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

FORM 10-K

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from to
Commission File Number: 001-40877

CERO THERAPEUTICS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**81-4182129**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 Haskins Way, Suite 230 South San Francisco, CA	**94080**
(Address of principal executive offices)	(Zip Code)

(650) 407-2376
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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	CERO	Nasdaq Capital Market
Warrants to purchase one share of Common Stock	CEROW	Nasdaq Capital Market

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

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting securities held by non-affiliates was approximately $5,765,325 based on the number of shares held by non-affiliates and the last reported sales price of the registrant's Class A common stock as of that date.

As of April 11, 2025, the registrant had 5,380,723 shares of common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2025 Annual Meeting of Stockholders, which the Registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the Registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, results of preclinical studies, clinical trials, research and development ("R&D") costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- our financial performance;
- our ability to obtain additional cash and the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements, including the development and, if approved, commercialization of our product candidates;
- our ability to realize the benefits expected from the business combination (the "Business Combination") pursuant to the Business Combination Agreement, dated as of June 4, 2023 (as amended, the "Business Combination Agreement"), by and among CERo Therapeutics, Inc. ("Legacy CERo"), Phoenix Biotech Acquisition Corp. ("PBAX") and PBCE Merger Sub, Inc. ("Merger Sub");
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- the scope, progress, results and costs of developing CER-1236 or any other product candidates we may develop, and conducting preclinical studies and clinical trials;
- the timing and costs involved in obtaining and maintaining regulatory approval of CER-1236 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations or accelerated approvals for our drug candidates for various indications;
- current and future agreements with third parties in connection with the development and commercialization of CER-1236 or any other future product candidate;
- our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials to demonstrate the safety and efficacy of CER-1236 and any other product candidates we may develop, and other positive results;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our plans relating to the commercialization of CER-1236 and any other product candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales team;

- the success of competing drugs, therapies or other products that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our plans relating to the further development and manufacturing of CER-1236 and any other product candidates we may develop, including additional indications that we may pursue for CER-1236 or other product candidates;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply CER-1236 and any other product candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of CER-1236 and any other product candidates we may develop, as well as the pricing and reimbursement of CER-1236 and any other product candidates we may develop, if approved;
- our expectations regarding our ability to obtain, maintain, protect and enforce intellectual property protection for CER-1236 and for any other product candidate;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of third parties;
- our ability to successfully defend litigation that may be instituted against us;
- our ability to realize the anticipated benefits of any strategic transactions;
- our ability to attract and retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel and our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- our ability to maintain proper and effective internal controls;
- the ability to obtain or maintain the listing of our common stock, and our public warrants on the Nasdaq Stock Market ("Nasdaq");
- the impact of macroeconomic conditions and geopolitical turmoil on our business and operations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and as a smaller reporting company under the federal securities laws; and
- our anticipated use of our existing cash, cash equivalents and marketable securities.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in "*Risk Factors*" and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Annual Report, whether as a result of any new information, future events or otherwise.

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

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

Unless the context otherwise requires, all references herein to "we," "us," "our" or "the Company" refer to the business and operations of CERo Therapeutics Holdings, Inc. ("CERo") and its subsidiaries.

SELECTED DEFINITIONS

As used in this Annual Report, unless otherwise noted or the context otherwise requires, references to the following capitalized terms have the meanings set forth below:

"*Arena*" refers to Arena Business Solutions Global SPC II, Ltd. on behalf of and for the account of Segregated Portfolio #13 – SPC #13.

"*Arena Commitment Shares*" refer to up to 10,000 shares of Common Stock issued to Arena as consideration for executing and delivering the Arena Purchase Agreement.

"*Arena Purchase Agreement*" refers to the Purchase Agreement, dated as of February 23, 2024, by and between CERo and Arena.

"*Board*" refers to the board of directors of CERo.

"*Business Combination*" or "*Merger*" refers to the transactions contemplated by the Business Combination Agreement, including the merger between Merger Sub and Legacy CERo.

"*Business Combination Agreement*" refers to the Business Combination Agreement, dated as of June 4, 2023, as amended by Amendment No. 1, dated February 5, 2024 and Amendment No. 2, dated February 13, 2024, by and between PBAX, Merger Sub and Legacy CERo.

"*Bylaws*" refers to the Amended and Restated Bylaws of CERo.

"*Charter*" refers to CERo's Second Amended and Restated Certificate of Incorporation, as filed with the Secretary of the State of Delaware February 14, 2024.

"*Class A Common Stock*" refers to the CERo Class A common stock, par value $0.0001 per share.

"*Closing*" refers to the closing of the Business Combination.

"*Common Stock*" refers to the Class A common stock, par value $0.0001 per share, of CERo.

"*Common Warrants*" refers to the Public Warrants, Private Placement Warrants, the Conversion Warrants, the Series A Warrants, the Series C Warrants, the December 2024 Common Warrants, the January 2025 Common Warrants, the February 2025 Common Warrants and the Pre-Funded Warrants.

"*Conversion Warrants*" refer to the warrants initially issued by CERo Therapeutics, Inc. and converted into warrants to purchase Common Stock in connection with the Business Combination.

"*December 2024 Common Warrants*" refer to the warrants to purchase shares of Common Stock, at a current exercise price of $5.61 per share, issued by the Company in a private placement on December 23, 2024.

"*DGCL*" refers to the Delaware General Corporation Law, as may be amended from time to time.

"*Earnout Shares*" refer to the Primary Earnout Shares, the Secondary Earnout Shares and the Tertiary Earnout Shares, collectively.

"*February 2025 Common Warrants*" refer to the warrants to purchase shares of Common Stock, at a current exercise price of $1.96 per share, issued by the Company in a public offering on February 7, 2025.

"*First PIPE Financing*" refers to the private placement pursuant to which we issued and sold, and the PIPE Investors purchased, shares of Series A Preferred Stock, the Series A Warrants and Preferred Warrants, on the terms and conditions set forth in the First Securities Purchase Agreement.

"*First PIPE Registration Rights Agreement*" refers to the Registration Rights Agreement, dated as of February 14, 2024, by and between CERo and certain PIPE Investors.

"*First Securities Purchase Agreement*" refers to the Amended and Restated Securities Purchase Agreement, dated as of February 14, 2024, by and among PBAX, Legacy CERo and certain PIPE Investors, pursuant to which CERo agreed to issue and sell 10,039 shares of Series A Preferred Stock, 6,127 Series A Warrants and 2,500 Preferred Warrants.

"*Initial Public Offering*" refers to the initial public offering of PBAX, which closed on October 8, 2021.

"*January 2025 Common Warrants*" refer to the warrants to purchase shares of Common Stock, at a current exercise price of $5.82 per share, issued by the Company in a private placement on January 6, 2025.

"*Keystone*" refers to Keystone Capital Partners, LLC.

"*Keystone Commencement Date*" refers to the time when all of the conditions to our right to commence sales of Common Stock to Keystone set forth in the respective Keystone Purchase Agreements have been satisfied.

"*Keystone Commitment Shares*" refers to the 19,833 shares of Common Stock that have been issued to Keystone as consideration for Keystone entering into the Keystone Purchase Agreements.

"*Keystone Purchase Agreements*" refers to the Old Keystone Purchase Agreement and the New Keystone Purchase Agreement.

"*Keystone Purchase Shares*" refers to the shares of Common Stock that CERo may elect to issue and sell to Keystone after the Keystone Commencement Date.

"*Legacy CERo*" refers to CERo Therapeutics, Inc.

"*Legacy CERo common stock*" refers to the common stock, par value $0.0001 per share, of Legacy CERo.

"*Legacy CERo preferred stock*" refers to the preferred stock, par value $0.0001 per share, of Legacy CERo.

"*Legacy CERo options*" refers to the options to purchase shares of Legacy CERo common stock.

"*Legacy CERo Stockholders*" refers to the holders of Legacy CERo common stock and/or Legacy CERo preferred stock prior to the Business Combination.

"*Legacy CERo warrants*" refers to the warrants to purchase shares of Legacy CERo preferred stock.

"*Merger Sub*" refers to PBCE Merger Sub, Inc., a Delaware corporation.

"*New Keystone Purchase Agreement*" refers to the Common Stock Purchase Agreement, dated as of November 8, 2024, by and between CERo and Keystone.

"*Old Keystone Purchase Agreement*" refers to the Common Stock Purchase Agreement, dated as of February 14, 2024, by and between PBAX and Keystone.

"*PIPE Financings*" refers to the First PIPE Financing, the Second PIPE Financing and the Third PIPE Financing.

"*PIPE Investors*" refer to the investors in the PIPE Financings.

"*PIPE Registration Rights Agreement*" refers to the First PIPE Registration Rights Agreement, the Second PIPE Registration Rights Agreement and the Third PIPE Registration Rights Agreement.

"*Pre-Funded Warrants*" refer to the warrants to purchase shares of Common Stock, at an exercise price of $0.0001 per Share, issued in a public offering on February 7, 2025.

"*Preferred Stock*" refers to the shares of Series A, Series B, and Series C Preferred Stock, par value $0.0001 per share, of CERo.

"*Preferred Shares*" refer to the shares of Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock issued in the PIPE Financings, including the Warrant Preferred Shares.

"*Preferred Warrants*" refer to warrants to purchase shares of Series A Preferred Stock.

"*Primary Earnout Shares*" refer to the 12,000 shares of Common Stock issued to the holders of Legacy CERo common stock and Legacy CERo preferred stock in connection with the Business Combination, 10,000 of which are subject to vesting upon the achievement of certain stock price-based earnout targets and 2,000 of which are subject to vesting upon a change of control, respectively.

"*Private Placement Warrants*" refer to private placement warrants to purchase shares of Common Stock, at an exercise price of $1,150.00 per share, that were originally sold in a private placement concurrently with the Initial Public Offering.

"*Public Warrants*" refer to the warrants to purchase shares of Common Stock, at an exercise price of $1,150.00 per share, that were originally issued in the Initial Public Offering.

"*Reverse Stock Split*" refers to the Company's reverse stock split that became effective at 12:01 a.m. Eastern time on January 8, 2025, pursuant to which each 100 shares of Common Stock outstanding immediately prior thereto was converted into 1 share of Common Stock outstanding immediately thereafter.

"*Rollover Warrants*" refer to warrants to purchase shares of Common Stock, at an exercise price of $1,000.00 per share, that were converted from Legacy CERo warrants in connection with the Business Combination.

"*SEC*" refers to the U.S. Securities and Exchange Commission.

"*Secondary Earnout Shares*" refer to the 8,750 shares of Common Stock issued to the holders of Legacy CERo common stock and Legacy CERo preferred stock in connection with the Business Combination, which became fully vested at Closing.

"*Second PIPE Financing*" refers to the private placement pursuant to which we issued and sold, and the PIPE Investors purchased, shares of Series B Preferred Stock, on the terms and conditions set forth in the Second Securities Purchase Agreement.

"*Second PIPE Registration Rights Agreement*" refers to the Registration Rights Agreement, dated as of March 29, 2024, by and between CERo and certain PIPE Investors.

"*Second Securities Purchase Agreement*" refers to the Securities Purchase Agreement, dated as of March 29, 2024, by and among CERo and certain PIPE Investors, pursuant to which CERo agreed to issue and sell 626 shares of Series B Preferred Stock.

"*Series A Preferred Stock*" refers to the Series A convertible preferred stock, $0.0001 par value per share, of CERo.

"*Series A Warrants*" refers to warrants to purchase Common Stock, at a current exercise price of $139.00 per share, sold to certain PIPE Investors pursuant to the First Securities Purchase Agreement.

"*Series B Preferred Stock*" refers to the Series B convertible preferred stock, $0.0001 par value per share, of CERo.

"*Series C Preferred Stock*" refers to the Series C convertible preferred stock, $0.0001 par value per share, of CERo.

"*Series C Warrants*" refers to warrants to purchase shares of Common Stock, at a current exercise price of $0.04 per share, sold to certain PIPE Investors pursuant to the Third Securities Purchase Agreement.

"*Sponsor*" refers to Phoenix Biotech Sponsor, LLC, a Delaware limited liability company.

"*Tertiary Earnout Shares*" refer to the 10,000 shares of Common Stock issued to the holders of Legacy CERo common stock and Legacy CERo preferred stock in connection with the Business Combination, which became fully vested upon the achievement of certain regulatory milestone-based earnout targets.

"*Third PIPE Financing*" refers to the private placement pursuant to which we issued and sold, and the PIPE Investors purchased, shares of Series C Preferred Stock, on the terms and conditions set forth in the Third Securities Purchase Agreement.

"*Third PIPE Registration Rights Agreement*" refers to the Registration Rights Agreement, dated as of September 26, 2024, by and between CERo and certain PIPE Investors.

"*Third Securities Purchase Agreement*" refers to the Securities Purchase Agreement, dated as of September 25, 2024, by and among CERo and certain PIPE Investors, pursuant to which CERo agreed to issue and sell 2,853 shares of Series C Preferred Stock and the Series C Warrants to purchase 81,753 shares of Common Stock.

"*Warrant Preferred Shares*" refer to the shares of Preferred Stock underlying the Preferred Warrants.

"*Warrants*" refer to the Rollover Warrants, the Private Placement Warrants, the Common Warrants, the Preferred Warrants, the Public Warrants, the February 2025 Common Warrants and the Pre-Funded Warrants.

RISK FACTORS SUMMARY

Our business is subject to numerous risks and uncertainties that you should consider before investing in our securities. Some of the principal risk factors are summarized below:

- We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- There is substantial doubt as to our ability to continue as a going concern.
- Our business is highly dependent on the success of our lead product candidate. If we are unable to advance clinical development, obtain approval of and successfully commercialize our lead product candidate for the treatment of patients in approved indications, our business would be significantly harmed.
- Our engineered Chimeric Engulfment Receptor T ("CER-T") cells represent a novel approach to cancer treatment that creates significant challenges for us.

  Our current product candidates are in early clinical or preclinical development and have never been tested in humans. One or all of our current product candidates may fail in clinical development or suffer delays that materially and adversely affect their commercial viability.
- Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.
- Manufacturing genetically engineered products is complex and we, or our third-party manufacturers, may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.
- Genetic engineering of T cells to create CER-T cells is a relatively new technology, and if we are unable to use this technology in our intended product candidates, our revenue opportunities will be materially limited.
- We may not be successful in our efforts to identify or discover additional product candidates.
- Data from our preclinical studies is limited and may change as patient data becomes available or may not be validated in any future or advanced clinical trial.
- Clinical trials are difficult to design and implement, involve uncertain outcomes and may not be successful.
- We will depend on enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We face competition from companies that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop platform technologies or product candidates more rapidly than we do, if their platform technologies or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected.

- We are highly dependent on our key personnel, including individuals with expertise in cell therapy development and manufacturing, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

- We will need substantial additional financing to develop our product candidates and implement our operating plans, which financing we may be unable to obtain, or unable to obtain on acceptable terms. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

- The issuance of shares of our common stock upon conversion or exercise of our outstanding Preferred Shares and Common Warrants and other securities that we may issue in future financing transactions may result in substantial dilution to our stockholders.

- If our security measures, or those of our contract research organizations ("CROs"), contract development and manufacturing organizations ("CDMOs"), collaborators, contractors, consultants or other third parties upon whom we rely, are compromised or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, we could experience a material adverse impact.

- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

- We will rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

- We rely on third parties to manufacture and store our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved. There can be no assurance that we will be able to establish or maintain relationships with such third parties. We may in the future establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on third parties for the manufacture of our product candidates, which would be costly, time-consuming and which may not be successful.

- We maintain single supply relationships for certain key components, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our suppliers' manufacturing process increases.

- Our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

- Clinical development and the regulatory approval process involve a lengthy and expensive process with an uncertain outcome and results of earlier studies and preclinical data, and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

- Regulatory requirements in the United States and abroad governing cell therapy products have changed frequently and may continue to change in the future, which could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all.

- We are subject to stringent and changing privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to enforcement or litigation (that could result in fines or penalties), a disruption of clinical trials or commercialization of products, reputational harm, or other adverse business effects.

- Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand.

- Sales of a substantial number of our securities in the public market by our existing securityholders could cause the price of our Common Stock and Warrants to fall.

- Certain existing securityholders purchased our securities at a price below the current trading price of such securities, and may experience a positive rate of return based on the current trading price. Future investors in us may not experience a similar rate of return.

- Most of our outstanding Common Warrants are "out-of-the-money." If the trading price of our Common Stock does not increase, the holders thereof will be unlikely to exercise such Common Warrants and we will not receive the proceeds of such exercises.

- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

- We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, results of operations, and financial condition.

- We have identified a material weakness in our internal control over financial reporting. If our remediation of such material weaknesses is not effective, or if we identify additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

- Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities.

- Our Warrants are exercisable for Common Stock, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

PART I

Item 1. Business.

Overview

We are an innovative immunotherapy company advancing the development of next-generation engineered T cell therapeutics for the treatment of cancer. Our proprietary approach to T cell engineering, which enables us to integrate certain desirable characteristics of both innate and adaptive immunity into a single therapeutic construct, is designed to engage the body's full immune repertoire to achieve optimized cancer therapy. Our novel cellular immunotherapy platform is designed to redirect patient-derived T cells to eliminate tumors by building in pathways that employ both cytotoxic and phagocytic mechanisms to destroy cancer cells, creating what we refer to as CER-T cells. Our lead molecule is CER-1236, an autologous T-cell product that targets a novel tumor antigen, TIM-4 ligand. Unlike currently approved chimeric antigen receptor ("CAR-T") therapies which have largely been active in hematological B cell malignancies, we believe CER-1236 will be active in both hematological malignancies and solid tumors.

On November 14, 2024, we received notice from the FDA that the Investigational New Drug Application ("IND") was cleared after being put on a brief clinical hold due to insufficient nonclinical data to adequately judge off target toxicity. The clinical hold was lifted after additional in vitro experiments were performed. We submitted a second IND application for the investigation of CER-T cell therapy in non-small cell lung cancer ("NSCLC") and ovarian cancer, which was accepted by the FDA on March 27, 2025.

