of each other or joint venturers or partners.

13.10 **Use of Name; Press Releases.** By entering into this Agreement, the Leidos Biomedical does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this Agreement or to any patent or other intellectual-property license or agreement that implements this Agreement by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that Leidos Biomedical or its employees endorse any product or service. Each Party agrees to provide proposed press releases that reference or rely upon the work under this Agreement to the other Party for review and comment at least [***] prior to publication. Either Party may disclose the Summary Page to the public without the approval of the other Party.

13.11 **Reasonable Consent.** Whenever a Party's consent or permission is required under this Agreement, its consent or permission will not be unreasonably withheld.

13.12 **Export Controls.** Collaborator agrees to comply with U.S. export law and regulations. If Collaborator has a need to transfer any CRADA Materials made in whole or in part by Leidos Biomedical, or Leidos Biomedical Materials, or Leidos Biomedical's Confidential Information, to a person located in a country other than the United States, to an Affiliate organized under the laws of a country other than the United States, or to an employee of Collaborator in the United States who is not a citizen or permanent resident of the United States, Collaborator will acquire any and all necessary export licenses and other appropriate authorizations.

13.13 **Entire Agreement.** This Agreement constitutes the entire agreement between the Parties concerning the subject matter of this Agreement and supersedes any prior understanding or written or oral agreement.

13.14 **Survivability.** The provisions of Paragraphs 3.2, 4.2, 4.3, 5.2, 5.3, 6.1-9.2, 10.4-10.5, 11.1, 12.1-12.3, and 13.1-13.3, 13.10, 13.14 will survive the expiration or early termination of this Agreement.

SIGNATURES BEGIN ON THE NEXT PAGE

SIGNATURE PAGE

ACCEPTED AND AGREED

BY EXECUTING THIS AGREEMENT, EACH PARTY REPRESENTS THAT ALL STATEMENTS MADE HEREIN ARE TRUE, COMPLETE, AND ACCURATE TO THE BEST OF ITS KNOWLEDGE. COLLABORATOR ACKNOWLEDGES THAT IT MAY BE SUBJECT TO CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES FOR KNOWINGLY MAKING A FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIM.

FOR LEIDOS BIOMEDICAL:

/s/ David C. Heimbrook	Mar 3, 2017
Signature	Date

David C. Heimbrook
Typed Name

President, Leidos Biomedical Research
Title

FOR COLLABORATOR:

/s/ Michael Henderson	January 5, 2017
Signature	Date

Michael Henderson
Typed Name

VP of BD
Title

CONTACTS PAGE

[***]

SUMMARY PAGE

[***]

APPENDIX A

JOINT WORK STATEMENT

[***]

APPENDIX B

STAFFING, FUNDING AND MATERIALS/EQUIPMENT CONTRIBUTIONS OF THE PARTIES

[***]

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 1 to Agreement
("Amendment No. 1")

Date: January 19, 2018

Name of Original Agreement:	Cooperative Research and Development Agreement (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRas targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Parties:	TheRas ("TheRas") and Leidos Biomedical Research, Inc. ("Leidos Biomedical Research")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement,

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. Defined Terms. Capitalized terms used but not defined herein shall have the respective meanings ascribed to such terms in the Agreement.

2. Amendment(s) to the Agreement.

2.18 "**UCSF License Agreement**" shall mean the agreement entered into between the Collaborator and the University of California, San Francisco (UCSF) for exclusive license rights to the technology entitled [***].

Appendix A, Joint Work Statement. In addition to the previously defined Joint Work Statement activities, the following work will be performed: [***].

3. Ratification of the Agreement. Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 01 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

4. Counterparts. This Amendment No. 01 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

SIGNATURES IMMEDIATELY FOLLOWING ON NEXT PAGE

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 01 as of the date first above written.

Leidos Biomedical Research, Inc.

By:	/s/ Ethan Dmitrovsky
Print Name:	Ethan Dmitrovsky
Title:	President
Date:	1/24/2018

(Duly authorized)

TheRas

By:	/s/ Michael Henderson
Print Name:	Michael Henderson
Title:	VP of BD & Ops
Date:	1/22/2018

(Duly authorized)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 2 to Agreement
("Amendment No. 2")

Date: January 2, 2019

Name of Original Agreement:	Cooperative Research and Development Agreement (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRas targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Parties:	TheRas ("TheRas") and Leidos Biomedical Research, Inc. ("Leidos Biomedical Research")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement including duration of Term,

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. Amendment(s) to the Agreement.

   2.19 "**Leidos Biomedical License Agreement**" shall mean the agreement entered into between the Collaborator and Leidos Biomedical (Leidos Biomed) for exclusive license rights to the technology entitled [***].

2. The Term of the Agreement will be extended for an additional one year period. The end date of the Agreement is March 2, 2020.

3. Dr. Anjali Pandey will serve as the Principal Investigator for TheRas.

Appendix A, Joint Work Statement. The work proposed in the Joint Work Statement will remain unchanged.

Appendix B- Staffing, Funding and Materials/Equipment Contributions of the Parties

Staffing Contribution

Additional funding will be used to continue research as proposed in the Joint Work Statement and to continue funding 6.0 FTE effort per year as required to complete the CRADA research.

Funding Contributions:

Collaborator agrees to provide additional funding in the amount of $1,000,000 for a total amount of funding in the amount of $2,631,080.

[***].

1. Ratification of the Agreement. Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 02 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

2. Counterparts. This Amendment No. 02 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

SIGNATURES IMMEDIATELY FOLLOWING ON NEXT PAGE

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 02 as of the date first above written.

Leidos Biomedical Research, Inc.

By:	/s/ Ethan Dmitrovsky
Print Name:	Ethan Dmitrovsky
Title:	President
Date:	3/13/2019

(Duly authorized)

TheRas, Inc.