The ability to enhance the activity of T cells against human cancers through genetic engineering has been among the most significant advances in cancer therapy in the last decade. One of the more promising therapeutic uses of T cells to emerge has been CAR-T cell technology. However promising CAR-T cell therapy has been, its use has been largely limited to the treatment of certain hematological cancers due to lack of specific tumor-associated antigens and CAR-T cells' limited ability to proliferate, traffic, and circulate in solid tumors. Curative cell therapies for solid tumors currently do not exist, and the significance of this limitation is underscored by the prevalence of solid tumor malignancies. The American Cancer Society estimates that solid tumor cancers accounted for more than 1.7 million of the 1.9 million people newly diagnosed with cancer in 2022. Even in hematological malignancies with approved CAR-T cell therapies, cure rates do not exceed 60%. Nevertheless, despite such limitations, sales of CAR-T cell therapies are anticipated to grow rapidly over the next several years and are expected to exceed $10 billion globally by 2030.

We believe that the preferential attributes engineered into our CER-T cell therapy enables us to overcome many of the limitations which hinder the wider application of CAR-T technology. Our CER-T cells employ a novel targeting mechanism that targets a ligand broadly expressed on tumor cells but not healthy cells. Specifically, CER-1236 targets the TIM-4 Ligand ("TIM-4-L"), otherwise known as phosphatidylserine ("PS"), a critical component of the cell's plasma membrane that has a key role in cell removal. Exposure of TIM-4-L on the outer surface of the plasma membrane acts as an "eat-me" signal and marks abnormal, stressed and dying or dead cells for phagocytosis. The pro-phagocytic activities of CER-T cells are designed to integrate innate immune effector functions into cytotoxic killer T cells, creating within a single T cell the ability to directly mediate cytotoxic effects and indirectly prime other immune cells. Moreover, in preclinical studies, we have observed that CER-1236 cells exhibit superior cross-presentation abilities compared to conventional T cells, potentially triggering a broad complement of immune effector cells against tumors. Since externally oriented TIM-4-L is broadly expressed by numerous cancer cell types but has very limited exposure on normal healthy cells, we envision CER-1236 as having differentiated therapeutic utility with application across a wide array of cancer types.

We have patterned the design of our CER-T constructs based upon many of the components found in existing conventional CAR-T cell therapies, which we believe could shorten development timelines and enhance commercial application. The processes and protocols used to genetically modify a patient's T cells to produce CAR-T cells are already well recognized, as is the use of lentivirus in the manufacture of these therapies. Accordingly, we have developed CER-T cell manufacturing processes that closely resemble those used to produce existing engineered CAR-T cells. We also expect to benefit from the well-defined and recognized regulatory guidelines established by both U.S. and European regulatory authorities related to CAR-T therapies and their use. In contrast to these attributes, we believe that other emerging CAR-based drug candidates which involve immune effector cells other than T cells, such as CAR-NK and CAR-M therapies, are unlikely to enjoy similar benefits.

In preclinical studies, we have observed CER-1236 to display attractive functional attributes, among which are:

- target-dependent activation, cytotoxicity, anti-tumor cytokine production, and high proliferative capacity;
- phagocytosis of tumor cells;
- distinct transcriptome, cytokine and chemokine signatures that substantiate the complementary activity of both the innate and adaptive immune response;
- enhanced antigen acquisition, processing and presentation;
- no evidence of T cell exhaustion despite repeated challenges;
- no observed off-target or off-tumor toxicities;
- expression and maintenance of diverse T cell populations, including naïve and memory cells, likely indicative of response persistence and durability; and
- well defined and scalable manufacturing protocols.

Based on the preclinical data regarding the use of CER-1236 T cells to combat hematologic malignancies, we anticipate beginning clinical trials in the first half of 2025. We anticipate that our initial targets will be relapsed, remitting acute myeloid leukemia ("AML") patients as well as AML patients with measurable residual disease ("MRD") and patients with mutations in TP53, a gene mutation associated with aggressive AML. AML is a heterogenous and aggressive hematopoietic malignancy characterized by the rapid buildup of immature myeloid cells in the bone marrow and blood. This process results in the inhibition of normal hematopoiesis, manifesting as neutropenia, anemia, thrombocytopenia, and the clinical features of bone marrow failure. According to the American Cancer Society, AML accounts for 90% of all acute leukemias in adults, with an estimated 22,010 new cases and 11,090 deaths expected in the United States in 2025. The current treatment has remained largely unchanged over several decades with combination chemotherapy with cytarabine for 7 days and an anthracycline for 3 days ("7+3"). Newer, targeted approaches that include multi-kinase domain inhibitors and antibody-drug conjugates are now available during induction chemotherapy for certain patients. For patients that are sufficiently healthy and at unfavorable risk, allogeneic Hematopoietic Stem Cell Transplants ("HSCTs") are commonly performed. Despite these interventions, there is significant unmet medical need for novel therapies, including cell therapeutic approaches. Given the incidence of AML, CER-1236 T cell therapy may qualify for an Orphan Drug Designation by the FDA, and we have submitted an application to the FDA for an Orphan Drug Designation on March 18, 2025.

Our Phase 1 AML clinical trial is intended to evaluate the safety, potential therapeutic utility and applicable dose of CER-1236. The approved starting dose for the clinical trial is sufficiently high that we expect to begin to see clinical activity by the second dose level cohort. Concurrent with a trial in these hematological malignancies, we intend to expand the clinical development of CER-1236 with an additional IND submission, which has been approved, to investigate solid tumors such as NSCLC and ovarian cancer. We believe that CER-1236 has the potential to address unmet medical needs in the targeted indications, and be differentiated from currently available therapeutics by its safety, tolerability and efficacy. Since no clinical trials of CER-1236 have commenced, none of the abovementioned statements regarding any of our products in development are intended to be a prediction or conclusion of efficacy.

Our Strategy

Our intent is to become a leading biopharmaceutical company focused on the capital-efficient advancement of innovative anti-cancer product candidates targeting the unmet medical need associated with aggressive and difficult-to-treat hematological malignancies and solid tumors. To accomplish this objective, the key elements of our strategy include:

- *Advance the clinical development of CER-1236 for the treatment of AML patients*. Based on preclinical data generated to date related to the use of CER-1236 to treat hematological cancers, we intend to initially target relapsed and refractory AML patients for clinical development. These are aggressive cancers with limited treatment options. Moreover, these cancers represent a significant unmet medical need, and to date there are no approved CAR-T cell therapies for patients diagnosed with AML. There are approximately 20,800 cases of AML diagnosed annually in the U.S.

- *Leverage past and current CAR-T product approvals to shorten the regulatory and manufacturing pathway for CER-1236*. We have designed our CER-T cells to share similar construction to currently approved CAR-T cell therapies. The processes and protocols used to produce autologous CAR-T cells are well recognized, and we expect to benefit from the well-defined regulatory guidelines established by both U.S. and European regulatory authorities related to CAR-T cell therapy manufacture. Accordingly, we have configured CER-T cell manufacturing processes to share similarities with those employed in the production of CAR-T cells.

- *Expand CER-1236 development activities to target solid tumors*. We intend to expand the clinical development of CER-1236 to include solid tumors. To this end, we plan on evaluating the potential therapeutic utility of CER-1236 to treat NSCLC and ovarian cancer, indications for which efficacious treatments have proven elusive. We believe CER-1236's differentiated mechanism of action enables the enhanced activity of a broader contingent of immune effector cells, which may allow CER-1236 to achieve success treating cancers for which currently approved CAR-T cell therapies have demonstrated little clinical benefit.

The Immune System and its Function

The immune system is a host defense system comprising multiple structures and processes within an organism that protects against disease. As with other mammalian species, the human immune system is segregated into two separate yet interconnected components, the innate immune system and the adaptive immune system. The innate immune system is responsible for an immediate, non-specific response to infected or diseased cells. Triggering its activation are pathogen-associated and damage-associated molecular patterns recognized by preconfigured pattern recognition receptors which reside on the surface of various types of leukocytes, or white blood cells, that make up the innate immune system, including macrophages, dendritic cells, eosinophils and natural killer ("NK") cells. In addition to its direct participation in eliminating damaged or diseased cells, certain components of the innate immune system function significantly as antigen-presenting cells ("APCs") promoting the activity of the adaptive immune system.

The adaptive immune system is composed of special types of leukocytes known as T and B lymphocytes, also known as T and B cells, respectively. T cells participate primarily in the cell-mediated immune response while B cells are involved in the humoral immune response. T cells are an essential component of the adaptive immune system, targeting specific antigens and either destroying targeted cells directly or participating in their destruction by activating other immune cells. T cells use T cell specific receptors to recognize antigens presented via major histocompatibility complex ("MHC") molecules on APCs. Through this mechanism, T cells have the ability to target tumor-transformed or virus infected cells, as well as help coordinate the activity of other immune cells.

T cells are differentiated by the expression of protein markers on their surface. The two most prominent types of T cells are those that express CD8 molecules and are known as CD8 T cells, and those that express CD4 molecules and are known as CD4 T cells. CD8 T cells, also referred to as cytotoxic lymphocytes ("CTLs"), eliminate cells which they encounter that are recognized as being infected with viruses or other pathogens or are otherwise damaged or dysfunctional through a process referred to as cell lysis, which involves the release by these killer T cells of perforins and granzymes to compromise the integrity of the target cell's membrane. Endogenous pathogens are broken down by mechanisms present in virtually all cells into smaller fragments and presented to CD8 T cells in combination with an MHC Class I molecule. CD4 T cells, also referred to as T helper cells, have limited cytotoxic activity and typically do not kill infected or dysfunctional cells or eliminate pathogens directly. Instead, they participate in the immune response by providing signals which activate and orchestrate other types of immune cells to perform these tasks. Professional APCs, such as dendritic cells and macrophages, process exogenous pathogens and then present small fragments of the degraded pathogen to CD4 T cells in combination with an MHC Class II molecule, through a phenomenon known as cross-presentation, while antigens of exogenous origin are coupled with an MHC Class I molecule to amplify CD8 T cell activity. Antigen cross presentation is of particular importance in the immune system's response to cancer.

Genetically Engineered T Cells

The ability to enhance the activity of T cells against human cancers through genetic engineering has been among the most significant advances in cancer therapy in the last decade. Advances in understanding T cells and their role in immunology, and an appreciation of their potential use to treat cancer, has increased interest in the clinical application of T cells in recent years, with the field of adoptive immunotherapy attaining increased prominence as a means of enhancing immune control over tumors. Modern molecular biological techniques allow scientists to introduce genes into human T cells that enhance T cell activity, expand their numbers and infuse them back into the patient from whom they were originally collected. We have developed a novel approach to T cell engineering which has enabled us to integrate certain desirable characteristics of both the innate immune system and the adaptive immune system into a single therapeutic construct intended to optimize cancer therapy. This novel cellular immunotherapy platform is designed to redirect T cells to eliminate tumors by building in engulfment pathways that employ phagocytic programs, creating our CER-T cell therapy.

Phagocytosis is a vital cellular process by which a phagocytic cell engulfs and internalizes a target for elimination and is a major mechanism for the removal of pathogens and unwanted cells to maintain tissue homeostasis. The human body removes billions of cells daily through phagocytic processes. Phagocytic removal employs specific cell clearance programs and machinery to eliminate target cells. The process is a crucial part of the innate immune system and is distinct from the adaptive immune response which involves the generation of cytotoxic T cells to elicit antigen-specific, cytolytic target elimination. Compared to traditional CAR-T cell approaches, which largely target the adaptive immune system, we developed CER-T cell therapy to collaboratively mediate both cytotoxic and phagocytic mechanisms to optimize anti-tumor function. By leveraging both immune responses, we believe CER-T cell therapy has the potential to eliminate cancer cells more effectively and with fewer side effects than traditional CAR-T cell therapies.

The recognition of phagocytosis as a therapeutic modality to directly clear cancer cells and initiate anti-tumor T cell immune responses has fueled interest in effectively engaging phagocytes for use in cancer therapy. Macrophage cell engineering and macrophage-targeting approaches that enhance cytotoxic, phagocytic and cytokine-mediated anti-tumor function are in development. Early clinical trial data from therapeutic candidates targeting myeloid inhibitor function has demonstrated the potential to elicit clinical responses. However, the diverse pro-tumor functions of myelo-monocytic cells may offset these efforts by supporting cancer cell survival, proliferation and the release of factors that may impede anti-tumor immune responses. Limited in vivo proliferation and manufacturing challenges have also been hurdles in the development of macrophage-based cellular therapy.

Experimental evidence demonstrates the ability of CER-T cells to engulf targeted cells, employ cytolytic and non-cytolytic killing mechanisms, and exhibit pro-inflammatory and antigen processing capabilities that augment the current capabilities of T cell immunotherapy. To that end, we believe CER-1236 cell therapy, if approved, may become a component of standard of care treatment regimens, used as a monotherapy or in combination with both small molecule therapeutics and biologics to direct robust tumor elimination.

The Increasing Prominence of CAR-T Technology

Immunotherapy is a treatment that harnesses the components and mechanics of the immune system to address diseases and disorders. Cellular immunotherapy is a form of immunotherapy that focuses on modulating or enhancing the activity of different immune cells. One of the more prominent and promising therapeutic uses of T-cells to emerge has been CAR-T cell technology.

CAR-T therapy recognizes specific antigens that are present on the surface of tumor cells and destroys them. The concept of CAR-T builds upon the normal biology of CTLs, whereby naturally occurring receptors serve to activate these cells when a foreign pathogen or cancerous cell is detected. Conventional CAR-T cell therapy involves the genetic manipulation of a patient's T cells to enable these modified cells to express a receptor designed to bind to a specific surface antigen. To engineer these cells, a fraction of a patient's T cells are collected from their blood, and a viral vector containing the genetic instructions for the CAR is used to insert those genes into the genome of the T cell through a process known as transduction. Contained in a single viral vector are the genes encoding for each component of the CAR. Typical CAR-T cells include the following components:

- *Antigen recognition domain*. At one end of the CAR is a binding domain that is specific to a targeted antigen. This domain is exposed to the outside of the engineered lymphocyte, where it can recognize the target antigen or antigens. The extracellular target binding domain of CAR-T therapies currently approved by the FDA typically use a single-chain variable fragment ("scFv"), consisting of the heavy-chain and light-chain variable regions of an antibody.

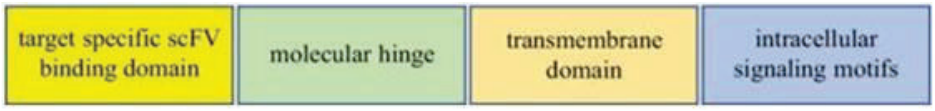
- *Extracellular hinge domain*. The hinge domain is a small structural component which extends from the outer cell membrane to the antigen recognition domain and provides conformational flexibility to facilitate optimal binding of the antigen recognition domain to the targeted antigen on the surface of the cancer cell.

- *Transmembrane domain*. This middle portion of the CAR links the antigen recognition domain to the activating elements inside the cell. The transmembrane domain anchors the CAR in the lymphocyte's membrane, bridging the extracellular hinge and antigen recognition domains with the intracellular signaling domain and provides critical stability to the CAR. In addition, the transmembrane domain may also interact with other transmembrane proteins that enhance CAR function.

- *Intracellular signaling domain*. The other end of the CAR, inside the T cell, is connected to two or more contiguous domains responsible for activating the lymphocyte when the CAR binds to its target antigen. The first, found in almost all CAR constructs, is called CD3ξ. The CD3ξ domain delivers an essential primary signal within the T cell and is the natural basis for activation of these lymphocytes. The current generation of CAR-T configurations generally employ one or more costimulatory domains, such as CD28, to provide enhanced activation signals and augment lymphocyte activity. Together, these signals result in the proliferation of the CAR-enabled T cells and selective cellular destruction. In addition, activated CAR-T cells stimulate the local secretion of cytokines and other molecules that can recruit and activate additional immune cells to increase target elimination.

The assembly of these core CAR components is depicted in the schematic presented below to which certain non-coding regulatory sequences may be used to augment viral gene expression.

Delivery of conventional CAR-T cell therapies involves a single viral vector.



Conventional CAR-T cell therapies often utilize a lentiviral vector for the delivery of CAR specific genes. Lentiviral particles offer a well-characterized transduction mechanism and are recognized as efficient and convenient vehicles for gene transfer as they demonstrate broad tropism, or activity, in a wide array of cell types, and can be used to target quiescent, or non-dividing, cells. In addition, they do not integrate close to the promoter regions of genes with the frequency of other gene delivery alternatives and lack the immunogenicity of DNA-based vectors, characteristics which provide for enhanced safety. The use of a lentiviral vector to facilitate ex vivo clinical gene transfer has been demonstrated to be safe in humans for two decades with minimal genotoxicity observed in hundreds of patients following gene transfer into T cells or hematopoietic progenitor cells.

Currently, six CAR-T cell therapies have been approved by the FDA for the treatment of certain types of hematological cancers. The first two, approved in 2017, are axicabtagene ciloleucel, sold by Gilead Sciences under the brand name Yescarta, and tisagenlecleucel, sold by Novartis under the brand name Kymriah. A third CAR-T cell therapy, brexucabtagene autoleucel, which is comparable to Yescarta and sold by Gilead under the tradename Tecartus, was approved in 2020. Lisocabtagene matraleucel, sold by Bristol Myers Squibb under the brand name Breyanzi, received FDA approval in February 2021 with Bristol Myers Squibb also receiving approval for idecabtagene vicleucel, sold under the tradename Abecma, in March of that year. Most recently, Janssen Biotech received FDA approval for ciltacabtagene autoleucel, brand name Carvykti, to treat adult patients with relapsed or refractory multiple myeloma and which targets the BCMA protein expressed on cancer cells rather than CD19, the target of the other approved CAR-T cell therapies. Each of these therapies is an autologous therapy and is made from T cells first collected from the patient, which are then genetically modified and administered back to the same patient. Sales of CAR-T cell therapies are anticipated to grow rapidly over the next several years and are expected to exceed $10 billion by 2030. CAR-constructs incorporating alternate immune effector cell types, including NK cells and macrophages, are in earlier stages of clinical development and have only recently entered clinical trials. To date, no CAR-based therapies that employ NK cells or macrophages have received FDA approval. There are at present no FDA approved CAR T cell products for AML.

The Limitations of Current CAR-T Technology

Much of the excitement of cellular therapy surrounds the curative potential of adoptive transfer of genetically engineered T cells. Adoptively transferred T cells proliferate upon their engagement with target antigens and represent a form of therapy that can be appropriately characterized as living and expanding. Efficient targeted killing and tumor elimination may be achieved in a short period of time. However, multiple barriers limit the efficacy of conventional CAR-T cell therapy. A high rate of side effects often accompany treatment with currently approved products, especially in those patients with high tumor burdens. In addition, partial responses occur, often associated with immune escape of the tumor from the CAR or the display by the T cells of an exhaustion phenotype. Moreover, while engineered CAR-T cells have shown remarkable potential in the treatment of hematological cancers, they have not demonstrated equivalent efficacy in the treatment of solid tumors. Curative cell therapies for solid tumors currently do not exist and the importance of this limitation is underscored by the prevalence of solid tumor malignances. The American Cancer Society estimates that solid tumor cancers accounted for more than 1.7 million of the 1.9 million people newly diagnosed with cancer in 2021. Even in hematological malignancies with approved CAR-T cell therapies, less toxic orthogonal treatment approaches are needed as cure rates for CD19-targeted CAR-T cell therapies do not exceed 60%.

Challenges to the use of cellular therapy to address solid tumors often relate to difficulty in developing receptors directed towards targets expressed in high frequency on cancer cells as well as overcoming the immunosuppressive microenvironments that contribute to ineffective immune responses. The tumor stroma, made up of a dense fibrotic matrix, often surrounds solid tumors and acts as a physical barrier, which restricts CAR-T cell access to the tumor. CAR-T cell activity may be further hindered by the tumor microenvironment ("TME"). In the TME, multiple cell types which drive immunosuppression infiltrate solid tumors, including myeloid-derived suppressor cells, tumor-associated macrophages, and regulatory T cells. The interaction of these cells and the tumor cells increases the expression of signaling molecules that enable tumor cell proliferation while dampening the generation of co-stimulatory signals necessary for T cell expansion and persistence. In addition, TME-associated immune dysfunction may result in a down regulation of MHC class I molecules, limiting proper antigen presentation and T cell proliferation. Collectively, these attributes of solid tumors enable them to avoid normal immune surveillance. Increased engagement of the endogenous host response is an important, if not critical, component of CAR-T cell therapy clinical success as the recruitment into the tumor of bystander lymphocytes has been observed in tumor biopsies from patients with curative CAR-T cell therapy. Enhancing the host's own response to tumor cells offers an important opportunity to improve current CAR T cell responses.

CAR-T recipients may also incur serious adverse events ("SAEs"), perhaps the most prominent of which is cytokine release syndrome ("CRS"). Believed to be related to the rapid proliferation and activation of T cells upon detection of a target antigen, severe or life-threatening CRS was noted in a significant number of patients who participated in the registrational trials of FDA-approved CAR-T therapies. These SAEs can result in patients requiring longer hospitalizations and more intensive medical care. The frequency and severity of observed SAEs is one of the primary reasons that administration of currently approved CAR-T therapy is restricted to a select number of treatment centers. Moreover, aside from the low-level expression of certain cancer specific neoantigens, most tumor associated antigens are also found on normal cells which may lead to serious, if not life threatening, "on-target, off-tumor" toxicities.

We believe that the preferential attributes engineered into our CER-T cell therapies have the potential to represent a next-generation adoptive cellular immunotherapy approach and enable us to overcome many of the limitations which hinder the wider application of current CAR-T technology. The prophagocytic and immunomodulatory properties of CER-T cells are designed to overcome some of the immunosuppressive elements in many solid tumors. In addition, their anticipated superior antigen presentation properties may enhance a patient's ongoing immune response against tumor antigens. Lastly, healthy cells have minimal expression of TIM-4-L as compared to tumor cells, reducing the potential for on-target off-tumor effects. In consequence, we envision CER-1236 as having a differentiated mechanism for tumor clearance that enables the potential for enhanced activity across a broad array of hematological malignancies and solid tumors.

CER-T Cell Therapy Technology

Distinguishing our CER-1236 cell therapy candidate is the integration into a single therapeutic construct of many of the anti-tumor capabilities resident in both the innate and the adaptive immune systems. We believe the coupling of these functions better emulates normal immune system activity which may promote enhanced T cell activation, proliferation and durability for more robust elimination of cancerous cells and reduction in tumor burden.

We have designed our CER-T constructs to embrace many of the components found in conventional CAR-T cell therapies. The processes and protocols used to genetically modify a patient's T cells to produce CAR-T cells are well recognized, as is the use of lentivirus in the manufacture of these therapies. Accordingly, we have constructed CER-1236 cell manufacturing processes to be similar to those of CAR-T cells. We expect to benefit from the well-defined regulatory guidelines established by both U.S. and European regulatory authorities related to CAR-T cell therapy and its use.

The biological foundations for CER-T cell therapy

PS, or TIM-4 ligand, is a component of a cell's plasma membrane and has a key role in cell removal. Under normal physiological conditions, TIM-4-L is restricted to the inner leaflet of the phospholipid bilayer which makes up the plasma membrane of a cell. However, cellular stresses cause the externalization of TIM-4-L to the cell surface. Exposure of TIM-4-L on the outer surface acts as an "eat-me" signal and marks abnormal, stressed and dying or dead cells for phagocytic clearance. A variety of tumors have been shown to have constitutively increased surface TIM-4-L as a result of altered plasma membrane regulation. Among hematologic tumors, loss-of-function mutations in the flippase chaperone transmembrane protein 30A ("TMEM30A"), have been identified in approximately 11% of patients with diffuse large B cell lymphoma ("DLBCL"), and this mutation was correlated with improved response to the standard therapeutic regimen suggesting the host's immune elimination of TIM-4-L positive tumor cells enhances tumor clearance. We are seeking to exploit the presence of TIM-4-L expressed on the outer cell surface of both hematological malignancies and solid tumors.

CER-1236: Our Lead Development Candidate

As externally oriented TIM-4-L is present on many cancerous cells regardless of tumor type, we believe a single CER construct may demonstrate clinical utility in treating an array of cancers. To that end, we have focused our development activities on optimizing the cancer killing capabilities of a specific CER-T therapeutic design. These efforts have resulted in our lead clinical candidate, CER-1236. In preclinical studies, we have observed CER-1236 to display attractive functional capabilities and product characteristics, among which are:

- target-dependent activation, cytotoxicity, anti-tumor cytokine production, and high proliferative capacity;
- tumor cell phagocytosis;
- distinct transcriptome, cytokine and chemokine signatures that substantiate the complementary activity of both the innate and adaptive immune response;
- enhanced antigen acquisition, processing and presentation;
- no evidence of T cell exhaustion despite repeated challenges;
- no observed off-target or off-tumor toxicities;
- expression and maintenance of diverse T cell populations, including naïve and memory cells, likely indicative of response persistence and durability; and
- well defined and scalable manufacturing protocols.

We have designed CER-1236 to align with components included in the current generation of conventional CAR-T configurations by fusing the external domain of TIM-4, a phagocytic receptor, with intracellular signaling domains from T cells and innate immune cells. TIM-4 harbors endogenous phagocytic capacity through its binding to the pro-phagocytic "eat-me" signal TIM-4-L. CER-1236's intracellular signaling domains, including TLR2, CD28 and CD3ξ motifs, are designed to augment both TIM-4 mediated phagocytosis and cytotoxic T cell function. Another similarity between conventional CAR-T therapeutic formats and our CER-T design is the delivery vehicle used in transduction. As is found in many approved CAR-T therapies, our CER-T technology also employs a lentiviral vector to facilitate gene delivery to patient-derived T cells. A schematic of the structural elements of CER-1236 is presented below.

Schematic of CER-1236

Abbreviations: TIM-4 = ectodomain of the T cell immunoglobulin mucin domain protein 4; TLR2 = toll-like receptor 2.

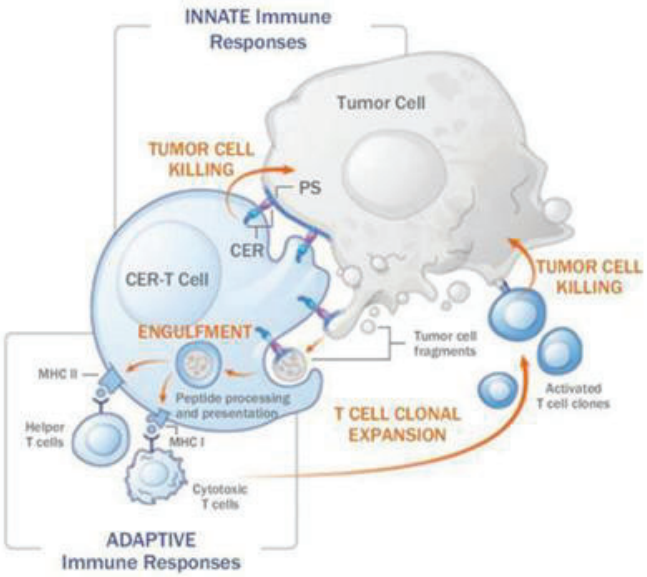
CER-1236 employs an innovative mechanism of action

CER-1236 is an autologous T cell therapy candidate designed to target TIM-4-L through the external domain of the prophagocytic receptor TIM-4 protein. This therapeutic construct was developed to combine adaptive T cell killing activity with phagocytic clearance and antigen presentation activity to create T cells with enhanced cancer immunotherapy capabilities. The approach builds on the early success of adoptive T cell transfer, which has demonstrated the ability of T cells to proliferate, traffic, and circulate within both primary and metastatic tumors.

By enhancing phagocytic clearance and antigen presentation activity and integrating them into T cells, we believe CER-T cells offer the potential for more effective elimination of cancer cells. The industry's decades-long experience with engineered T cell use provides a solid foundation for the development of CER-1236.

As the target ligand of our initial CER-T cell is not an antigen restricted to only certain tumors, CER-1236 T cells may provide clinical benefit across multiple tumor types. The functional interaction of CER-1236 T cells is depicted in the illustration presented below.

CER-1236 T cells are designed to harness the power of both the innate and adaptive immune systems



CER-1236 expresses the external domain of the prophagocytic receptor TIM-4 which is linked to T cell and innate immune cell intracellular signaling domains. TIM-4 is normally expressed on subsets of macrophages and dendritic cells and harbors endogenous phagocytic capacity through its binding to and recognition of TIM-4-L. The intracellular signaling domains in CER-1236 are designed to trigger T cell cytotoxic function and enhance TIM-4 mediated phagocytosis. CD3ξ is the signaling component of the TCR and CD28 is a co-stimulatory domain needed for optimal activation. The TLR2 domain is involved in both innate and adaptive immune responses and activation of TLR2 further enhances signaling through both NF-κB and the mitogen-activated protein ("MAP") kinase family, promoting T cell activity and phagocytic uptake. Both CD28 and CD3ξ signaling domains are incorporated into approved CAR-T cell products. A third generation anti-CD19 CAR-T cell that incorporates a TLR2 domain is currently in clinical development.

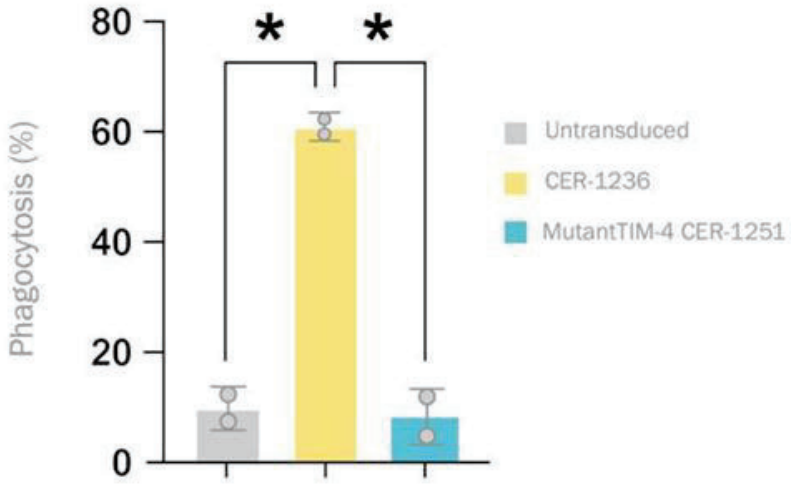
By virtue of the TIM-4 engulfment receptor and the intracellular signaling domains, CER-1236 combines attributes of both T cells and phagocytic cells. In phagocytic cells, such as macrophages and dendritic cells, recognition of TIM-4-L on the surface of apoptotic cells by native TIM-4 leads internalization by utilizing integrin coreceptors to activate phagocytic signaling. TIM-4-mediated phagocytosis depends on activation of the RAC1 GTPase which is similarly targeted by TLR signaling, especially TLR9 and TLR2. However, it has been shown that the intracellular portion of TIM-4 is not required for phagocytosis, and therefore the extracellular domain ("ECD") of TIM-4 appears to function as a tether during phagocytosis to allow intracellular signaling by other transmembrane phagocytic molecules with which it associates, such as the integrins which are expressed ubiquitously on T cells. Since CER-1236 contains only the ECD of TIM-4, binding to TIM-4-L on tumor cells recruits the cell-surface phagocytosis machinery, and simultaneously directly activates CER-1236 T cells through the intracellular CD3ξ and CD28 costimulatory domains. Phagocytosis and cytokine secretion are further enhanced by the TLR2 intracellular signaling domain.

In preclinical studies, CER-1236 empowers T cells with phagocytic and cytotoxic potency

In an *in vitro* evaluation of the phagocytic potential of CER-1236, CER-transduced T cells demonstrated robust phagocytosis of TIM-4-L. CER-1236 T cells were produced by transducing donor T cells using a lentiviral vector encoding for the chimeric receptor CER-1236, yielding a high percentage of T cells expressing the TIM-4 receptor, in similar CD4:CD8 ratios to untransduced cells. CER-1251 T cells, which express matching intracellular signaling domains but are unable to bind to TIM-4-L due to a mutation in the gene encoding for the TIM-4 binding site, were also produced as a negative control.

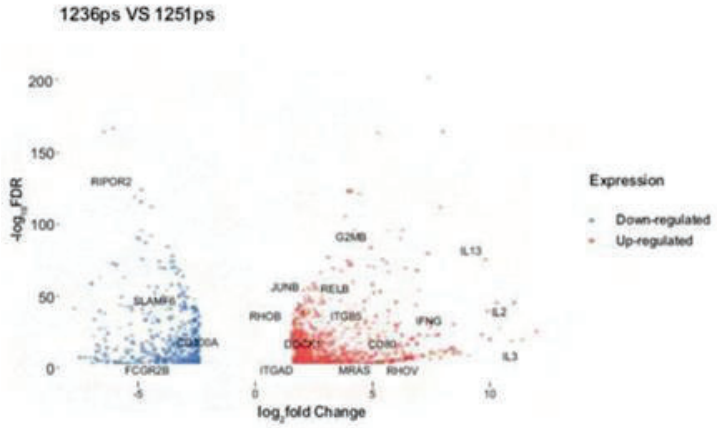
TIM-4-L-coated agarose beads were prelabeled with pHrodo red, a pH-sensitive dye which displays limited fluorescence at neutral pH but generates significant fluorescence in acidic pH. The post-phagocytic fusion of phagosomes and lysosomes leads to a drop in pH which can be detected by pH-sensitive dyes. As is illustrated in the graphic below, CER-1236 T cells co-cultured with TIM-4-L-coated beads displayed significant phagocytic activity with up to 60% of CER-T cells acquiring a pHrodo red signal, indicative of bead capture and internalization. By contrast, untransduced T cells and CER-1251 T cells, with a mutation in the TIM-4 binding site, demonstrated minimal phagocytosis.

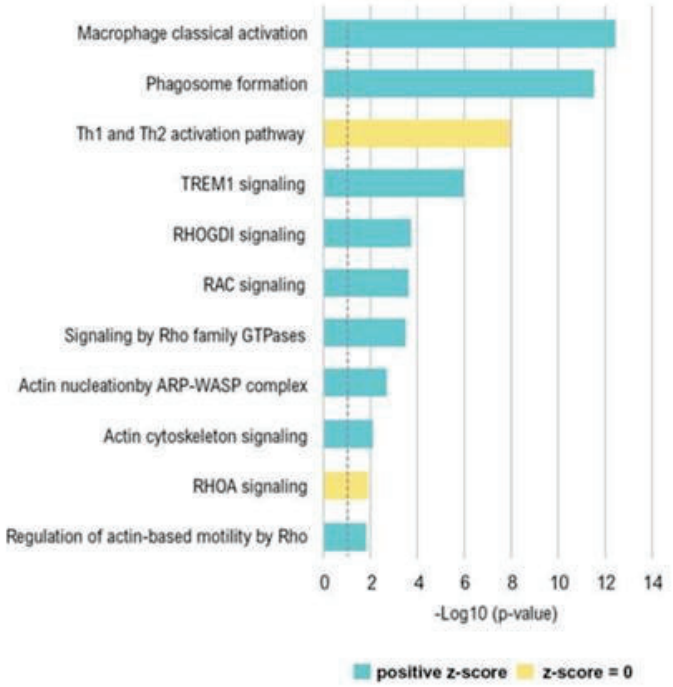
CER-1236 displays robust, target-specific phagocytic activity



Gene expression patterns demonstrate the combined cytotoxic and phagocytic functions of CER-1236 T cells. RNA-sequencing enables the interrogation of the transcriptional profile of CER-1236 T cells after stimulation with TIM-4-L, with defined separation between the CER-1236 activated cells and the untransduced and CER-1251 control T cells. As shown in the gene expression profile below, over 1,700 genes were noted to be differentially expressed in CER-1236 stimulated T cells in comparison to CER-1251 stimulated T cells. Among these genes were those related to pathways with well-known involvement in regulating phagocytosis, genes involved in nucleation of the ARP-WASP complex, Rho family GTPases, RAC signaling and phagosome formation. Of note, the RhoG subfamily of GTPase has been previously implicated in TCR-driven phagocytic processes. This aggregate of transcriptional signatures is indicative of the multi-modal immune response elicited by CER-1236 T cells.