By:	/s/ Eric Gomez
Print Name:	Eric Gomez
Title:	VP, Business Development
Date:	3/22/2019

(Duly authorized)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 03 to Agreement
("Amendment No. 03")

Date: November 14, 2019

Name of Original Agreement:	Cooperative Research and Development Agreement (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRAS targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Execution Date of Amendment No. 1:	January 19, 2018
Execution Date of Amendment No. 2:	January 2, 2019
Parties:	TheRas ("TheRas") and Leidos Biomedical Research, Inc. ("Leidos Biomedical")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. AMENDMENT(S) TO THE AGREEMENT:
   a. Section 2.19 from Amendment No. 02 shall be deleted its entirety and replaced with the following:

      2.19 "**Leidos Biomedical License Agreement**" shall mean the agreement entered into between the Collaborator and Leidos Biomedical (Leidos Biomed) for exclusive license rights to the technology entitled [***].

   b. Amendment to the Term (Summary Page, page 18):

      The Term of the Agreement will be extended for an additional two year period. The end date of the Agreement is March 2, 2022.

   c. Amendment to the Collaborator Principal Investigator (Summary Page, page 18):

      Dr. Robert Zamboni will serve as the Principal Investigator for TheRas.

   d. The ABSTRACT OF THE JOINT WORK STATEMENT shall be deleted in its entirety and replaced with the following (Summary Page, page 18): [***].

   e. Amendments to Appendix A, Joint Work Statement: [***].

   f. Amendments to Appendix B – Staffing, Funding and Materials/Equipment Contributions of the Parties: [***].

2. Ratification of the Agreement. Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 03 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. Counterparts. This Amendment No. 03 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

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SIGNATURES IMMEDIATELY FOLLOWING ON NEXT PAGE

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 03 as of the date first above written.

Leidos Biomedical Research, Inc.

By:	/s/ Ethan Dmitrovsky
Print Name:	Ethan Dmitrovsky, MD.
Title:	President
Date:	11/15/19

(Duly authorized)

TheRas, Inc.

By:	/s/Eric Gomez
Print Name:	Eric Gomez
Title:	VP
Date:	11/15/2019

(Duly authorized)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 04 to Agreement
("Amendment No. 04")

Date: January 13, 2020

Name of Original Agreement:	Cooperative Research and Development Agreement (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRAS targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Execution Date of Amendment No. 1:	January 19, 2018
Execution Date of Amendment No. 2:	January 2, 2019
Execution Date of Amendment No. 3:	November 15, 2019
Parties:	TheRas ("TheRas") and Leidos Biomedical Research, Inc. ("Leidos Biomedical")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. Amendment(s) to the Agreement:

The TheRas Principal Investigator shall be Dr. Eli Wallace.

2. Ratification of the Agreement. Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 04 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. Counterparts. This Amendment No. 04 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

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SIGNATURES IMMEDIATELY FOLLOWING ON NEXT PAGE

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 04 as of the date first above written.

Leidos Biomedical Research, Inc.

By:	/s/ Ethan Dmitrovsky
Print Name:	Ethan Dmitrovsky, MD
Title:	President
Date:	2/3/2020

(Duly authorized)

TheRas, Inc.

By:	/s/ Howard Chang
Print Name:	Howard Chang
Title:	VP
Date:	1/13/2020

(Duly authorized)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 05 to Agreement
("Amendment No. 05")

Date: September 22, 2021

Name of Original Agreement:	Cooperative Research and Development Agreement ("CRADA") (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRAS targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Execution Date of Amendment No.1:	January 19, 2018
Execution Date of Amendment No. 2:	January 2, 2019
Execution Date of Amendment No. 3:	November 14, 2019
Execution Date of Amendment No. 4:	January 13, 2020
Parties:	TheRas ("TheRas") and Leidos Biomedical Research, Inc. ("Leidos Biomedical")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. Amendment(s) to the Agreement:

   a. Section 10.3 shall be deleted its entirety and replaced with the following:

      10.3 "**Unilateral Termination**. Either Leidos Biomedical or Collaborator may unilaterally terminate this Agreement at any time by providing written notice at least [***] before the desired termination date. Leidos Biomedical may, at its option, retain funds transferred to Leidos Biomedical before unilateral termination by Collaborator for use in completing the Joint Work Statement.

   b. Amendment to the Term (Summary Page, page 18):

      The Term of the Agreement will be extended for an additional eighteen (18) month period. The end date of the Agreement is September 3, 2023.

c. Amendments to Appendix A, Joint Work Statement:

In addition to the previously defined Joint Work Statement activities, the following additional work will be performed: [***].

d. Amendments to Appendix B – Staffing, Funding and Materials/Equipment Contributions of the Parties: [***].

2. Ratification of the Agreement. Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 05 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. Counterparts. This Amendment No. 05 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

[THE REMAINDER OF THIS PAGE IS LEFT INTENTIONALLY BLANK]
[SIGNATURES TO FOLLOW ON THE NEXT PAGE]

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 05 as of the date first above written.

Leidos Biomedical Research, Inc.		**TheRas, Inc.**	
By:	/s/ Ethan Dmitrovsky	By:	/s/ Howard Chang
Print Name:	Ethan Dmitrovsky, MD	Print Name:	Howard Chang
Title:	President	Title:	Head of Oncology Research Operations and Strategic Initiatives
Date:	9/23/2021	Date:	9/22/2021
	(Duly authorized)		(Duly authorized)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 6 to Agreement
("Amendment No. 6")

Date: March 27, 2023

Name of Original Agreement:	Cooperative Research and Development Agreement ("CRADA") (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRAS targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Execution Date of Amendment No.1:	January 19, 2018
Execution Date of Amendment No. 2:	January 2, 2019
Execution Date of Amendment No. 3:	November 14, 2019
Execution Date of Amendment No. 4:	January 13, 2020
Execution Date of Amendment No. 5:	September 22, 2021
Parties:	TheRas ("TheRas" or "Collaborator) and Leidos Biomedical Research, Inc. ("Leidos Biomedical")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. AMENDMENT(S) TO THE AGREEMENT:

   a. Amendment to the Term (Summary Page, page 18):

      The Term of the Agreement will be extended for an additional TWELVE (12) month period. The end date of the Agreement is September 3, 2024.

   b. Amendments to Appendix A, Joint Work Statement:

      In addition to the previously defined Joint Work Statement activities, the following additional work will be performed: [***].

2. RATIFICATION OF THE AGREEMENT: Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 6 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. COUNTERPARTS: This Amendment No. 6 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

[THE REMAINDER OF THIS PAGE IS LEFT INTENTIONALLY BLANK]
[SIGNATURES TO FOLLOW ON THE NEXT PAGE]

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 6 as of the date first above written.

Leidos Biomedical Research, Inc.		**TheRas, Inc.**	
By:	/s/ Ethan Dmitrovsky	By:	/s/ Howard Chang
Print Name:	Ethan Dmitrovsky, MD	Print Name:	Howard Chang
Title:	President	Title:	Head of Oncology Research Operations and Strategic Initiatives
Date:	3/30/2023	Date:	March 30, 2023
	(Duly authorized)		(Duly authorized)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 7 to Agreement
("Amendment No. 7")

Date: August 20, 2024

Name of Original Agreement:	Cooperative Research and Development Agreement ("CRADA") (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRAS Targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Execution Date of Amendment No.1:	January 19, 2018
Execution Date of Amendment No. 2:	January 2, 2019
Execution Date of Amendment No. 3:	November 14, 2019
Execution Date of Amendment No. 4:	January 13, 2020
Execution Date of Amendment No. 5:	September 22, 2021
Execution Date of Amendment No. 6:	March 27, 2023
Parties:	TheRas ("TheRas" or "Collaborator") and Leidos Biomedical Research, Inc. ("Leidos Biomedical")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. AMENDMENT(S) TO THE AGREEMENT:

   a. Amendment to the Term:

      The Term of the Agreement will be extended for an additional ONE (1) YEAR. The expiration date of the Agreement is September 3, 2025.

   b. Amendments to Appendix A, Joint Work Statement: [***].

   c. Amendments to Appendix B – Staffing, Funding and Materials/Equipment Contributions of the Parties:

      Funding Contributions:

      Collaborator agrees to provide additional funding in the amount of [***] for a total amount of funding in the amount of $15,409,123.00.

      [***].

2. RATIFICATION OF THE AGREEMENT: Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 7 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. COUNTERPARTS: This Amendment No. 7 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 7 as of the date first above written.

Leidos Biomedical Research, Inc.

By:	/s/ Ethan Dmitrovsky
Print Name:	Ethan Dmitrovsky, MD
Title:	President
Date:	9/25/2024

(Duly authorized)

TheRas, Inc.

By:	/s/ Eli Wallace
Print Name:	Eli Wallace
Title:	CEO
Date:	9/24/2024

(Duly authorized)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 8 to Agreement
("Amendment No. 8")

Date: September 2, 2025

Name of Original Agreement:	Cooperative Research and Development Agreement ("CRADA") (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRAS Targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Execution Date of Amendment No. l:	January 19, 2018
Execution Date of Amendment No. 2:	January 2, 2019
Execution Date of Amendment No. 3:	November 14, 2019
Execution Date of Amendment No. 4:	January 13, 2020
Execution Date of Amendment No. 5:	September 22, 2021
Execution Date of Amendment No. 6:	March 27, 2023
Execution Date of Amendment No. 7:	August 20, 2024
Parties:	TheRas, Inc. ("TheRas" or "Collaborator) and Leidos Biomedical Research, Inc. ("Leidos Biomedical")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. AMENDMENT(S) TO THE AGREEMENT:

   a. Amendment to the Term (Summary Page. 18):

      The Term of the Agreement will be extended for an additional THREE (3) MONTHS. The expiration date of the Agreement is December 3, 2025.

   b. Amendments to Appendix A. Joint Work Statement:

      In addition to the previously defined and ongoing Joint Work Statement activities, the following additional work will be performed:

      [***]

   c. Amendments to Appendix B - Staffing. Funding and Materials/Equipment Contributions of the Parties:

      Funding Contributions:

Collaborator agrees to provide additional funding in the amount of [***] for a total amount of funding in the amount of [***].

Payment will be made in accordance with the following schedule:

[***]

2. RATIFICATION OF THE AGREEMENT: Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 8 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. COUNTERPARTS: This Amendment No. 8 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 8 as of the date first above written.

Leidos Biomedical Research, Inc.		**TheRas, Inc.**	
By:	/s/ Ethan Dmitrovsky	By:	/s/ Eli Wallace
Print Name:	Ethan Dmitrovsky, MD	Print Name:	Eli Wallace, PhD
Title:	President, Leidos Biomedical Research, Inc.	Title:	Chief Executive Office
Date:	10/27/2025	Date:	10/27/2025

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment No. 9 to Agreement
("Amendment No. 9")

Date: December 3, 2025

Name of Original Agreement:	Cooperative Research and Development Agreement ("CRADA") (the "Original Agreement," and together with any previous amendments which may be described below, the "Agreement")
Project Title:	**Development and Characterization of KRAS Targeting Compounds**
Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Effective Date of Amendment No.1:	January 19, 2018
Effective Date of Amendment No. 2:	January 2, 2019
Effective Date of Amendment No. 3:	November 14, 2019
Effective Date of Amendment No. 4:	January 13, 2020
Effective Date of Amendment No. 5:	September 22, 2021
Effective Date of Amendment No. 6:	March 27, 2023
Effective Date of Amendment No. 7:	August 20, 2024
Effective Date of Amendment No. 8:	September 2, 2025