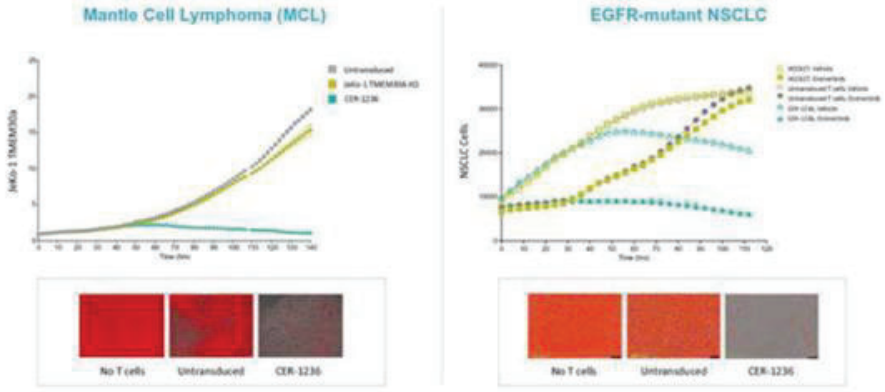
Phagocytic and cytotoxic transcriptional signatures demonstrate the plasticity of CER-1236 T cells





CER-1236 T cells were also observed to generate potent anti-cancer responses in cell lines derived from specific hematological malignancies and solid tumors. A mantle cell lymphoma ("MCL") cell line that has been modified to constitutively express externalized cell surface TIM-4-L was co-cultured with either CER-1236 T cells or untransduced T cells. Notably, CER-1236 T cells eliminated 87% of the MCL cells while the untransduced cells demonstrated minimal cytotoxic ability. In addition, CER-1236 T cells secreted multiple cytokines, including IFNγ, granzyme B and TNFα, all indicative of robust and sustained T cell cytotoxicity. Cytokine secretion was determined to be dependent on binding to TIM-4-L, as CER-1251 T cells did not secrete cytokines despite exposure to cell surface TIM-4-L. Further visual evidence of the cancer-killing capacity of CER-1236 T cells is illustrated in the staining assays depicted in the graphs presented below. In the assays with no CER-1236 T cells, significant proliferation of cancer cells was observed, as evidenced by the increase in red staining, while the growth of cancer cells when exposed to CER-1236 T cells was limited. These results are presented in the graph to the left below.

CER-1236 T cells demonstrate potent cytotoxic responses to cancer cells in vitro



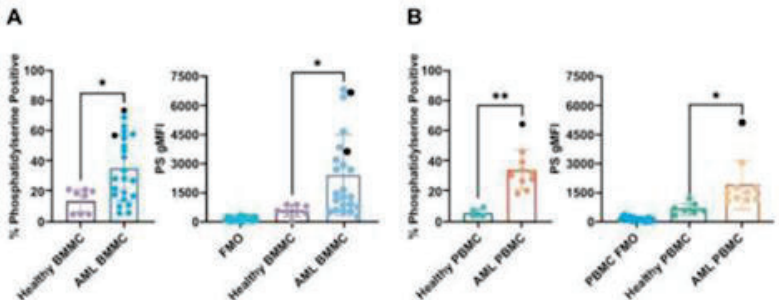
Significant cytotoxic activity of CER-1236 was also noted in an advanced NSCLC cell line, HCC827, which has a mutation in its epidermal growth factor receptor ("EGFR") gene, a cancer type accounting for between 10% and 15% of all lung adenocarcinoma cases in persons of European descent and higher among the Asian population. As is depicted in the above, right graph, while the addition of CER-1236 demonstrates moderate cancer cell killing activity, the addition of osimertinib, the preferred tyrosine kinase inhibitor option for first-line treatment of EGFR-mutation positive advanced NSCLC, substantially enhanced CER-1236 T cell killing in an osimertinib concentration dependent manner. In contrast, HCC827 cells co-cultured with untransduced T cells displayed minimal changes in cell number as compared to cells incubated in the absence of T cells, at all drug concentrations tested. Conditional cytokine proliferation was also observed with CER-1236 T cell treatment, with IFNγ levels over 400-fold higher in cancer cell cultures which used CER-1236 T cells, in contrast to co-cultures which used untransduced T cells. The addition of osimertinib to co-cultures further increased IFNγ levels by more than two-fold, compared with CER-1236 treatment alone. Similar trends were observed with TNFα and Granzyme B levels and increases in osimertinib concentrations led to dose-dependent CER-1236 T cell proliferation. These results demonstrated that CER-1236 T cell activity could be significantly enhanced by upregulating target expression through concomitant dosing of standard of care medication.

TIM-4-L, a lipid moiety recognized by phagocytic cells as an "eat me" signal, has previously been shown to be aberrantly upregulated on acute promyelocytic ("APL") blasts, a subset of AML. To further interrogate TIM-4-L across other AML subtypes, we evaluated a panel of primary bone marrow samples and peripheral blood from AML patients. We screened a preliminary panel of primary, treatment-naïve or on-therapy AML bone marrow and PBMC samples by flow cytometry: (n=5 adverse, n=5 intermediate, n=1 APL, n=1 familial, n=5 N/A) (Table 1). We observed both high percent (35.5 % ± 21.6) and geometric mean fluorescence index ("gMFI") of cell surface TIM-4-L on a range of AML bone marrow samples. The median gMFI of tertiles 1-3 was: T1 n=7, gMFI = 5033; T2 n=8, gMFI = 1873; T3 n=8, gMFI = 611. Of note, the two on-therapy samples showed high percent and gMFI of cell surface TIM-4-L, with a patient receiving 5-azacytidine showing 1.8 fold TIM-4-L gMFI over median. The second patient receiving TKI therapy showed 3.3 fold TIM-4-L gMFI over median. Healthy donor samples had much lower cell surface TIM-4-L, with a mean gMFI of 582. Circulating AML leukemic blasts were also evaluated for cell surface TIM-4-L and showed high concordance with BM blasts, with high levels of cell surface TIM-4-L compared to healthy donor peripheral blood mononuclear cells ("PBMCs").

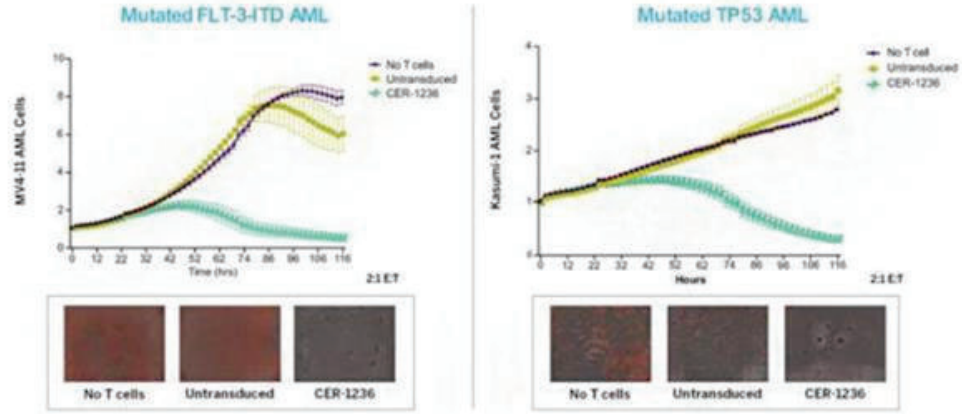
Table 1. AML patient characteristics

Patient: Patient ID	Treatment Status: Disease Status	Previous Treatments	Patient Age At Collection	Gender	Race	Patient: Ethnicity	% Blast Cells	Risk Category	Genetic Abnormality	Cytogenetics
200001107	Newly Diagnosed	none	67	Female	White	Non-Hispanic/Latino	91	Adverse	RUNX1	N/A
200015767	Newly Diagnosed	none	59	Female	White	Non-Hispanic/Latino	35	Adverse	TP53	N/A
200013141	Newly Diagnosed	none	69	Male	White	Non-Hispanic/Latino	75	Intermediate	VAF ASXL1 < 50%	N/A
200015300	Newly Diagnosed	none	59	Male	White		93.03		N/A	
200018491	Newly Diagnosed	none	62	Female	White	Non-Hispanic/Latino	30	Adverse	TP53	N/A
130802218	Newly Diagnosed	none	71	Male	White		94.77		N/A	
200018493	Newly Diagnosed	none	48	Male	White	Non-Hispanic/Latino	82	Adverse	ASXL1, FLT3-ITD	N/A
200015400	Newly Diagnosed	none	51	Male	White	Non-Hispanic/Latino	80.2	Familial	GATA2 Deficiency	N/A
130776684	Newly Diagnosed	none	38	Female	White		89.78		N/A	
200055487	Newly Diagnosed	none	74	Male	White		80.9		N/A	
130781611	Newly Diagnosed	none	62	Female	White		81.67	Intermediate	N/A	Normal
200015406	Newly Diagnosed	none	43	Male	White		91.37	Adverse	FLT-3 ITD	N/A
200036152	Newly Diagnosed	none	85	Female	White		70.13			
200015557	Newly Diagnosed	none	69	Female	White	Non-Hispanic/Latino	84	Intermediate	DNMT3A	N/A
200019235	Stable	Azacitidine 8 cycles	71	Female	White		72.63	Intermediate	N/A	N/A
200018645	Newly Diagnosed	none	41	Male	White		76.54	APL	N/A	t(15;17)
200015508	Progressive	Imatinib 400 mg.	63	Female	White	Non-Hispanic/Latino	50	Intermediate	VAF < 50%	N/A
200019095	Newly Diagnosed	none	63	Female	White		82.65			
200013114	Newly Diagnosed	none	83	Male	White		56.8		NRAS	
130800395	Newly Diagnosed	none	72	Female	White		75.7	Adverse	TET2, ASXL1, TP53	
200015280	Newly Diagnosed	none	67	Female	White		15.3		ETV6, BCORL, KRAS	
200009820	Newly Diagnosed	none	31	Male	White		85.7		KRAS	
200009056	Newly Diagnosed	none	21	Female	White		94.8	Adverse	DNMT3A, BCORL1, TP53	

AML from bone marrow or PBMC have elevated cell surface TIM-4-L



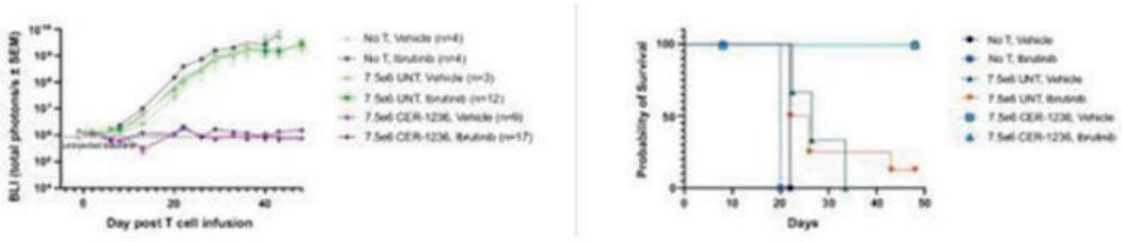
CER-1236 T cells were also observed to generate potent anti-cancer responses against myeloid malignancies. AML is a heterogenous, and aggressive hematopoietic malignancy characterized by the rapid buildup of immature myeloid cells in the bone marrow and blood. We used AML cell lines depicted in the graph below, Kasumi-1 and MV-4-11, to demonstrate cytotoxic anti-AML responses in co-culture studies with CER-1236. Similar to in vitro cytotoxicity results observed with B cell malignancy and NSCLC cell lines, we show the addition of CER-1236 alone to AML cell lines demonstrates potent cell killing activity. Kasumi-1 harbors a p53 mutation, marking a subset of unfavorable disease risk AML patients, while MV4-11 cells carry a FLT-3 mutation, a proliferative AML leukemia subset. Both cell lines co-cultured with untransduced T cells displayed minimal changes in cell number as compared to cells incubated in the absence of T cells. CER-1236 T cells secreted multiple cytokines in co-cultures with AML cell lines, including IFNγ, granzyme B and TNFα, all indicative of robust and sustained T cell cytotoxicity.



CER-1236 T cells demonstrate robust in vivo elimination of MCL xenografts

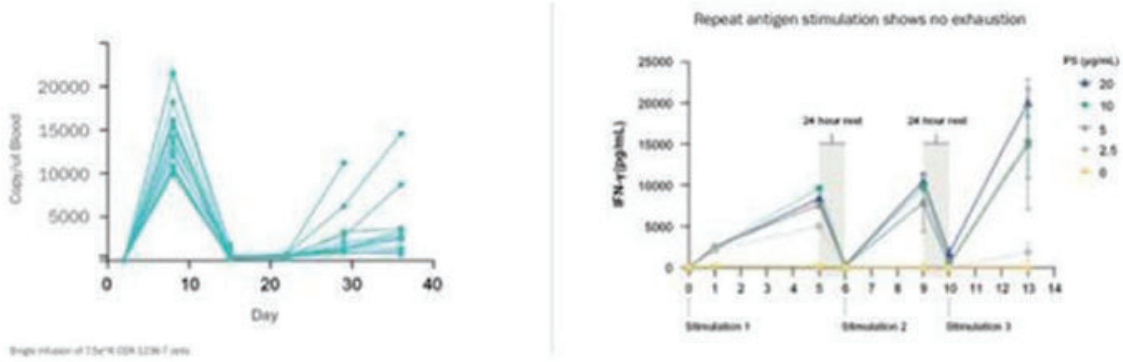
The cancer killing capacity of CER-1236 that was demonstrated in studies involving MCL cell lines was also noted in a mouse xenograft model. Immune deficient NOD scid gamma ("NSG") mice were xenografted with the human REC-1 cell line at Day -2 and then treated with 8 mg/kg ibrutinib or vehicle and administered CER-1236 T cells daily from Day -1 to study completion. Administration of 7.5e6 CER-1236 T cells in the presence of ibrutinib resulted in the elimination of REC-1 tumor burden in all 11 of the mice in this treatment cohort. The administration of CER-1236 T cells in the absence of ibrutinib eliminated the tumors in all nine animals treated with CER-1236 T cells alone. No tumor growth inhibition was observed in either the vehicle-treated or ibrutinib-treated control groups. Median survival for mice receiving CER-1236 T cells with or without co-administration of ibrutinib was not reached during the study period. The results of this study are presented in the charts below.

A single infusion of CER-1236 T cells eliminates tumors and improves survival



The level of CER-1236 T cells in peripheral blood displayed robust expansion at Day 7, with or without the concomitant administration of ibrutinib. Animals that received CER-1236 T cells demonstrated an expansion of over 400-fold as compared to Day 2 levels both in the absence and presence of ibrutinib. High levels of CER-1236 T cells did not persist in the periphery and animals that received CER-1236 T cells showed a greater than 95% contraction in cell count from peak numbers by Day 14 with subsequent CER-T cell expansion likely prompted by residual tumor cell encounters. CER-1236 T cells also maintained robust proliferative capacity despite repeated in vitro antigen challenges with no evidence of T cell exhaustion noted. These findings are illustrated in the following charts.

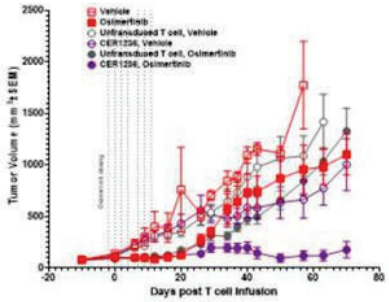
A single infusion of CER-1236 T cells generated rapid cell expansion across repeated challenges

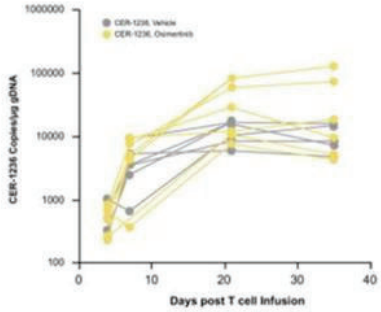


CER-1236 demonstrates in vivo tumor clearance in NSCLC adenocarcinoma xenograft

We envisioned that the simultaneous exposure to both osimertinib and CER-1236 would lead to synergistic in vivo anti-tumor responses. HCC827 NSCLC cells were inoculated into the flanks of NSG mice. Once established, the mice were dosed with a short course of the EGFR inhibitor osimertinib to prime TIM-4-L antigen on tumors and administered 2.5e6 CER-1236 T cells. Treatment groups that received the EGFR inhibitor alone, after initial tumor regression, developed progressive disease, as evidenced in the below left graph. In contrast, animals infused with CER-1236 T cells demonstrated potent anti-tumor responses in the presence of osimertinib. CER-1236 T cells expanded rapidly in the blood, with the highest expansion observed in the osimertinib-treated cohorts, as observed in the below right graph. Importantly, no evidence of organ toxicity or weight loss was observed with increases in body weight recorded in all groups over the course of the study. Analysis of the tumors post-infusion indicated extensive infiltration of T cells compared to untransduced controls.

CER-1236 T cells infused to Osimertinib dosed animals showed tumor elimination and higher levels of T cell expansion



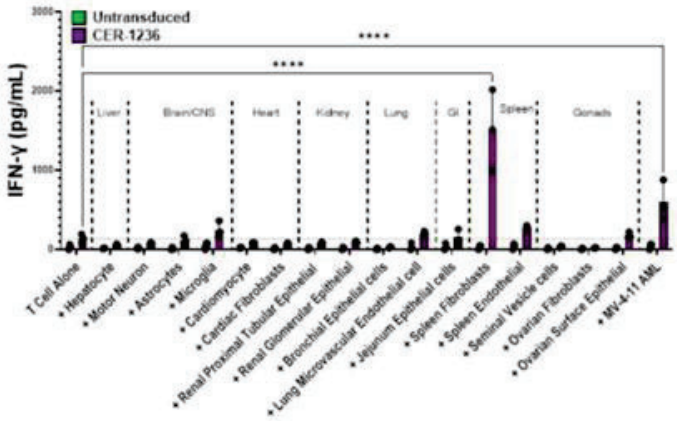


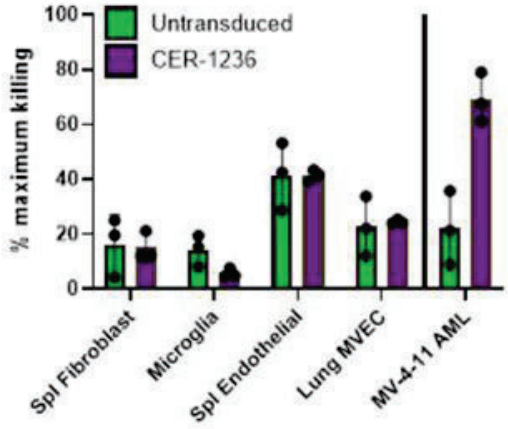
We believe that the preclinical models of AML, MCL, ovarian cancer and EGFR-mutation positive NSCLC demonstrate the ability of CER-1236 T cells to induce collaborative innate-adaptive anti-tumor immune responses in both in vitro and in vivo studies. Moreover, concurrent treatment with standard-of-care therapeutics for each of these indications increases target ligand, conditionally bolstering CER-1236 T cell function to augment anti-tumor activity. Additionally, in antigen presentation assays, activated CER-1236 T cells exhibited superior cross-presentation ability relative to conventional T cells, triggering specific TCR-T cell responses in an MHC class I and TLR-2 dependent manner, overcoming the limited antigen presentation capabilities of conventional T cells. These results indicate that CER-1236 T cells have the potential to achieve optimal tumor control by eliciting both cytotoxic effects and cross-priming.