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. AMENDMENT(S) TO THE AGREEMENT:

   a. Amendment to the Term (Summary Page, 18):

      The Term of the Agreement is set to expire on December 3, 2025. By this Amendment, the Term of the Agreement will be extended for an additional NINE (9) MONTHS and the expiration date of the Agreement is September 3, 2026.

   b. Amendments to Appendix B – Staffing, Funding and Materials/Equipment Contributions of the Parties:

      Funding Contributions:

      Collaborator agrees to provide additional funding in the amount of [***] for a total amount of funding in the amount of [***].

      Payment will be made in accordance with the following schedule:

      [***]

2. RATIFICATION OF THE AGREEMENT: The Parties hereby agree, ratify and approve the performance of the Interim Activity and agree that the terms and conditions of the Agreement and this Amendment No.: shall apply to the performance of the Interim Activity. Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 9 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. COUNTERPARTS: This Amendment No. 9 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 9 effective as of the date first above written.

Leidos Biomedical Research, Inc.		**TheRas, Inc.**	
By:	/s/ Ethan Dmitrovsky	By:	/s/ Eli Wallace
Print Name:	Ethan Dmitrsvsky, MD	Print Name:	Eli Wallace, PhD
Title:	President	Title:	Chief Scientific Officer
Date:	1/12/2026	Date:	1/6/2026

Amendment No. 10 to Agreement
("Amendment No. 10")

Date: August 11, 2026

Name of Original Agreement: Cooperative Research and Development Agreement ("CRADA") (the "Original Agreement and together with any previous amendments which may be described below, the "Agreement")

Project Title: Development and Characterization of KRAS Targeting Compounds

Effective Date of Original Agreement:	March 3, 2017 ("Effective Date")
Effective Date of Amendment No.1:	January 19, 2018
Effective Date of Amendment No. 2:	January 2, 2019
Effective Date of Amendment No. 3:	November 14, 2019
Effective Date of Amendment No. 4:	January 13, 2020
Effective Date of Amendment No. 5:	September 22, 2021
Effective Date of Amendment No. 6:	March 27, 2023
Effective Date of Amendment No. 7:	August 20, 2024
Effective Date of Amendment No. 8:	September 2, 2025
Effective Date of Amendment No. 9:	December 3, 2025

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. AMENDMENT(S) TO THE AGREEMENT:

   a. Amendment to the Term (Summary Page, 18):

      The Term of the Agreement is set to expire on September 3, 2026. By this Amendment, the Term of the Agreement will be extended for an additional SIX (6) MONTHS and the expiration date of the Agreement is March 3, 2027.

   b. Amendments to Appendix B – Staffing, Funding and Materials/Equipment Contributions of the Parties:

Funding Contributions:

Collaborator agrees to provide additional funding in the amount of [***] for a total amount of funding in the amount of $18,409,106.00. Additional funding is to perform the activities as detailed in the attached Joint Works Statement

(Appendix A) which is a continuation of the ongoing work as outlined in the original Agreement.

Payment will be made in accordance with the following schedule:

Payment Description	Due Date	Amount (U.S. Dollars)
First Payment	At DATE of execution	[***]
Second Payment	THREE (3) MONTHS from date of execution	[***]
TOTAL		[***]

2. RATIFICATION OF THE AGREEMENT: The Parties hereby agree, ratify and approve the performance of any Interim Activity and agree that the terms and conditions of the Agreement and this Amendment No. 10 shall apply to the performance of such Interim Activity. Except as expressly set forth above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 10 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

3. COUNTERPARTS: This Amendment No. 10 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

IN WITNESS WHEREOF, the duly authorized representatives of TheRas and Leidos Biomedical Research have executed this Amendment No. 10 effective as of the date first above written.

Leidos Biomedical Research, Inc.

By: /s/ Jay Schnitzer
Print Name: Jay Schnitzer, MD, PhD
Title: President, Leidos Biomedical Research, Inc.
Date: 9/9/2026

TheRas, Inc.

By: /s/ Pedro J. Beltran
Print Name: Pedro J. Beltran
Title: Chief Executive Officer
Date: 9/8/2026

LBR CRADA No.: 10056-16

APPENDIX A

[***]

LBR CRADA No.: 10056-16

AMENDMENT NO. 10

TO TRANSITION SERVICES AGREEMENT

This Amendment No. 10 ("**Amendment No. 10**") to the Agreement (as defined below) is entered into as of September 15, 2026 (the "**Effective Date**") by and among BridgeBio Services Inc., a Delaware corporation ("**BBIO**"), TheRas, Inc., a Delaware corporation ("**BBOT**"), BridgeBio Pharma LLC ("**BBP LLC**"), and BridgeBio Oncology Therapeutics, Inc. ("**PubCo**"). BBIO, BBOT, BBP LLC and PubCo may be referred to herein by name or individually, as a "**Party**" and collectively, as the "**Parties**." Capitalized terms used and not otherwise defined herein shall have the meanings given such terms in the Agreement (as defined below) to the extent defined therein.

WHEREAS, BBIO and BBOT entered into that certain Transition Services Agreement, dated April 30, 2024, as amended (the "**Agreement**");

WHEREAS, the Parties now wish to further amend the Agreement to update the Service Schedule on Exhibit A thereto;

NOW, THEREFORE, in consideration of the covenants, conditions and undertakings hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. **Amendment to Service Schedule**. Exhibit A of the Agreement is hereby deleted in its entirety and replaced with the following new Exhibit A attached hereto.