CER-1236 T cells did not elicit safety signals in preclinical safety/toxicology studies

Importantly, no evidence of toxicity was observed during a safety/toxicology study conducted in mice, a clinically relevant model that has an identical structure of TIM-4-L as humans. The effects of CER-1236 administration were evaluated at 2 doses at 3- and 28-day timepoints. No incidence of anemia, thrombocytopenia, neutropenia or coagulation abnormalities were recorded in any condition. Hematologic indices, including hemoglobin/hematocrit, platelets and neutrophils remained stable throughout the study. No perturbation of clinical chemistries was noted. None of the animals experienced weight loss, morbidity or unexpected mortality. No clinically relevant tissue abnormalities were noted at either timepoint at the high dose in any organ evaluated. Overall, these data demonstrate a lack of on-target off-tumor responses and support the safety profile of CER-1236.

The potential for off-target toxicity by CER-1236 was also tested against primary human cells or iPSC-derived human cells representing vital organs, including the CNS, heart, lungs, liver, spleen, kidneys, GI tract, and gonads. CER-1236 was co-cultured with these cells and activation was monitored by IFNγ secretion or cytotoxic effect. Over the time points tested, CER-1236 showed potent activation and cytotoxicity against AML cells (Below, top and bottom graphs), but limited activation (Below, top graph) and no cytotoxicity (Below, bottom graph) against any of the human cell types tested. These experiments support the lack of off-target responses by CER-1236 T cells.





CER-1236 Clinical Development Strategy

Based on the extensive preclinical data that we have assembled regarding the use of CER-1236 T cells to combat cancer, we intend to commence clinical trials with our initial treatment target being patients suffering from relapsed, or refractory AML as well as those subsets who are positive for Minimal Residual Disease and the TP53 mutation. We subsequently intend to expand the clinical development of CER-1236 to include solid tumors such as NSCLC and ovarian cancer. We expect these clinical trials to evaluate the safety, the potential therapeutic utility and applicable dose of CER-1236. In addition, we anticipate that these clinical trials may provide insight into the possible use of CER-1236 to treat an array of hematologic and solid tumors.

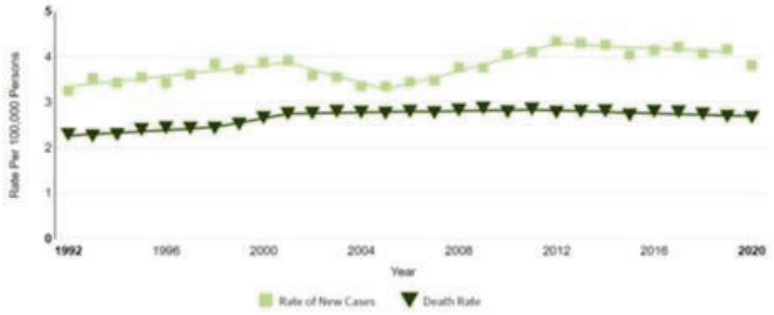
We believe this drug candidate has the potential to be a therapy for the unmet needs of targeted indications, if approved, and by leveraging the innate immune system's phagocytic capabilities, could be differentiated by its safety, tolerability, efficacy and clinical benefit over current therapeutic approaches, which have been observed in preclinical studies. None of the abovementioned statements regarding any of our products in development are intended to be a prediction or conclusion of efficacy. No clinical trials on our product candidates have commenced so no conclusions relating to such attributes can be made.

Disease backgrounds

Acute Myeloid Leukemia

AML is a cancer of the blood and bone marrow that affects myeloid cells, cells which normally develop into the various types of mature blood cells. It is a fast-progressing and aggressive form of blood cancer, with a median time from diagnosis to death of just 5.5 months. Despite over 20 FDA approvals for AML, the death rate in AML patients has only moderately diminished since the 1990s, with the disease hovering around a 32% 5-year overall survival rate according to the National Cancer Institute. AML was diagnosed in 21,000 Americans in 2019, and there were 11,000 AML-related deaths in the same year, according to the Leukemia and Lymphoma Society. Like most cancers, it is a terrifying diagnosis for patients which often leads to many rounds of treatment and a complete disruption of their lives.

Figure 1: Rate of new cases of AML and associated mortality in the United States 1992-2020



Source: NIH, National Cancer Institute

According to Alliance Global Partners, the total AML therapeutic market is estimated to be approximately USD $1B-$1.5B as of 2023 and projected to grow at a compound annual growth rate (CAGR) of ~9% based on the historical growth rate, the anticipated approval of new therapeutics, and an increase in the number of total patients to be diagnosed in the coming years. According to estimates, by 2028, the AML therapeutic market will likely grow to over $2B+, highlighting the significant economic upside associated with any improvements to the standard of care from the current pipeline therapeutics.

Current therapies and their limitations

Currently, there are over 20 FDA approved therapeutics in the AML space, with eight approvals having come in just two years from 2017-2019. Before then, AML was treated with decades-old combination chemotherapy regimens, including cytarabine and anthracycline. This regimen has about a 70-80% complete response ("CR") rates of adults younger than 60 years and 40-60% of fit adults older than 60 years old. For those eligible for the chemotherapy regimen and experiencing a CR, many patients with adverse features (70%) undergo allogeneic HSCT which, in some patients are "curative." Unfortunately, a significant proportion (up to 50%) of AML patients are over the age of 65 and are "unfit" for intensive chemotherapy, requiring different treatment approaches for medically unfit patients. The treatment landscape for older unfit adults with AML fundamentally changed with the recent availability of new drugs, in particular the oral B-cell lymphoma 2 inhibitor venetoclax. Venetoclax is used in conjunction with azacytidine to treat these patients, with a complete response rate ~65%. However the majority of adult patients with AML experience relapse despite initially attaining CR; a venetoclax-based doublet therapy for medically less-fit adults carries a median survival of ~14.7 months. The prognosis for patients who are refractory to or relapse after frontline azacitidine venetoclax is dismal with median overall survival of 2.4 months, making this an area of high unmet need. Such patients who do not respond to frontline therapy with azacitidine or venetoclax, and the subset who do not respond to targeted therapies, e.g., IDH1/2 inhibitors, are candidates for investigational trials. To date, there are no approved cell therapeutic approaches to treat AML.

Ovarian Cancer

The American Cancer Society estimates for ovarian cancer in the United States for 2024 are:

- About 19,680 women will receive a new diagnosis of ovarian cancer.
- About 12,740 women will die from ovarian cancer.

Ovarian cancer is one of the leading causes of cancer deaths among women. A woman's risk of getting ovarian cancer during her lifetime is about 1 in 87. Her lifetime chance of dying from ovarian cancer is about 1 in 130. (These statistics don't count low malignant potential ovarian tumors.) This cancer mainly develops in older women. About half of the women who are diagnosed with ovarian cancer are 63 years or older. It is more common in White women than Black women.

Non-Small Cell Lung Cancer

Most lung cancer statistics include both small cell lung cancer ("SCLC") and NSCLC. In general, about 10% to 15% of all lung cancers are SCLC, and about 80% to 85% are NSCLC. Lung cancer (both small cell and non-small cell) is the second most common cancer in both men and women in the United States (not counting skin cancer).

The American Cancer Society's estimates for lung cancer in the US for 2024 are:

- About 234,580 new cases of lung cancer (116,310 in men and 118,270 in women)
- About 125,070 deaths from lung cancer (65,790 in men and 59,280 in women)

Lung cancer mainly occurs in older people. Most people diagnosed with lung cancer are 65 or older; a very small number of people diagnosed are younger than 45. The average age of people when diagnosed is about 70.

Lung cancer is by far the leading cause of cancer death in the US, accounting for about 1 in 5 of all cancer deaths. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined.

Overall, the chance that a man will develop lung cancer in his lifetime is about 1 in 16; for a woman, the risk is about 1 in 17. These numbers include both people who smoke and those who don't smoke. For people who smoke, the risk is much higher, while for those who don't, the risk is lower.

- Black men are about 12% more likely to develop lung cancer than White men. The rate is about 16% lower in Black women than in White women.
- Black and White women have lower rates than men, but the gap is closing. The lung cancer rate has been dropping among men over the past few decades, but only for about the past decade in women.
- Despite their overall risk of lung cancer being higher, Black men are less likely to develop SCLC than White men.

Statistics on survival in people with lung cancer vary depending on the type of lung cancer, the stage (extent) of the cancer when it is diagnosed, and other factors.

5-year relative survival rates for non-small cell lung cancer

These numbers are based on people diagnosed with NSCLC between 2012 and 2018.

SEER stage	5-year relative survival rate
Localized	65%
Regional	37%
Distant	9%
All SEER stages combined	28%

Our therapeutic approach and development program

We anticipate the design of the clinical development program for CER-1236 to enable our evaluation of its therapeutic utility in treating both hematologic and solid tumors, as the capacity of a single therapeutic construct to provide clinical benefit across this diversity of tumor types would represent a significant advance in cancer immunotherapy. Due to the therapy's novel mechanism of action, engaging both the innate and the adaptive immune response, and the broad expression profile of PS on a variety of hematologic and solid tumors, we intend to employ an adaptive Phase 1 trial design to evaluate patient response to CER-1236. As such, the dosing protocol will emphasize a gradual increase in the delivered dose with the objective of achieving a clinical signal, while ensuring patient safety. We also intend our Phase 1 trial design to enable an evaluation of appropriate dosing strategies to optimize CER-T engagement and proliferation.

We believe, subject to discussions with the FDA and other regulatory authorities, that there may be a full development path to registration and use in the larger AML patient populations on achieving positive safety data along with indications of therapeutic benefit in these initial trial cohorts. We believe CER-1236 may provide significant treatment advantages over currently available therapeutics, including CAR-T therapy as a result of its potential to enhance objective response rates and the duration of response related to the comprehensive, coordinated engagement of the innate and adaptive immune systems and a sustained signaling environment. We believe this novel mechanism of action will enable our advance of a single therapeutic construct to address the substantial unmet need for a safe and effective cell therapy offering an improved therapeutic profile, despite significant competition. We subsequently anticipate initiating clinical trials for additional indications, including the possible application of CER-1236 in the treatment of certain solid tumors such as EGFR mutation positive NSCLC and ovarian cancer.

Manufacturing Strategy

The manufacture of product candidates derived from our autologous CER-1236 T cells involves the same type of equipment, materials and protocols already used in the manufacture of currently FDA-approved CAR-T cell therapies, which we believe will provide us numerous benefits. We are planning for CER-1236 cell product to be manufactured using an automated closed process, with product manufacture continuous from bulk harvested cells through to cryopreserved drug product bags. There are multiple factors involved in the manufacturing process needed to ensure proper CER-T cell cryopreservation both preceding and following freezing, including the thawing process and post-thaw handling prior to patient administration. These factors are well understood and procedures have been identified to optimize yield, activity, stability and consistency. In addition, we may be able to take advantage of the increasing regulatory familiarity with these established protocols. Our expected manufacturing process embraces a fully automated, closed-system design intended to minimize exposure to potential contaminants and ensure consistent successful manufacture of the product. The product will be manufactured in a contract manufacturing facility which maintains a quality system compliant with current Good Manufacturing Practice ("cGMP") requirements.

Lentivirus containing CER-1236 will be produced following a cGMP process using cGMP plasmids.

We have entered into a contract manufacturing agreement related to the production of drug product for our clinical trials, and we anticipate entering into similar arrangements regarding plasmid, viral vector and final drug product manufacture for drug product to be used in subsequent clinical trial phases in the future. We intend to advance related process development work both internally and with our contract manufacturing organization ("CMO") partners. In the event a product candidate receives regulatory approval, we anticipate entering into contract manufacturing agreements with one or more CMOs to support product launch and commercial manufacture.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. Our commercial success will depend in part on obtaining and maintaining patent protection for our current and future product candidates. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending our patent rights. When available to expand market exclusivity, our strategy is to obtain or license additional intellectual property related to current or contemplated development platforms, core elements of technology, and/or clinical candidates. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity, and patent term extensions, where available. In addition to patent protection, we also may rely on trademark registration, trade secrets, know-how, other proprietary information, and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent 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 other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available.

In some instances, we submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We will file U.S. non-provisional applications and Patent Cooperation Treaty ("PCT") applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the provisional patent application, and to designate all of the PCT member states in which national phase patent applications can later be pursued based on the international patent application filed under the PCT. The PCT search authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase patent applications. At the end of the period of 30 months from the first priority date of the provisional patent application, separate national phase patent applications can be pursued in any of the PCT member states either by direct national filing, or in some cases, by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications, and enables substantial savings where applications are abandoned within the first thirty months of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We continuously reassess the number and type of patent applications, as well as the scope of our patent claims to pursue coverage and value for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We have sought patent protection in the United States and various international jurisdictions related to the CER-1236 T cell technology platform and its constructs, as well as their use as individual cellular compositions and product candidates targeting specific diseases. We also intend to seek patent protection related to the processes and materials used in CER-1236 T cell expression as well as its use in combination therapies. As of April 8, 2025, our patent portfolio comprises nine different patent families filed in various jurisdictions worldwide. These patent families include two issued patents in the United States, one of which relates to CER-1236; two allowed U.S. applications, which both relate to CER-1236; nine pending U.S. applications; thirteen issued patents in France, Germany, Italy, Spain, United Kingdom, China, Japan, Hong Kong, and Mexico; and thirty-one pending applications in Canada, China, Europe, Hong Kong, Japan, and Korea. These patents and applications, if and when issued, are projected to expire from 2037 to 2042, absent any available patent term adjustments or extensions. We intend to pursue, when possible, further composition, method of use, dosing, formulation, and other patent protection directed to our current and new product candidates. We may also pursue patent protection with respect to manufacturing and drug development processes and technology.

The following issued patents are directed at a composition of matter and provide coverage for our CER-1236 T cell candidate:

U.S. Patent No. 11,708,423, having an anticipated expiration date of March 26, 2039, including 186 days of patent term adjustment awarded by the USPTO;

EP Patent No. 3,519,441 (validated in the United Kingdom, France, Spain, Germany, and Italy), having an anticipated expiration date of September 26, 2037, absent any available patent term adjustments or extensions;

JP Patent No. 7286658 having an anticipated expiration date of September 21, 2038, absent any available patent term adjustments or extensions; and

CN Patent No. ZL201880076426.1 having an anticipated expiration date of September 21, 2038, absent any available patent term adjustments or extensions.

Competition

The biotechnology and pharmaceutical industries have made substantial investments in recent years into the rapid development of novel immunotherapies for the treatment of a range of pathologies, including cancers, making this a highly competitive market.

We face substantial competition from multiple sources, including large and specialty pharmaceutical, biopharmaceutical and biotechnology companies, academic research institutions and governmental agencies, and public and private research institutions. Our competitors compete with us based on the specific technologies employed, and on the stage of product candidate development. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development, and commercialization of products, or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates.

In addition to the current standard of care treatments for patients with cancer, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates in the field of immunotherapy. Results from these studies and trials have fueled increasing levels of interest in the field of immunotherapy. Accordingly, we face competition from numerous pharmaceutical and biotechnology entities related to the development of cellular-based therapies to treat cancer. We expect to face competition from other companies developing TCR T therapies, such as Adaptimmune Therapeutics, plc GlaxoSmithKline plc, MediGene AG, TCR2 Therapeutics Inc., TScan Therapeutics Inc. and Ziopharm Oncology, Inc. We also may compete with other T cell therapy companies with target discovery platforms, such as Adaptive Therapeutics, Inc., Immatics, N.V., 3T Biosciences, Inc., and Sana Biotechnology, Inc., among others. We may also compete against a significant number of companies engaged in the development of autologous and allogeneic CAR- T, CAR-NK, TIL and T cell engager technologies including larger companies such as Gilead Sciences, Inc., Bristol-Myers Squibb Company and Amgen, Inc. as well as smaller companies such as Nkarta Inc., Allogene Therapeutics Inc., Century Therapeutics Inc., and Fate Therapeutics Inc., among others.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in R&D, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisitions activity in the pharmaceutical, biopharmaceutical, and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience, and treatment cost.

In the event we receive regulatory approval for any of our product candidates, we will likely compete with other cost-effective and reimbursable treatments used to treat cancer. The most common treatment modalities for patients with cancer are surgery, radiation, and drug therapy, including chemotherapy, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, immunotherapy, and cell-based therapy, used alone or in combination to enhance efficacy. Our CER-T cell therapy candidates, if any are approved, may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of any of our CER-T cell therapies that we successfully introduce to the market may pose challenges.