2. **Miscellaneous.** This Amendment No. 10 together with the Agreement constitutes the entire agreement of the Parties with respect to the matters set forth in this Amendment No. 10 and there are no other agreements, commitments or understandings among the Parties with respect to the matters set forth herein. All terms and conditions of the Agreement not expressly amended herein shall remain in full force and effect. The terms and conditions of this Amendment No. 10 shall prevail over any conflicting terms and conditions in the Agreement with regard to the subject matter herein. This Amendment No. 10 shall be construed and enforced in accordance with the laws of California.

IN WITNESS WHEREOF, each Party hereto has executed this Amendment No. 10 as of the date first above written.

BRIDGEBIO SERVICES INC.

By: /s/ Neil Kumar
Name: Neil Kumar
Title: President & Chief Executive Officer

BRIDGEBIO PHARMA LLC

By: /s/ Neil Kumar
Name: Neil Kumar
Title: President & Chief Executive Officer

THERAS, INC.

By: /s/ Idan Elmelech
Name: Idan Elmelech
Title: Chief Operating Officer

BRIDGEBIO ONCOLOGY THERAPEUTICS, INC.

By: /s/ Idan Elmelech
Name: Idan Elmelech
Title: Chief Operating Officer

EXHIBIT A

SERVICE SCHEDULE

Services from July 1, 2026 through September 30, 2026

[***]

Exhibit 10.3

BRIDGEBIO ONCOLOGY THERAPEUTICS, INC.

EXECUTIVE SEVERANCE PLAN

1. Purpose. BridgeBio Oncology Therapeutics, Inc. (the "Company") considers it essential to the best interests of its stockholders to foster the continuous employment of key management personnel. The Board of Directors of the Company (the "Board") recognizes, however, that, as is the case with many publicly-held corporations, the possibility of an involuntary termination of employment, either before or after a Change in Control (as defined in Section 2 hereof), exists and that such possibility, and the uncertainty and questions that it may raise among management, may result in the departure or distraction of management personnel to the detriment of the Company and its stockholders. Therefore, the Board has determined that the BridgeBio Oncology Therapeutics, Inc. Executive Severance Plan (the "Plan") should be adopted to reinforce and encourage the continued attention and dedication of the Company's Covered Executives (as defined in Section 2 hereof) to their assigned duties without distraction. Nothing in this Plan shall be construed as creating an express or implied contract of employment and nothing shall alter the "at will" nature of the Covered Executives' employment with the Company.

2. Definitions. The following terms shall be defined as set forth below:

(a) *"Accounting Firm"* shall mean a nationally recognized accounting firm selected by the Company.

(b) *"Administrator"* means the Board or the Compensation Committee of the Board.

(c) "*Base Salary*" shall mean the annual base salary in effect immediately prior to the Date of Termination, unless the Covered Executive has resigned for Good Reason following a material diminution in the Covered Executive's annual base salary, in which case the annual base salary immediately prior to such diminution shall be the Base Salary.

(d) "*Cause*" shall mean, and shall be limited to, the occurrence of any one or more of the following events:

(i) the Covered Executive's unauthorized use or disclosure of the Company's (or successor entity's, as applicable) confidential information or trade secrets;

(ii) the Covered Executive's material breach of any agreement between the Covered Executive and the Company (or successor entity, as applicable);

(iii) the Covered Executive's material failure to comply with the Company's (or successor entity's, as applicable) written policies or rules;

(iv) the Covered Executive's gross negligence or willful misconduct in connection with the Covered Executive's performance of his/her duties to the Company (or successor entity, as applicable);

(v) the Covered Executive's continuing failure to perform assigned duties after receiving written notification of the failure from the Company (or successor entity, as applicable) and, if curable, a period of thirty (30) days to cure such failure;

(vi)the conviction of, indictment for or plea of nolo contendere by the Covered Executive to a felony or a crime involving moral turpitude; or

(vii)the Covered Executive's failure to cooperate in good faith with a governmental or internal investigation of the Company (or successor entity, as applicable) or its directors, officers or employees, if the Company (or successor entity, as applicable) has requested the Covered Executive's cooperation.

(e) "*Change in Control*" shall mean a Sale Event, as defined in the BridgeBio Oncology Therapeutics, Inc. 2025 Stock Option and Incentive Plan, as amended from time to time.

(f) "*Change in Control Period*" shall mean the period beginning three (3) months prior to a Change in Control and ending twelve (12) months following the date of the Change in Control.

(g) *"Code"* shall mean the Internal Revenue Code of 1986, as amended.

(h) "*Covered Executives*" shall mean Tier 1 Executive and those other employees designated by the Administrator in its sole discretion as the Tier 2 Executives and Tier 3 Executives, and, in each case, who meet the eligibility requirements set forth in Section 4 of the Plan.

(i) "*Date of Termination*" shall mean the date that a Covered Executive's employment with the Company (or any successor) ends, which date shall be specified in the Notice of Termination. Notwithstanding the foregoing, a Covered Executive's employment shall not be deemed to have been terminated solely as a result of the Covered Executive becoming an employee of any direct or indirect successor to the business or assets of the Company.

(j) "*Disability*" shall mean the following: if through any illness, injury, accident or condition of either a physical or psychological nature, the Covered Executive becomes unable to perform substantially all of his duties and responsibilities for a continuous period of sixteen (16) consecutive weeks or for any twenty-six (26) weeks within a fifty-two (52) week period. Determinations as to whether Covered Executive is Disabled shall be made by a physician selected by the Board or its insurers and acceptable to the Covered Executive or the Covered Executive's legal representative, such agreement as to acceptability not to be unreasonably withheld or delayed.

(k) *"Good Reason"* shall mean that the Covered Executive has complied with the "Good Reason Process" following the occurrence of any of the following events without the Covered Executive's consent:

(i) a material diminution in the Covered Executive's annual base salary and/or target annual bonus opportunity as a percentage of annual base salary (other than, in either case, across the board decreases similarly affecting all senior executives of the

Company (or successor entity, as applicable));

(ii) (A) the Company (or successor entity, as applicable) requiring the Covered Executive to relocate (other than for travel incident to the Covered Executive's performance of his or her duties on behalf of the Company (or successor entity, as applicable)), a distance of more than thirty-five (35) miles from the Covered Executive's current principal place of business or (B) to the extent the Covered Executive's services to the Company (or successor entity, as applicable) immediately prior to the occurrence of the event under this prong is in a fully remote capacity, the Company (or successor entity, as applicable) requiring the Covered Executive to be present in person on a regular basis and no longer permitting the Covered Executive to work in a fully remote capacity (excluding any travel incident to the Covered Executive's performance of his or her duties on behalf of the Company (successor entity, as applicable));

(iii) any material diminution in the Covered Executive's position, responsibilities, authority, duties or reporting relationship; or

(iv) failure of any successor to the Company to assume and agree to be bound by the terms and conditions of this Plan with respect to the applicable covered Executive.

For purposes of Section 2(k)(iii), a change in a title will not, by itself, be sufficient to constitute a material diminution of responsibilities, authority or duty.

(l) "*Good Reason Process*" shall mean:

(i) the Covered Executive reasonably determines in good faith that a "Good Reason" condition has occurred;

(ii) the Covered Executive notifies the Company (or successor entity, as applicable) in writing of the first occurrence of the Good Reason condition within sixty (60) days of the first occurrence of such condition;

(iii) the Covered Executive cooperates in good faith with the Company's (or successor entity's, as applicable) efforts, for a period of not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition;

(iv) notwithstanding such efforts, the Good Reason condition continues to exist following the Cure Period; and

(v) the Covered Executive terminates his or her employment and provides the Company (or successor entity, as applicable) with a Notice of Termination with respect to such termination, each within sixty (60) days after the end of the Cure Period.

If the Company (or successor entity, as applicable) cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(m) "*Notice of Termination*" shall mean a written notice which shall indicate the specific termination provision in this Plan relied upon for the termination of a Covered Executive's employment and the Date of Termination.

(n) *"Participation Agreement"* shall mean a fully executed agreement between a Covered Executive and the Company by which the Covered Executive's acknowledges and agrees to the terms and conditions of the Covered Executive's participation in the Plan.

(o) *"Qualified Termination Event"* shall mean (i) a termination of the Covered Executive's employment by the Company other than for Cause, death or Disability or (ii) the Covered Executive's resignation from the Company for Good Reason.

(p) "*Restrictive Covenants Agreement*" shall mean the Proprietary Information and Inventions Agreement (or similar agreements) entered into between the Covered Executive and the Company.

(q) "*Tier 1 Executive*" shall mean the Company's Chief Executive Officer.

(r) "*Tier 2 Executives*" shall mean the individuals designated as such by the Administrator and who are listed in Exhibit A, attached hereto, as such exhibit is amended by the Administrator from time to time.

(s) "*Tier 3 Executives*" shall mean the individuals designated as such by the Administrator and who are listed in Exhibit B, attached hereto, as such exhibit is amended by the Administrator from time to time.

3. Administration of the Plan.

(a) Administrator. The Plan shall be administered by the Administrator.

(b) Powers of Administrator. The Administrator shall have all powers necessary to enable it properly to carry out its duties with respect to the complete control of the administration of the Plan. Not in limitation, but in amplification of the foregoing, the Administrator shall have the power and authority in its discretion to:

(i) construe the Plan to determine all questions that shall arise as to interpretations of the Plan's provisions;

(ii) determine which individuals are and are not Covered Executives, designate an individual as a Tier 2 Executive or Tier 3 Executive, determine the benefits to which any Covered Executives may be entitled, the eligibility requirements for participation in the Plan and all other matters pertaining to the Plan;

(iii) adopt amendments to the Plan which are deemed necessary or desirable to comply with all applicable laws and regulations, including but not limited to Code Section 409A and the guidance thereunder;

(iv) make all determinations it deems advisable for the administration of

the Plan, including the authority and ability to delegate administrative functions to a third party;

(v) decide all disputes arising in connection with the Plan; and

(vi)otherwise supervise the administration of the Plan.

(c) All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Covered Executives.

4. Eligibility. All Covered Executives who have executed and submitted to the Company a Participation Agreement, and satisfied such other requirements as may be determined by the Administrator, are eligible to participate in the Plan. The Administrator may determine at any time that a Covered Executive should no longer be designated as such as a result of a material change in such Covered Executive's role, and such individual shall cease to be eligible to participate in the Plan upon the Administrator taking action by resolution to update the applicable Exhibit hereto.

5. Termination Benefits Generally. In the event a Covered Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Covered Executive any earned but unpaid salary, unpaid expense reimbursements in accordance with Company policy and any vested benefits the Covered Executive may have under any employee benefit plan of the Company in accordance with the terms and conditions of such employee benefit plan (collectively, the "Accrued Benefits"), within the time required by law but in no event more than sixty (60) days after the Date of Termination.