Government Regulation

In the United States, biological products are licensed by the FDA for marketing under the Public Health Service Act ("PHS Act") and regulated under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Both the FDCA and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, efficacy, labeling, packaging, storage, recordkeeping, distribution, marketing, sales, import, export, reporting, advertising, and other promotional practices involving biological products. FDA clearance of an IND application must be obtained before commencing clinical testing of biological products. FDA licensure also must be obtained before marketing of biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to Good Laboratory Practices ("GLPs") and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- preparation of clinical trial material in accordance with cGMPs;
- submission to the FDA of an application for an IND application, which must become effective before human clinical trials may begin;
- approval by an institutional review board ("IRB"), reviewing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practice ("GCP") requirements and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity, potency, and efficacy, of the proposed biological product for its intended use;
- submission to the FDA of a Biologics License Application ("BLA") for marketing approval that includes substantive evidence of safety, purity, potency, and efficacy from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection prior to BLA approval of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMPs, to assure that the facilities, methods, and controls are adequate to preserve the biologic's identity, strength, quality, and purity;

- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA;
- potential FDA advisory committee meeting to elicit expert input on critical issues and including a vote by external committee members;
- FDA review and approval, or licensure, of the BLA, and payment of associated user fees, when applicable; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post approval studies.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, pharmacology, toxicity, and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

The clinical study sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical protocol, to the FDA as part of the IND. Some nonclinical testing typically continues after the IND is submitted. An IND is an exemption that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA requests certain changes to a protocol before the trial can begin, or the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials may involve the administration of the biological product candidate to healthy volunteers or subjects under the supervision of qualified investigators. Clinical trials involving some products for certain diseases, including some rare diseases may begin with testing in patients with the disease. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection, and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects or his or her legal representative provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee.

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

- ***Phase 1***. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for rare diseases, the initial human testing is often conducted in patients.

- ***Phase 2***. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product for specific targeted diseases, and determine dosage tolerance, optimal dosage, and dosing schedule.

- ***Phase 3***. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. In biologics for rare diseases where patient populations are small and there is an urgent need for treatment, Phase 3 trials might not be required if an adequate risk/benefit can be demonstrated by the Phase 2 trial.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, the FDA requires extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of serious suspected adverse reactions over those listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for such reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biologics, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

There are also various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with the research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Information about certain clinical trials must be submitted within specific timeframes for public dissemination on the clinicaltrials.gov website. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the product begins. The BLA must include results of product development, laboratory, and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling, and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA may be accompanied by a significant user fee. Under federal law, the submission of most applications is subject to an application user fee. The sponsor of an approved application is also subject to an annual program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The application also needs to be published and submitted in an electronic format that can be processed through the FDA's electronic systems. If the electronic submission is not compatible with the FDA's systems, the BLA can be refused for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a REMS is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA may inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical trial sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money, and effort in the areas of training, record keeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor interprets the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, such as requiring labeling changes, or major, such as requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. As a condition for approval, the FDA may also require additional nonclinical testing as a Phase 4 commitment.

One of the performance goals agreed to by the FDA under the PDUFA is to review standard BLAs in ten months from filing and priority BLAs in six months from filing, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Following approval, the manufacturing facilities are subject to inspections by the FDA, and such inspections may result in an issuance of FDA Form 483 deficiency observations, untitled letter, or a warning letter, which can lead to plant shutdown and other more serious penalties and fines. Prior to the institution of any manufacturing changes, a determination needs to be made regarding whether FDA approval is required in advance. If not done in accordance with FDA expectations, the FDA may restrict supply and may take further action. Product reports are required to be submitted annually. Other post-approval requirements applicable to biological products include reporting of cGMP deviations that may affect the identity, potency, purity, and overall safety of a distributed product, recordkeeping requirements, reporting of adverse events, reporting updated safety and efficacy information, and complying with electronic record and signature requirements.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA may conduct laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. Systems need to be put in place to record and evaluate adverse events reported by health care providers and patients and to assess product complaints. An increase in severity or new adverse events can result in labeling changes or product recall. Defects in manufacturing of commercial products can result in product recalls.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or inpatient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and they are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain cGMP compliance. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Orphan Drug Designation

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

If a product that has ODD receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same biological product for the same indication for seven years, except in limited circumstances, such as not being able to supply the product for patients or showing clinical superiority to the product with orphan exclusivity.

Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, priority review, accelerated approval, and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of biological products that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new biological products to patients earlier than under standard FDA review procedures. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a biological product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a fast track BLA before the application is complete, a process known as rolling review.

The FDA may give a priority review designation, such as a rare pediatric disease designation, to biological products that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Most products that are eligible for fast track designation may also be considered appropriate to receive a priority review. In addition, biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a biological product receiving accelerated approval to perform adequate and well-controlled post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval.

Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period.

Moreover, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological 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. Drug and biological products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

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

Biologics Price Competition and Innovation Act

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), created an abbreviated approval pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product via an approved BLA. Biosimilarity to an approved reference product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity is demonstrated in steps beginning with rigorous analytical studies or "fingerprinting", in vitro studies, in vivo animal studies, and generally at least one clinical study. If at any point in the stepwise biosimilarity process a significant difference is observed, then the products are not biosimilar, and the development of a standalone BLA is necessary. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being evaluated by the FDA. Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product.

Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing clinical studies, commercial sales, and distribution of our products. Most countries outside of the United States require that clinical trial authorization applications be submitted to and approved by the local regulatory authority for each clinical study. In the European Union, for example, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Under the Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System for clinical trial authorization in up to 30 EU/EEA countries at the same time and with a single set of documentation.

The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union member states in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a reference Member State. Part II is assessed separately by each Member State concerned. The role of the relevant ethics committees in the assessment procedure continues to be governed by the national law of the Member State concerned, however overall related timelines are defined by the Clinical Trials Regulation. The Clinical Trials Regulation also provides for simplified reporting procedures for clinical trial sponsors.

In addition, whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can commence marketing of the product in those countries. The approval process and requirements vary from country to country, so the number and type of nonclinical, clinical, and manufacturing studies needed may differ, and the time may be longer or shorter than that required for FDA approval.

To obtain regulatory approval of our medicinal products under the European Union regulatory system, we are required to submit a marketing authorization application ("MAA"), to be assessed in the centralized procedure. The centralized procedure allows applicants to obtain a marketing authorization ("MA") that is valid throughout the European Union, and the additional countries of the European Economic Area (Iceland, Liechtenstein and Norway) ("EEA"). It is compulsory for medicinal products manufactured using biotechnological processes, orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance which is not authorized in the European Union and which is intended for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, auto-immune and other immune dysfunctions, viral diseases or diabetes. The centralized procedure is optional for any other products containing new active substances not authorized in the European Union or for products which constitute a significant therapeutic, scientific, or technical innovation or for which a centralized authorization is in the interests of public health at European Union level. When a company wishes to place on the market a medicinal product that is eligible for the centralized procedure, it sends an application directly to the EMA, to be assessed by the Committee for Medicinal Products for Human Use ("CHMP"). The CHMP is responsible for conducting the assessment of whether a medicine meets the required quality, safety, and efficacy requirements, and whether the product has a positive risk/benefit profile. The time limit for the evaluation procedure is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). The EMA then has fifteen days to forward its opinion to the European Commission, which will make a binding decision on the grant of an MA within 67 days of the receipt of the CHMP opinion.

National marketing authorizations, which are issued by the competent authorities of the Member States of the European Union and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the European Union, this national authorization can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

In the European Union, new active substances (including both small molecules and biological medicinal products) approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. Data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA, for a period of eight years from the date on which the reference product was first authorized in the European Union. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be a new active substance, and products may not qualify for data exclusivity. Even if the innovator gains the prescribed period of data exclusivity, another company could nevertheless also market another version of the product if such company obtained an MA based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition that affects no more than five in 10,000 persons in the European Union when the application is made. In addition, orphan designation can be granted if the product is intended for a life threatening, seriously debilitating, or serious and chronic condition in the European Union and, without incentives, it is unlikely that sales of the product in the European Union would be sufficient to justify the necessary investment in its development. Orphan designation is only available if there is no other satisfactory method approved in the European Union of diagnosing, preventing, or treating the applicable orphan condition, or if such a method exists, the proposed orphan medicinal product will be of significant benefit to patients affected by such condition, as defined in Regulation (EC) 847/2000.

Orphan designation provides opportunities for fee reductions, protocol assistance, and access to the centralized procedure. Fee reductions are limited to the first year after an MA is granted, except for small and medium enterprises. In addition, if a product which has an orphan designation subsequently receives a centralized MA for the indication for which it has such designation, the product is entitled to orphan market exclusivity, which means the EMA may not approve any other application to market a similar medicinal product for the same indication as the authorized orphan product for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The exclusivity period may be reduced to six years if, at the end of the fifth year, it is shown that the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, an MA may be granted to a similar medicinal product for the same indication as an authorized orphan product at any time if:

- the second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior;
- the MA holder of the authorized orphan product consents to a second medicinal product application; or
- the MA holder of the authorized product cannot supply enough orphan medicinal product.

A pediatric investigation plan ("PIP") in the European Union is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children, through studies in children. All applications for MAs for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when an MA holder wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines for children are available in the European Union. Medicines authorized across the European Union with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate ("SPC") by six months (provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires). This is the case even when the studies' results are negative. For orphan medicinal products, the incentive is an additional two years of market exclusivity. Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use MA ("PUMA"). If a PUMA is granted, the product will benefit from ten years of market protection as an incentive.

In March 2016, the EMA launched an initiative, the PRIority MEdicines ("PRIME") scheme, to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact and rapporteur from the CHMP or from the Committee for Advanced Therapies ("CAT") are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's committee level. An initial meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

The aforementioned European Union rules are generally applicable in the EEA.

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval, and, in April 2024, the European Parliament proposed amendments to the legislative proposals. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

The United Kingdom left the European Union on January 31, 2020. As a result of the Northern Ireland protocol, following Brexit, the EMA remained responsible for approving novel medicines for supply in Northern Ireland under the EU centralized procedure, and a separate authorization was required to supply the same medicine in Great Britain (England, Wales and Scotland). On February 27, 2023, the United Kingdom government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, and the medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the previous system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. In particular, the MHRA is now responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland), and the EMA no longer has any role in approving medicinal products destined for Northern Ireland under the European Union centralized procedure. A single United Kingdom-wide MA will be granted by the MHRA for all novel medicinal products to be sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom. In addition, the new arrangements require all medicines placed on the UK market to be labelled "UK only", indicating they are not for sale in the European Union.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. On January 1, 2024, the MHRA put in place an international recognition framework under which the MHRA may have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new Great Britain MA.

There is now no pre-MA orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the UK market, i.e., the prevalence of the condition in UK (rather than the European Union) must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in the UK.

Healthcare Laws and Regulations

Sales of our product candidate, if approved, or any other future product candidate, will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value;

- Federal false claims, and false statement laws, including the federal civil False Claims Act, and Civil Monetary Penalties Law, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs and biologics, that are false or fraudulent;

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, imposes obligations on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information;

- 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 the Centers for Medicare and Medicaid Services ("CMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.;

- Federal and state laws that require pharmaceutical manufacturers to report product pricing information; and

- The Foreign Corrupt Practices Act prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business.

Many states have similar laws and regulations, such as anti-kickback and false claims laws, that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug and biologics manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products. In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations.

Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and could increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs and biologics. In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs and biologics administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs and biologics, expanded the 340B program, and revised the definition of average manufacturer price ("AMP"), which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs.

Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, included automatic reductions to several government programs, including aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which remain in effect through 2031. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been executive, judicial and congressional challenges to the Affordable Care Act. We cannot predict what additional challenges to the Affordable Care Act may arise in the future, the outcome thereof, or the impact any such actions may have on our business. Additionally, the Biden administration has introduced various measures in recent years, focusing on healthcare and medical-product pricing, in particular. It remains to be seen how these measures will affect our business and there is uncertainty as to what other healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S., but it is possible that such initiatives could have an adverse effect on our ability to obtain FDA approval or clearance and/or successfully commercialize products in the U.S. in the future. For example, any changes that reduce, or impede the ability of healthcare providers to obtain reimbursement for medical procedures in which the products we currently, or intend to, commercialize are used, or that reduce medical procedure volumes, could adversely affect our operations and/or future business plans. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for medical devices affected by the legislation. From time to time, legislation is drafted, introduced, and passed that could significantly change the statutory provisions governing coverage, reimbursement, pricing, and marketing of medical device products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

Further legislative and regulatory changes under the Affordable Care Act remain possible, and it is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The Affordable Care Act requires pharmaceutical manufacturers to provide a 50% discount (increased by subsequent legislation to a 70% discount) off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the “donut hole.” The Inflation Reduction Act of 2022 (“IRA”) includes provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the donut hole. The IRA also requires pharmaceutical manufacturers to provide a 10% discount of all biosimilar and brand name prescription drugs covered under the Medicare Part D plan benefit during the initial coverage period before the beneficiary reaches the $2,000 out-of-pocket spending cap. Once the patient reaches the out-of-pocket spending cap, they enter catastrophic coverage and drug manufacturer liability for biosimilar and brand name drugs increases to 20%. Furthermore, the IRA allows the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; requires companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delays until January 1, 2032 the implementation of a U.S. Department of Health and Human Service (“HHS”) rebate rule that would have limited the fees that pharmacy benefit managers can charge.

The Affordable Care Act also expanded the Public Health Service’s 340B drug pricing program, which requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, each as defined by the Affordable Care Act. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase.

The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's AMP, for single source and innovator multiple source drugs, beginning January 1, 2024. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. For example, CMS may develop new payment and delivery models, such as bundled payment models.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for pharmaceutical products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Employees and Human Capital Resources

As of April 8, 2025, we had eight full-time employees, including two executive officers and six employees conducting Research and Development. Our employees are not represented by labor unions or covered by collective bargaining agreements and we consider our relationship with our employees to be good.

Compensation and Benefits

Our employee-related objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our management team and our clinical, scientific and other employees and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and motivate personnel through the granting of stock-based and cash-based compensation awards, in order to align our interests and the interests of our stockholders with those of our employees and consultants. In addition, all of our employees are eligible for health insurance, paid and unpaid leaves including paid parental leave, a retirement plan, life and disability/accident coverage, and parking or commuter assistance and an employee assistance.

Corporate Information

We were incorporated under the laws of the state of Delaware on October 2, 2020 under the name Phoenix Biotech Acquisition Corporation. Legacy CERo was incorporated under the laws of the state of Delaware on September 23, 2016. On February 14, 2024, we consummated a merger with Legacy CERo and subsequently changed our name to "CERo Therapeutics Holdings, Inc." Our corporate headquarters are currently located at 210 Haskins Way, Suite 230, South San Francisco, California 94080, and our telephone number is (650) 407-2376. Our website is *www.cero.bio*. The information on our website is not incorporated by reference in this filing or in any other filings we make with the SEC.

Available Information

Our internet address is *www.cero.bio*. Our investor relations website is located at *www.cero.bio/investors*. We make available free of charge on our investor relations website under "SEC Filings" our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors' and officers' Section 16 reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the SEC. They are also available for free on the SEC's website at *www.sec.gov*.

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

Item 1A. Risk Factors.

In evaluating our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report and in other documents that we file with the SEC. An investment in our securities involves a high degree of risk. You should carefully consider the risks described below before making an investment decision. Our business, prospects, financial condition or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. The trading price of our securities could decline due to any of these risks, and, as a result, you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. Certain statements in this "Risk Factors" section are forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to our Business and Industry

We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history, and we have incurred significant net losses since our inception in 2016. We incurred net losses of approximately $8.3 million and $7.3 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $70.9 million. We have funded our operations to date primarily with proceeds from the sale of our equity securities in private financing transactions.

We have no products approved for commercial sale and we are devoting, and expect to continue devoting, substantially all of our financial resources and efforts to R&D of our only programmed CER-T cell product candidate, CER-1236, as well as to building out our manufacturing infrastructure, CDMO relationships and CER-T cell programming technologies. Investment in biopharmaceutical product development, especially preclinical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will not successfully undergo or complete necessary clinical trials, fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable.

We expect that it could take several years until any of our product candidates, which at present is solely CER-1236, receive regulatory and marketing approval and are commercialized, and we may never be successful in obtaining regulatory and marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned R&D activities for our CER-T cell therapies and product candidates;
- pursue preclinical studies and initiate clinical trials for our CER-T cell therapies and other product candidates;
- seek to discover and develop additional product candidates and further expand our product pipeline;
- seek regulatory and marketing approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop and refine the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers of biological materials or product candidates;

- establish or supplement relationships with CDMOs, CROs and other third-party collaborators;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- hire clinical, quality control and manufacturing personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials for our product candidates, preparing a satisfactory filing package for regulatory authorities, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development, manufacturing, delivery and commercialization of complex autologous cell therapies, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we 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 depress the value of our securities and could impair our ability to raise capital, expand our business, maintain our R&D efforts or continue our operations. A decline in the value of our securities could also cause you to lose all or part of your investment.

There is substantial doubt as to our ability to continue as a going concern.

As of December 31, 2024, the Company reported $3.3 million of cash and cash equivalents, with an accumulated deficit of $70.9 million. Additional funds are necessary to maintain current operations and to continue R&D activities. However, there can be no assurance that sufficient funding will be available to allow the Company to successfully continue its R&D activities and planned regulatory filings with the FDA. If the Company is unable to obtain the necessary funds, significant reductions in spending and the delay or cancellation of planned activities may be necessary. These actions would have a material adverse effect on the Company's business, results of operations, and prospects. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these accompanying financial statements are issued. In its report on our financial statements for the year ended December 31, 2024, our independent registered public accounting firm included an explanatory paragraph that expressed substantial doubt about our ability to continue as a going concern. Our current cash level raises substantial doubt about our ability to continue as a going concern. In addition, our future financial statements may include similar qualifications about our ability to continue as a going concern. Our financial statements were prepared assuming that we will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to meet our current operating costs, we will need to seek additional financing or modify or cease our operational plans. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

Our limited operating history makes it difficult to evaluate our business and assess our future viability and prospects.

We are a clinical stage company with a limited operating history. We commenced operations in 2016, and our operations to date have been limited to organizing and planning our development efforts, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies, and establishing arrangements with third parties for the manufacture of initial quantities of CER-1236 and component materials. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a R&D focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Our business is highly dependent on the success of our lead product candidate. If we are unable to advance clinical development, obtain approval of and successfully commercialize our lead product candidate for the treatment of patients in approved indications, our business would be significantly harmed.

Our business and future success depends on our ability to advance clinical development, obtain regulatory approval of, and then successfully commercialize, CER-1236, our lead product candidate. Because our CER-1236 product candidate will be among the first autologous T cell product candidates engineered with cytotoxic and phagocytic potency to be evaluated in clinical trials, the failure of such product candidate, or the failure of other autologous T cell therapies, including for reasons due to safety, efficacy or durability, may impede our ability to develop our product candidates, and significantly influence physicians' and regulators' opinions with regard to the viability of our entire pipeline of autologous T cell therapies.

All of our product candidates, including our lead product candidate, will require additional preclinical, clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because our other product candidates are based on similar technology as our lead product candidate, if the lead product candidate encounters additional safety issues, efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

We have not generated any revenue and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue. We do not expect to generate significant revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, our product candidates. We do not know when, or if, we will generate any revenue. We received clearance of our IND for our first product candidate, CER-1236, and the rest of our product candidates are in the preclinical stages of development. Our product candidates will require additional preclinical studies, clinical development regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete preclinical studies and clinical trials for our CER-T cell product candidates;
- timely file and receive acceptance of INDs, and amendments thereto, as applicable, in order to commence our planned and future clinical trials;
- successfully enroll subjects in, and complete, clinical trials for our CER-T cell product candidates;
- hire additional staff, including clinical, scientific and management personnel;
- timely file BLAs and receive regulatory approvals for our product candidates from the FDA and other regulatory authorities;

- initiate and successfully complete clinical trials and safety studies required to obtain U.S. and applicable foreign marketing approval for our product candidates;
- establish commercial manufacturing capabilities through third-party manufacturers and CDMOs for clinical supply and commercial manufacturing of our product candidates;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- maintain a continued acceptable safety profile of the product candidates following approval;
- obtain and maintain acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- position our products to effectively compete with other therapies;
- obtain and maintain favorable coverage and adequate reimbursement by third-party payors for our product candidates; and
- enforce and defend intellectual property rights and claims with respect to our product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we will be unable to continue operations without continued funding.

Our engineered CER-T cells represent a novel approach to cancer treatment that creates significant challenges for us.

We are developing autologous T-cell product candidates that are engineered from healthy donor T-cells to express chimeric engulfment receptors ("CERs") and are intended for use in patients with certain cancers. Advancing these novel product candidates creates significant challenges for us, including:

- manufacturing our product candidates to our regulatory specifications and in a timely manner to support our clinical trials, and, if approved, commercialization;
- sourcing clinical and, if approved, commercial supplies for the raw materials used to manufacture our product candidates;
- understanding and addressing variability in the quality of a donor's T cells, which could ultimately affect our ability to produce product in a reliable and consistent manner and treat certain patients;
- educating medical personnel regarding the potential side effect profile of our product candidates, if approved, such as the potential adverse side effects related to CRS, neurotoxicity, prolonged cytopenia, coagulation abnormalities, thrombosis, hypotension, aplastic anemia and neutropenic sepsis;
- using medicines to preempt or manage adverse side effects of our product candidates and such medicines may be difficult to source or costly or may not adequately control the side effects or may have other safety risks or a detrimental impact on the efficacy of the treatment;

- conditioning patients with cyclophosphamide, fludarabine, or bendamustine in advance of administering our product candidates, which may be difficult to source, costly or increase the risk of infections and other adverse side effects;

- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with development of CER T cell therapies for cancer;

- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and

- obtaining acceptance and approval by physicians, patients, hospitals, cancer treatment centers and others in the medical community.

Our current product candidates are in early clinical or preclinical development and have never been tested in humans. One or all of our current product candidates may fail in clinical development or suffer delays that materially and adversely affect their commercial viability.

Our current product candidates are in early clinical and preclinical development and we are subject to the risks of failure inherent in the development of product candidates based on novel approaches, targets and mechanisms of action. Although we received IND clearance for CER-1236 from the FDA in November 2024 and for additional indications in March 2025, and we anticipate beginning clinical trials in the first half of 2025, there is no guarantee that we will be able to proceed with clinical development of CER-1236 or any of our other product candidates or that any product candidate will demonstrate a clinical benefit once we advance these candidates to testing in patients. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by early clinical stage biotechnology companies such as ours.

Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.

Results from preclinical studies are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may ultimately fail to show the desired safety and efficacy in clinical settings despite positive results in preclinical studies or having successfully advanced through initial clinical trials. This failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates.

Manufacturing genetically engineered products is complex and we, or our third-party manufacturers, may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing genetically engineered products is complex and may require the use of innovative technologies to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at manufacturing facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA, the EMA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If we or our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, 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.

Genetic engineering of T cells to create CER-T cells is a relatively new technology, and if we are unable to use this technology in our intended product candidates, our revenue opportunities will be materially limited.

Our technology involves a relatively new approach to T cell gene therapy. This technology may also not be shown to be effective in clinical studies that we may conduct or may be associated with safety issues that may negatively affect the development of our product candidates. For instance, lentiviral gene transduction may create unintended changes to the DNA such as a non-target site gene insertion, a large deletion, or a DNA translocation, any of which could lead to oncogenesis.

We may not be successful in our efforts to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our CER-T cell technology. Our research programs may fail to identify other potential product candidates outside of CER-1236 for clinical development for a number of reasons. We may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our research, development or commercialization efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Even if we obtain regulatory approval of a product candidate, the product may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of engineered T cells as a potential cancer treatment is nascent and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We expect physicians with expertise in immunotherapy to be particularly important to the market acceptance of our products and we may not be able to educate them on the benefits of using our product candidates for many reasons. For example, certain of the product candidates that we will be developing may result in unacceptable and unanticipated side effects, including death. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;

- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Data from our preclinical studies is limited and may change as patient data become available or may not be validated in any future or advanced clinical trial.

Data from preclinical studies and any clinical trials that we may complete is subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. For example, preclinical and Phase 1 results are preliminary in nature and should not be viewed as predictive of ultimate success. It is possible that such results will not continue or may not be repeated in any clinical trial of our product candidates. For instance, our preclinical studies provide limited data and any clinical trials may not validate such results. Additionally, manufacturing can impact clinical outcomes and we have not yet completed manufacturing runs with a CDMO. We may also fail to develop and transfer to a CDMO any optimized manufacturing processes for any of our programs. Ultimately, if we cannot manufacture our product candidates with consistent and reproducible product characteristics, our ability to develop and commercialize any product candidate would be significantly impacted.

Preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, initial, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We may not be able to file INDs or IND amendments to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

The IND for CER-1236 was filed on June 28, 2024 and on November 15, 2024, the FDA cleared us to begin clinical trials for the treatment of AML and we submitted a second IND application for the investigation of CER-T cell therapy in NSCLC and ovarian cancer, which was accepted by the FDA on March 27, 2025, but there are no assurances regarding the acceptance of any amendments or future INDs, which may impact the timelines we expect. For example, we may experience manufacturing delays or other delays with future IND-enabling studies. Moreover, there can be no assurances that once trials begin, issues will not arise that suspend or terminate such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

Clinical trials are difficult to design and implement, involve uncertain outcomes and may not be successful.

Human clinical trials are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial that will be successful to achieve regulatory approval. There is a high failure rate for biological products proceeding through clinical trials, which may be higher for our product candidates because they are based on new technology and engineered on a patient-by-patient basis. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

We will depend on enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates will be critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size and nature of the patient population required for analysis of the trial's primary and secondary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving T cell-based immunotherapy;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment; and
- other public health factors, including the coronavirus pandemic or outbreaks of other infections.

In particular, some of our clinical trials will look to enroll patients with characteristics which are found in a very small population. For example, our clinical trial for CER-1236 will seek to enroll patients with hematologic malignancies, including AML, MCL, CLL, and other B cell and myeloid neoplasms. Other companies are conducting clinical trials with their engineered T cell therapies in hematologic malignancies and seek to enroll patients in their studies that may otherwise be eligible for our clinical trials, which could lead to slow recruitment and delays in our clinical trials. In addition, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites.

Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential study participants and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than participate in our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

If the market opportunities for any of our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

We are focused initially on the development of treatments for cancers such as AML, MCL and CLL, and plan to eventually extend our treatments to other forms of cancer. Our internal projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if licensed, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our product candidates following their approval. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

We face competition from companies that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop platform technologies or product candidates more rapidly than we do, if their platform technologies or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of cell and gene therapies is highly competitive. We compete with a variety of large pharmaceutical companies, multinational biopharmaceutical companies, other biopharmaceutical companies and specialized biotechnology companies, as well as technology and/or therapeutics being developed at universities and other research institutions. Our competitors are often larger and better funded than we are. Our competitors have developed, are developing or will develop product candidates and processes competitive with ours. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that are currently in development or that enter the market. 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 may try to develop product candidates. There is intense and rapidly evolving competition in the biotechnology and biopharmaceutical fields. We believe that while our T-cell based platform, its associated intellectual property portfolio, the characteristics of our current and potential future product candidates and our scientific and technical know-how together give us a competitive advantage in this space, competition from many sources remains.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our product candidates, the ease with which our product candidates can be administered, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products and product candidates could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products and product candidates may make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such product. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market.

We are highly dependent on our key personnel, including individuals with expertise in cell therapy development and manufacturing, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the expertise of our management, scientific and medical personnel, including our chief executive officer ("Chief Executive Officer"), Chris Ehrlich, our chief development officer ("Chief Development Officer"), Kristen Pierce, our chief financial officer ("Chief Financial Officer"), Andrew "Al" Kucharchuk and the head of our scientific advisory board, Lawrence Corey. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct substantially all of our operations at our facilities in the South San Francisco area. The San Francisco Bay Area region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Attrition may lead to higher costs for hiring and retention, diversion of management time to address retention matters and disrupt the business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity-based compensation for retention purposes. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements or consulting agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We will need to continue to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development, manufacturing and commercialization plans and strategies develop, we expect to add managerial, operational, sales, R&D, marketing, financial and other personnel. Current and future growth imposes and will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants. 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. We may also be subject to penalties or other liabilities if we mis-classify employees as consultants. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants 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 and retaining employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop, manufacture and commercialize our product candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals. Conversely, if we expand ahead of our business progress, we may take on unnecessary costs.

We may form or seek strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our 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 our product candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or new technologies or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. For instance, certain of our agreements may require significant R&D that may not result in the development and commercialization of product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

We will need substantial additional financing to develop our product candidates and implement our operating plans, which financing we may be unable to obtain, or unable to obtain on acceptable terms. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

We expect to spend a substantial amount of capital in the development and manufacturing of our product candidates, and we will need substantial additional financing to do so. In particular, we will require substantial additional financing to enable commercial production of our product candidates and initiate and complete registrational trials for multiple products in multiple regions. Further, if approved, we will require significant additional capital in order to launch and commercialize our product candidates.

As of December 31, 2024, we had approximately $3.3 million in cash and cash equivalents. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may also need to raise additional capital sooner than we currently anticipate if we choose to expand more rapidly than we presently plan. In any event, we will require additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other R&D initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our Common Stock to decline.

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

Until such time, if ever, as we can generate substantial revenue from the sale of our product candidates, we will need substantial additional financing to develop our product candidates and implement our operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or product candidates or grant licenses on terms that may not be favorable to us or that may be at less than the full potential value of such rights. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The issuance of shares of our Common Stock upon conversion or exercise of our outstanding Preferred Shares and Common Warrants and other securities that we may issue in future financing transactions may result in substantial dilution to our stockholders.

As of April 11, 2025, the Company currently has outstanding (i) 1,429 shares of Series A Preferred Stock with a conversion value of approximately $1.4 million, convertible into shares of Common Stock at a conversion rate of the stated value thereof divided by a current effective conversion price of $1.96; (ii) 198 shares of Series B Preferred Stock with a conversion value of approximately $0.2 million, convertible into shares of Common Stock at a conversion rate of the stated value thereof divided by a floating conversion price of 80% of the lowest volume weighted average price during the five trading days immediately prior to conversion; (iii) 2,537 shares of Series C Preferred Stock with a stated value of approximately $2.5 million, convertible into shares of Common Stock at a conversion rate of the stated value thereof divided by a conversion price of $1.96 (iv) Series A Warrants to purchase 6,127 shares of Common Stock at an exercise price of $139.00 per share; (v) Series C Warrants to purchase 81,753 shares of Common Stock at an exercise price of $0.04; (vi) December 2024 and January 2025 Common Warrants to purchase an aggregate of 247,914 shares of Common Stock at an exercise price ranging from $5.61 to $5.82, (vii) February 2025 Common Warrants to purchase an aggregate of 2,551,020 shares of Common Stock at an exercise price of $1.96, (viii) Pre-Funded Warrants to purchase an aggregate of 215,740 shares of Common Stock at an exercise price of $0.0001, and (ix) Public Warrants and Private Placement Warrants to purchase an aggregate of 91,925 shares of Common Stock at an exercise price of $1,150.00 per share.

Although each of the conversion price of the Preferred Shares and the exercise prices of the December 2024 Common Warrants, January 2025 Common Warrants, and Series A Warrants are at or above the trading price of our Common Stock as of the date of this Annual Report, if such trading price increases, such conversion prices and exercise prices will not change as a result thereof and could be below the trading price of our Common Stock as of the date of any future conversion or exercise thereof, resulting in dilution to our stockholders. In addition, the terms of the Series A Preferred Stock, the Series B Preferred Stock and the Series C Preferred Stock contain certain penalties and adjustments to the amount included in determination of the conversion rate following certain breaches of the Company's obligations thereunder, including, among other things, as a result of a failure to file or cause the SEC to declare one or more registration statements relating to the resale of the shares of Common Stock issuable upon conversion thereof by specified deadlines, certain defaults under indebtedness of the Company or judgments against the Company and failure to deliver shares of Common Stock upon conversion in a timely manner. For example, the penalties and adjustments include a 25% premium added to the stated value for determining the conversion rate in connection with breaches other than the breach of the requirement to redeem the shares of Series A Preferred Stock and Series B Preferred Stock by August 14, 2025, which results in a 50% premium, and the addition to the stated value of an amount equal to the value of the shares of Common Stock into which the Series A Preferred Stock or Series B Preferred Stock would have been convertible if the conversion price were equal to 80% of the lowest volume weighted average price during the five trading days immediately prior to conversion. Such penalties and adjustments, which applied during the period when substantially all of the conversions since the Business Combination described in the preceding paragraph occurred as a result of a failure to file and cause the SEC to declare a registration statement with respect to the resale of the underlying shares in a timely manner, have resulted and may in the future result in the issuance of shares of Common Stock at an effective conversion price below the trading price of our Common Stock at the time of such conversion.

We cannot assure you that we will remain in compliance with all of the terms of the Series A Preferred Stock, Series B Preferred Stock or Series C Preferred Stock and that such penalties and adjustments will not apply in the future. In addition, we cannot assure you that we will not issue additional convertible or other derivative securities with highly dilutive penalty or adjustment provisions. As described elsewhere in this Annual Report, the Company needs to obtain financing to fund its research and development activities and clinical trials, as well as other operations. Under challenging conditions in the equity capital markets, particularly for pre-commercialization biotech companies, we may have no viable alternatives to agreeing to inclusion of such provisions in the terms of future financings.

If our security measures, or those of our CROs, CDMOs, collaborators, contractors, consultants or other third parties upon whom we rely, are compromised or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, we could experience a material adverse impact.

In the ordinary course of our business, we may collect, process, receive, store, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively processing) proprietary, confidential and sensitive information, including personal data (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. We may also share or receive sensitive information with our partners, CROs, CDMOs, or other third parties. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If we (or a third party upon whom we rely) experience a security incident or compromise, or are perceived to have experienced a security incident or compromise, we may also experience adverse consequences.

Our internal computer systems and those of our CROs, CDMOs, collaborators, contractors, consultants or other third parties are vulnerable to damage from computer viruses, unauthorized access, cybersecurity threats, and telecommunication and electrical failures. In addition, as many of our personnel work from home at least part of the time and utilize network connections outside our premises, this poses increased risks to our information technology systems and data. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," "hacktivists," organized criminal threat actors, threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce and distribute our product candidates. We and the third parties upon which we rely are subject to a variety of evolving threats, including social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service (such as credential stuffing), credential harvesting, social engineering attacks (including through phishing attacks), viruses, ransomware, supply chain attacks, personnel misconduct or error and other similar threats. We may also be the subject of software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures or other similar issues. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruptions to our clinical trials, loss of data (including data related to clinical trials), significant expense to restore data or systems, reputational loss and the diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach to our information technology systems or the third-party information technology systems that support us and our services. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Any of the previously identified or similar threats could cause a security incident, compromise, or other interruption. A security incident, compromise, or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to manufacture or deliver our product candidates.

We may expend significant resources, or modify our business activities and operations, including our clinical trial activities, in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or use industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Although we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We, and the third parties on whom we rely, have experienced, and expect to continue to experience, threats to and attempts to compromise the security of our information technology systems or otherwise cause a security incident. Such security incidents or compromises, if experienced, could have an adverse impact on our business.

We may be unable to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate exploitable critical vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Any failure to prevent or mitigate security incidents or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state, federal, and international law and may cause a material adverse impact to our reputation, affect our ability to conduct our clinical trials and potentially disrupt our business.

Applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security incidents or compromises. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may also experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that the limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or adequately mitigate liabilities arising out of our privacy and security practices, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Disruptions at the FDA, the SEC and other government agencies caused by reduction in staffing, funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, 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 the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including staffing levels, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund R&D activities is subject to the political process, which is inherently fluid and unpredictable. The Trump Administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the SEC and the FDA. Any such reduction in personnel may result in longer review times by the FDA or SEC.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise, at the FDA and other government agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition to the potential reduction in staffing, a government shutdown could adversely affect the FDA review process. Over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel or otherwise, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed.

Business disruptions, including financial institution distress, could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CDMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical pandemics or epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. For more information, see the section entitled "*Business– Healthcare Laws and Regulations*."

The distribution of biotechnology and biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biotechnology and biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from other aspects of its business.

It is not always possible to identify and deter employee misconduct, and our code of ethics and the other precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, diminished profits and future earnings, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, 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, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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 European Union. The provision of benefits or advantages to induce or reward improper performance generally is typically governed by the national anti-bribery laws of European Union Member States, and in respect of the U.K. (which is longer a member of the European Union), the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. European Union Directive 2001/83/EC, which is the European Union Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the European Union. Payments made to physicians in certain European Union 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 European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018, as well as the United Kingdom's General Data Protection Regulations (the "UK GDPR"), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. 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, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, 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 or 4% of annual global revenues, whichever is greater; UK GDPR mirrors such fines under the GDPR. 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. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with European activities. This and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our product candidates, if approved, in some markets and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity, which could have an adverse effect on our reputation and business.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Future undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous T cell therapies and those under development by other companies have shown frequent rates of CRS, neurotoxicity, serious infections, prolonged cytopenia and hypogammaglobulinemia, and adverse events have resulted in the death of patients. Similar adverse events may occur for our T cell product candidates.