6. Termination Not in Connection with a Change in Control. In the event of a Qualified Termination Event any time other than during the Change in Control Period, with respect to such Covered Executive, in addition to the Accrued Benefits, subject to his or her execution of a separation agreement in a form and manner satisfactory to the Company containing, among other provisions, a general release of claims in favor of the Company and related persons and entities, confidentiality, return of property, non-disparagement and reaffirmation of the Restrictive Covenants Agreement (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable, all within the time period set forth in the Separation Agreement and Release but in no event more than sixty (60) days after the Date of Termination, and subject to the Covered Executive complying with the Separation Agreement and Release, the Company shall:

(a) (i) pay the Covered Executive an amount equal twelve (12) months' Base Salary for the Tier 1 Executive, nine (9) months' Base Salary for each Tier 2 Executive and 6 months' Base Salary for each Tier 3 Executive, and (ii) pay the Covered Executive, in a lump sum, a pro-rated portion of the Covered Executive's annual cash incentive bonus for the year in which the Date of Termination occurs, payable at the same time as such bonuses are paid to other executives of the Company; provided, that such amount shall be paid no later than 74 days after the end of the year in which the Date of Termination occurs and such pro-rated portion shall be based on the number of days of service provided by the Covered Executive during the year of the Date of Termination; and

(b) if the Covered Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the group health plan provider or the COBRA provider, as applicable, a monthly cash payment in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Covered Executive if the Covered Executive had remained employed by the Company, based on the premiums as of the Date of Termination, until the earlier of (i) twelve (12) months for the Tier 1 Executive, nine (9) months for each Tier 2 Executive and six (6) months for each Tier 3 Executive, (ii) the date on which the Covered Executive becomes eligible for group medical plan benefits under any other employer's group medical plan, or (iii) the cessation of the Covered Executive's health continuation rights under COBRA; provided, however, that if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider, as applicable, without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Covered Executive for the time period specified above. Such payments to the Covered Executive shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Section 6(a)(i) and (b), as applicable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over twelve (12) months for the Tier 1 Executive, nine (9) months for each Tier 2 Executive and six (6) months for each Tier 3 Executive, commencing within sixty (60) days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid in the second calendar year no later than the last day of such 60-day period; provided further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination.

7. Termination in Connection with a Change in Control. In the event a Qualified Termination Event occurs within the Change in Control Period, then with respect to such Covered Executive, in addition to the Accrued Benefits, subject to his or her execution and non-revocation of the Separation Agreement and Release, all within the time period set forth in the Separation Agreement and Release, but in no event more than sixty (60) days after the Date of Termination, the Company shall:

(a) cause 100% of the outstanding and unvested equity awards with time-based vesting held by the Covered Executive to immediately become fully vested, exercisable or nonforfeitable as of the Date of Termination or Change in Control, if later; provided, that the performance conditions applicable to any outstanding and unvested equity awards subject to performance conditions will vest pursuant to the applicable award agreement. Notwithstanding the foregoing, in the event of a Change in Control where the parties to such Change in Control do not provide for the assumption, continuation or substitution of equity awards of the Company, any and all outstanding and unvested equity awards held by the Covered Executive shall be subject to Section 3(d) of the Company's 2025 Stock Option and Incentive Plan, as amended from time to time;

(b) pay to the Covered Executive an amount equal to the sum of (i) 150% of Base Salary for the Tier 1 Executive, 100% of Base Salary for each Tier 2 Executive and 75% of

Base Salary for each Tier 3 Executive plus (ii) 150% for the Tier 1 Executive, 100% for each Tier 2 Executive and 75% for each Tier 3 Executive, of the Covered Executive's annual target bonus in effect immediately prior to the Qualified Termination Event (or the Covered Executive's target bonus in effect immediately prior to the Change in Control, if higher); and

(c) if the Covered Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the group health plan provider or the COBRA provider, as applicable, cash payment in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Covered Executive if the Covered Executive had remained employed by the Company, based on the premiums as of the Date of Termination until the earliest of (i) eighteen (18) months for the Tier 1 Executive, twelve (12) months for each Tier 2 Executive and nine (9) months for each Tier 3 Executive, (ii) the date that the Covered Executive becomes eligible for group medical plan benefits under any other employer's group medical plan, or (iii) the cessation of the Covered Executive's health continuation rights under COBRA; provided, however, that if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider, as applicable, without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Covered Executive for the time period specified above. Such payments to the Covered Executive shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Section 7(b), shall be paid out in a lump sum within sixty (60) days after the Date of Termination or Change in Control, if later, and the amounts payable under Section 7(c), as applicable, shall be paid out in a substantially equal installments in accordance with the Company's payroll practice over eighteen (18) months for the Tier 1 Executive, twelve (12) months for each Tier 2 Executive and nine (9) months for each Tier 3 Executive, commencing within sixty (60) days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid or begin to be paid , as applicable, in the second calendar year no later than the last day of the 60-day period; provided further, that if applicable, the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. For the avoidance of doubt, the severance pay and benefits provided in this Section 7 shall apply in lieu of, and expressly supersede, the provisions of Section 6 and no Covered Executive shall be entitled to the severance pay and benefits under both Section 6 and 7 hereof.

8. Additional Limitation.

(a) Anything in this Plan to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Covered Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Plan or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Covered Executive becomes subject to the excise tax imposed by Section 4999 of the

Code; provided that such reduction shall only occur if it would result in the Covered Executive receiving a higher After Tax Amount (as defined below) than the Covered Executive would receive if the Aggregate Payments were not subject to such reduction. In the event of such reduction, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (i) cash payments not subject to Section 409A of the Code; (ii) cash payments subject to Section 409A of the Code; (iii) equity-based payments and acceleration; and (iv) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(b) For purposes of this Section 8, the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Covered Executive as a result of the Covered Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Covered Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes (if any) which could be obtained from deduction of such state and local taxes.

(c) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 8(a) shall be made by the Accounting Firm, which shall provide detailed supporting calculations both to the Company and the Covered Executive within fifteen (15) business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Covered Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Covered Executive.

9. Restrictive Covenants Agreement.

As a condition to participating in the Plan, each Covered Executive shall continue to comply with the terms and conditions contained in the Restrictive Covenants Agreements (or similar agreement entered into between the Covered Executive and the Company) and such other agreement(s) as designated in the applicable Participation Agreement or the Covered Executive's employment agreement. If a Covered Executive has not entered into a Restrictive Covenants Agreement or similar agreement with the Company, he or she shall enter into such agreement prior to participating in the Plan.

10. Withholding. All payments made by the Company under this Plan shall be subject to any tax or other amounts required to be withheld by the Company under applicable law.

11. Section 409A.

(a) Anything in this Plan to the contrary notwithstanding, if at the time of the Covered Executive's "separation from service" within the meaning of Section 409A of the Code, the Company determines that the Covered Executive is a "specified employee" within the meaning

of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Covered Executive becomes entitled to under this Plan would be considered deferred compensation subject to the twenty (20) percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (i) six (6) months and one (1) day after the Covered Executive's separation from service, or (ii) the Covered Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) The parties intend that this Plan will be administered in accordance with Section 409A of the Code and that all amounts payable hereunder shall be exempt from the requirements of such section as a result of being "short term deferrals" for purposes of Section 409A of the Code to the greatest extent possible. To the extent that any provision of this Plan is not exempt from Section 409A of the Code and ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner to comply with Section 409A of the Code. Each payment pursuant to this Plan is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Plan may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(c) To the extent that any payment or benefit described in this Plan constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Covered Executive's termination of employment, then such payments or benefits shall be payable only upon the Covered Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) All in-kind benefits provided and expenses eligible for reimbursement under this Plan shall be provided by the Company or incurred by the Covered Executive during the time periods set forth in this Plan. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(e) The Company makes no representation or warranty and shall have no liability to the Covered Executive or any other person if any provisions of this Plan are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

12. Notice and Date of Termination.

(a) Notice of Termination. A termination of the Covered Executive's employment shall be communicated by Notice of Termination from the Company to the Covered Executive or vice versa in accordance with this Section 12.

(b) Notice to the Company. Any notices, requests, demands, and other communications provided for by this Plan shall be sufficient if in writing and delivered in person or sent by registered or certified mail, postage prepaid, to a Covered Executive at the last address the Covered Executive has filed in writing with the Company, or to the Company at the following physical or email address:

BridgeBio Oncology Therapeutics, Inc.
Attention: Legal Department
256 E. Grand Ave, Suite 104,
South San Francisco, CA 94080
legal@bbotx.com

13. No Mitigation. The Covered Executive is not required to seek other employment or to attempt in any way to reduce any amounts payable to the Covered Executive by the Company under this Plan.

14. Benefits and Burdens. This Plan shall inure to the benefit of and be binding upon the Company and the Covered Executives, their respective successors, executors, administrators, heirs and permitted assigns. In the event of a Covered Executive's death after a termination of employment but prior to the completion by the Company of all payments due to him or her under this Plan, the Company shall continue such payments to the Covered Executive's beneficiary designated in writing to the Company prior to his or her death (or to his or her estate, if the Covered Executive fails to make such designation).

15. Enforceability. If any portion or provision of this Plan shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Plan, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Plan shall be valid and enforceable to the fullest extent permitted by law.

16. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Plan, or the waiver by any party of any breach of this Plan, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

17. Non-Duplication of Benefits and Effect on Other Plans. Notwithstanding any other provision in the Plan to the contrary, the benefits provided hereunder shall be in lieu of any other severance payments and/or benefits provided by the Company, including any such payments and/or benefits pursuant to an employment agreement or offer letter between the Company and the Covered Executive, other than as provided in Section 3(d) of the Company's 2025 Stock Option and Incentive Plan, as amended from time to time.

18. No Contract of Employment. Nothing in this Plan shall be construed as giving any Covered Executive any right to be retained in the employ of the Company or shall affect the terms and conditions of a Covered Executive's employment with the Company.

19. Amendment or Termination of Plan. The Company may amend or terminate this Plan at any time or from time to time, but no such action shall adversely affect the rights of any Covered Executive without the Covered Executive's written consent.

20. Governing Law. This Plan shall be construed under and be governed in all respects by the laws of the State of Delaware, without giving effect to the conflict of laws principles.

21. Obligations of Successors. In addition to any obligations imposed by law upon any successor to the Company, any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company shall expressly assume and agree to perform this Plan in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

22. Effectiveness and Term. The Executive Severance Plan is effective as of the closing of the transactions contemplated by that certain Business Combination Agreement, dated February 28, 2025, by and among the Company, Helix Acquisition Corp. II, a Cayman Islands exempted company, and Helix II Merger Sub, Inc.

Exhibit A

Tier 2 Executives

Individual	**Title**
Yong Ben	Chief Medical and Development Officer
Idan Elmelech	Chief Operating Officer

Exhibit B

Tier 3 Executives

[***]

Exhibit 31.1

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

I, Pedro J. Beltran, Ph.D., certify that:

1. I have reviewed this Form 10-Q of BridgeBio Oncology Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2026

By: /s/ Pedro J. Beltran
Pedro J. Beltran, Ph.D.
Chief Executive Officer

Exhibit 31.2

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

I, Idan Elmelech, certify that:

1. I have reviewed this Form 10-Q of BridgeBio Oncology Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2026

By: /s/ Idan Elmelech
Idan Elmelech
Chief Operating Officer and Principal Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of BridgeBio Oncology Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition, and results of operations of the Company.

Date: November 10, 2026

By: /s/ Pedro J. Beltran

Pedro J. Beltran, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of BridgeBio Oncology Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition, and results of operations of the Company.

Date: November 10, 2026

By: /s/ Idan Elmelech

Idan Elmelech
Chief Operating Officer
(Principal Financial Officer)