In addition, we utilize a lymphodepletion regimen, which generally includes fludarabine, cyclophosphamide or bendamustine, that may cause serious adverse events. For instance, because the regimen will cause a transient and sometimes prolonged immune suppression, patients will have an increased risk of infection, such as to COVID-19, that may be unable to be cleared by the patient and ultimately lead to other serious adverse events or death. Our lymphodepletion regimen has caused and may also cause prolonged cytopenia and aplastic anemia.

We may also combine the use of our product candidates with other investigational or approved therapies that may cause separate adverse events or events related to the combination or potentiate side effects of approved drugs.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the EMA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Any data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our product candidates may target healthy cells expressing target antigens, leading to potentially fatal adverse effects.

Our product candidates target specific antigens that are also expressed on healthy cells. For example, cell surface phosphatidylserine, the target of CER-1236, has been observed on activated immune cells, including platelets, and in rapidly dividing cells across various organs including the gastrointestinal system, hepatic system, cardiovascular system, renal system, pulmonary system, and the central nervous system and related peripheral nervous system. Our product candidates may target healthy cells, leading to serious and potentially fatal adverse effects. Even though we intend to closely monitor the side effects of our product candidates in both preclinical studies and clinical trials, we cannot guarantee that products will not target and kill healthy cells.

Our product candidates may have serious and potentially fatal cross-reactivity to lipids, peptides or protein sequences within the body.

Our product candidates may recognize and bind to a peptide unrelated to the target antigen to which it is designed to bind. If this peptide is expressed within normal tissues, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse effects. Additionally, our product candidates may bind with non-targeted lipids, leading to off-target reactivity. Detection of any on-target off-tumor or non-specific-reactivity may halt or delay any ongoing clinical trials for any CER-T cell based product candidate and prevent or delay regulatory approval. Unknown binding-reactivity of the CER-T cell binding domain to related proteins could also occur. Any non-specific binding interactions that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization.

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

We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, packaging, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our stock price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we plan on purchasing clinical trial insurance, such insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Public opinion and scrutiny of cell-based immune-oncology therapies for treating cancer, or negative clinical trial results from our cell-based therapy competitors, or auto-immune cell therapy candidates, may impact public perception of our company and product candidates, or impair our ability to conduct our business.

Our autologous cell therapy platforms utilizes a relatively novel technology involving the genetic modification of cells, and no CER-T cell-based immunotherapy has been approved to date. Public perception may be influenced by claims, such as claims that cell-based immunotherapy is unsafe, unethical, or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general, or negative clinical trial results from our cell-based therapy competitors, or auto-immune cell therapy candidates, could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Adverse public attitudes may adversely impact our ability to enroll patients in clinical trials. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T-cell malignancies following BCMA-directed or CD19-directed autologous CAR-T cell immunotherapies following reports of T cell lymphoma in patients receiving these therapies. In January 2024, the FDA determined that new safety information related to T cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD-19-directed genetically modified autologous T cell immunotherapies. While CER-1236 and our engineered CER-T cells are designed to utilize a different mechanism of action, FDA's investigation into CAR-T therapies and other similar actions could result in increased government regulation, unfavorable public perception and publicity, potential impacts on enrollment in our clinical trials, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates.

Our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated, including from other therapeutic modalities.

The Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new products could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. In the United States, the principal decisions about reimbursement for new therapies are typically made by CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new therapy will be covered and reimbursed under Medicare, and private payors tend to follow CMS determinations to a substantial degree. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments, such as cellular immunotherapy. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products by government and third-party payors. In particular, there is no body of established practices and precedents for reimbursement of cellular immunotherapies, and it is difficult to predict what the regulatory authority or private payor will decide with respect to reimbursement levels for novel products such as ours. Our product candidates may not qualify for coverage or direct reimbursement, or may be subject to limited reimbursement. If reimbursement or insurance coverage is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income.

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our product candidates, if approved, may be reduced as compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved, and as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Even if we obtain regulatory and marketing approval for a product candidate, our product candidates will remain subject to regulatory oversight.

Even if we receive marketing and regulatory approval for CER-1236 or any other product candidates, regulatory authorities may still impose significant restrictions on the indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. CER-1236 and other product candidates will also be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and submission of safety and other post-market information. The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate serious safety risks related to the use of a biologic. Any regulatory approvals that we receive for CER-1236 or other product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-approval clinical trials, and surveillance to monitor the quality, safety, and efficacy of the product, all of which could lead to lower sales volume and revenue. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover(s) previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or our contractors fail to comply with applicable regulatory requirements following approval of CER-1236 or our other product candidates, a regulatory authority may:

- issue a warning letter, untitled letter, or Form 483, asserting that we are in violation of the law;
- request voluntary product recalls;
- seek an injunction or impose administrative, civil, or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;

- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto);
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize CER-1236 or other product candidates and adversely affect our business, financial condition, results of operations, and prospects.

Prior treatments can alter the cancer or target of CER-T cell therapy and negatively impact chances for achieving clinical activity with our programmed T cells.

Patients with hematological cancers receive highly toxic lympho-depleting chemotherapy as their initial treatment. These therapies can impact the viability of the T cells collected from the patient and can contribute to highly variable responses to programmed T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended programmed T cell product candidate and thereby lead to a selection of cancer cells with low or no expression of the target. Cancers also naturally evolve and select clones with low or no expression of the target. As a result, our programmed T cell product candidates may not recognize the cancer cell and may fail to achieve clinical activity. If any of our product candidates do not achieve a sufficient level of clinical activity, we may discontinue the development of that product candidate, which could adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Reliance on Third-Parties

We will rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We expect to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CDMOs and strategic partners to conduct our preclinical studies under agreements with us and in connection with our clinical trials. We expect to have to negotiate budgets and contracts with CROs, trial sites and CDMOs which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through 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 is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biological product produced under cGMP regulations, including current good tissue practice ("cGTP") regulations, and will 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.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or 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.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Additionally, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We rely on third parties to manufacture and store our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved. There can be no assurance that we will be able to establish or maintain relationships with such third parties. We may in the future establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on third parties for the manufacture of our product candidates, which would be costly, time-consuming and which may not be successful.

Our product candidates are manufactured in the United States by third parties, and we manage all other aspects of the supply, including planning, oversight, disposition and distribution logistics. There can be no assurance that we will not experience supply or manufacturing issues in the future.

We have a long-term agreement in place with a CDMO for the manufacture of CER-1236. However, we have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve manufacturing and processing and may be unable to create an inventory of mass-produced product to satisfy demands for any of our product candidates. Our clinical supply will also be limited to small quantities and any latent defects discovered in our supply could significantly delay our development timelines.

In addition, our actual and potential future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.

- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.

- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.

- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Our third-party manufacturers could breach or terminate their agreement with us.

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Our current and potential future CDMOs may also be required to shut down in response to the spread of health epidemics or pandemics, or they may prioritize manufacturing for therapies or vaccines for other diseases. In addition, our CDMOs have certain responsibilities for storage of raw materials and in the past have lost or failed to adequately store our raw materials. We will also rely on third parties to store our released product candidates, and any failure to adequately store our product candidates could result in significant delay to our development timelines. Any additional or future damage or loss of raw materials or product candidates could materially impact our ability to manufacture and supply our product candidates. Each of these risks could delay our clinical trials or the approval of any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue.

In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We maintain single supply relationships for certain key components, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our suppliers' manufacturing process increases.

We are dependent on sole suppliers or a limited number of suppliers for certain components that are integral to our product candidates, including CER-1236. If these or other suppliers encounter financial, operating or other difficulties or if our relationship with them changes, we may be unable to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. In addition, technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time-consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these suppliers to produce the needed equipment and materials in sufficient quantities to support our growth. Any one of these factors could harm our business and growth prospects.

Our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates, including CER-1236, require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. In addition, those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some of our raw materials are currently available from a single supplier, or a small number of suppliers. For example, the type of cell culture media and cryopreservation buffer that we currently use in our manufacturing process for the CER-T cells are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and modify our protocols if we change suppliers. Disruption of our cell manufacturing process may affect product health, fitness, and potentially anti-tumor activity and clinical responses. In addition, the cell processing equipment and tubing that we use in our current manufacturing process is only available from a single supplier. We also use certain biologic materials, including certain activating antibodies, that are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and potentially modify some of our protocols if we change suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. If we are required to change suppliers, the materials may only be available from another supplier on terms that are less favorable to us than the terms under which we currently obtain the materials. Accordingly, if we no longer have access to these suppliers, we may experience delays in our clinical or commercial manufacturing which could harm our business or results of operations.

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

Our R&D activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers 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 or federal 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. In addition, any violation in the use, manufacture, storage, handling and disposal under foreign law may subject us to additional liability.

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.

Risks Related to Government and Regulation

Clinical development and the regulatory approval process involve a lengthy and expensive process with an uncertain outcome and results of earlier studies and preclinical data, and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of biological products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite licensure from the applicable regulatory authorities of such jurisdictions. We have not previously submitted a BLA to the FDA or similar licensure applications to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and licensure may not be obtained.

We cannot be certain that our preclinical studies and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

We may experience delays in obtaining the FDA's authorization to initiate clinical trials under future INDs and completing ongoing clinical studies of our product candidates due to a variety of factors. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the availability of financial resources to commence and complete the planned trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory approval to commence a clinical trial;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates are safe, potent and pure;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for licensure;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain licensure of our product candidates in the United States or elsewhere;
- reaching agreement on acceptable terms with prospective CDMOs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CDMOs and clinical trial sites;
- obtaining IRB or ethics committee approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites;
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers;
- the FDA's or the applicable foreign regulatory agency's findings of deficiencies or failure to approve the manufacturing processes or facilities of third-party manufacturers upon which we rely; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- we may obtain a result from preclinical studies such as a binder specificity study or a safety toxicology study that require us to modify the design of our clinical trials, abandon our research efforts for product candidates, or result in delays;
- clinical trials of our product candidates may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. In addition, costs to treat patients with relapsed or refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than those for more conventional therapeutic technologies or drug product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, in July 2024, we announced a clinical hold as a result of insufficient data provided with regard to two issues within pharmacology and toxicology of CER-1236. In November 2024, we announced that the clinical hold was resolved and that the FDA had cleared our IND for Phase 1 clinical trials.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our CER-T cell platform would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, or a delay in such approval, which would significantly harm our business, results of operations, and prospects. Of the large number of biological products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Even if we eventually complete clinical testing and receive licensure from the FDA or applicable foreign regulatory authorities for any of our product candidates, the FDA or the applicable foreign regulatory may license our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not license our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates.

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 at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines, including cGTPs. 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, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our CER-T cells as a result of a failure of 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 CER-T cell programs, including leading to significant delays in the availability of our CER-T cells 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 CER-T cell 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 CER-T cell 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 our business.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA, EMA or any other comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, applicable product tracking and tracing requirements and continued compliance with cGMPs, including cGTPs, and GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with any future potential manufacturing facilities we may own, third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

- fines, untitled or warning letters or holds on clinical trials;
- refusal by the FDA, the EMA or any other comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Moreover, if any of our product candidates are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about biopharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our or our collaborators' ability to commercialize our product candidates, and harm our business, financial condition and results of operations.

In addition, the policies of the FDA, the EMA and other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements, or if we are unable to maintain regulatory compliance, marketing approval that has been obtained may be lost and we may not achieve or sustain profitability.

Regulatory requirements in the United States and abroad governing cell therapy products have changed frequently and may continue to change in the future, which could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all.

Regulatory requirements in the United States and abroad governing cell therapy products have changed frequently and may continue to change in the future. In 2016, the FDA established the Office of Tissues and Advanced Therapies ("OTAT") within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products ("OTP") and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. In addition, under guidelines issued by the National Institute of Health (the "NIH"), gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution's institutional review board, or IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell and gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

We may seek fast track and breakthrough therapy designations or priority review for one or more of our product candidates, but we might not receive such designation or priority review, and even if we do, such designation or priority review may not lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates. Even if a product qualifies for such designation or priority review, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek fast track, breakthrough therapy, and/or regenerative medicine advanced therapy designations or priority review for one or more of our product candidates.

The FDA may issue a fast track designation to a product candidate 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. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA during product development. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. However, the FDA's goal for reviewing a BLA fast track application under the PDUFA does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate 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 product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Fast track designation, priority review, and breakthrough therapy designation are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for any such designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of such designation may expedite the development or approval process, but do not change the standards for approval. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek approval of our product candidates, where applicable, under the FDA's accelerated approval pathway. This pathway may not lead to a faster development, regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage 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 or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, ("IMM") that is reasonably likely to predict an effect on IMM or other 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 IMM. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verity and describe the drug's clinical benefit. Under the FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of 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. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. 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 study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, 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. Moreover, even if we received accelerated approval, any post-approval studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. Receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA from approving other competing products.

Regulatory authorities may designate drugs for relatively small patient populations as "orphan" drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which, subject to certain exceptions, precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable market exclusivity period is seven years in the United States.

Obtaining orphan drug exclusivity for our product candidates may be important to our commercial strategy. If a competitor obtains orphan drug exclusivity for and approval of a product with the same indication as our product candidates before we do, and if the competitor's product is the same drug or a similar medicinal product as ours, we could be excluded from the market. Even if we obtain orphan drug exclusivity after FDA approval, we may not be able to maintain it. For example, if a competitive product that is the same drug or a similar medicinal product as our product candidate is shown to be clinically superior to our product candidate, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, orphan drug exclusivity will not prevent the approval of a product that is the same drug as our product candidates if the FDA finds that we cannot assure the availability of sufficient quantities of the drug to meet the needs of the persons with the disease or condition for which the drug was designated. If one or more of these events occur, it could have a material adverse effect on our company.

We are subject to stringent and changing privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to enforcement or litigation (that could result in fines or penalties), a disruption of clinical trials or commercialization of products, reputational harm, or other adverse business effects.

In the ordinary course of business, we will collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, processing) personal data and other sensitive information, including, but not limited to, proprietary and confidential business information, trade secrets, intellectual property, and information we collect about patients in connection with clinical trials. Accordingly, we are, or may become, subject to numerous federal, state, local and international data privacy and data security laws, regulations, guidance, and industry standards as well as external and internal privacy and data security policies, contracts and other obligations that apply to our processing of personal data and the processing of personal data on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws and other similar laws (e.g., unfair or deceptive acts or practices pursuant to Section 5(a) of the Federal Trade Commission Act). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, imposes requirements relating to the privacy, security and transmission of protected health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA as well as their covered subcontractors.

In addition, the California Consumer Privacy Act ("CCPA"), as amended by the California Privacy Rights Act, applies to personal information of consumers, business representatives, and employees, and creates individual privacy rights and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide disclosures to California consumers, affords California residents certain rights related to their personal data, including the right to opt-out of certain sales of personal data, and allow for a private cause of action for certain data breaches. The CCPA also created a new state regulatory agency to implement and enforce the law. Although there are limited exemptions for clinical trial data under the CCPA, as our business progresses, the CCPA may become applicable and significantly impact our business activities and exemplifies the vulnerability of our business to evolving regulatory environment related to personal data and protected health information. In addition, several other states have also passed comprehensive privacy laws, and similar laws are being considered in additional states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Moreover, some states, such as Washington, Nevada and Connecticut, adopted legislation protecting consumer health information specifically. Washington's My Health My Data Act, which is now in effect, features a private right of action, heightening noncompliance risks.

Outside the United States, there are an increasing number of laws, regulations and industry standards concerning privacy, data protection, information security and cross-border personal data transfers. For example, GDPR, UK GDPR, and China's Personal Information Protection Law impose strict requirements for processing personal data. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the European Union Member States may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, other administrative penalties, and private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expenses. European regulators have also ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. If any of our privacy policies or related materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. As a result, preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors, consultants or other third parties that process personal data on our behalf.

Although we endeavor to comply with all applicable privacy and security obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, third-party collaborators, service providers, contractors or consultants fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party service provider to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with obligations related to data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits and inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117 of February 28, 2024, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, as implemented by U.S. Department of Justice, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. 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.

Like many companies, we may use artificial intelligence and machine learning (AI) technologies, including generative AI, to efficiently grow and manage our business. These technologies have increasingly been the focus of attention for lawmakers and regulators around the globe.

The use of new and evolving technologies, such as artificial intelligence (AI), in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

We may continue to build and integrate AI into our offerings, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, 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 European Union's Artificial Intelligence Act ("AI Act") has now entered into force . This sweeping legislation, with broad extraterritorial reach, 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. If we develop or deploy AI systems that are governed by the AI Act, we may be required to adopt higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements.

Likewise, in the U.S., several states, including Colorado and California, passed laws that will take effect in 2026, to regulate various uses of artificial intelligence, including to make consequential decisions. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The U.S. Food and Drug Administration, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI 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. Our vendors may in turn incorporate AI tools into their own 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 AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. 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.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. For more information, see the section of this report titled "*Business – Healthcare Laws and Regulations – Healthcare Reform.*"

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our business could be negatively impacted by environmental, social and corporate governance matters or our reporting of such matters.

Investors have increased their emphasis on the environmental, social and governance ("ESG") practices of companies across all industries, including the environmental impact of operations and human capital management. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition, or results of operations.

While we have internal efforts directed at ESG matters and preparations for any increased required future disclosures, such initiatives may be costly and may not have the desired effect. We may be perceived to be not acting responsibly in connection with these matters, which could negatively impact us. Moreover, we may not be able to successfully complete such initiatives due to factors that are within or outside of our control. Even if this is not the case, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement on our ESG efforts, even if such initiatives are currently voluntary. In addition, investor or regulatory expectations for ESG practices may change materially as a result of the change in presidential administration and executive orders issued thereby restricting the implementation of diversity, equity and inclusion programs and we may be unable to adapt to such changes in a timely manner and/or without substantial cost.

Certain market participants, including major institutional investors and capital providers, use third-party benchmarks and scores to assess companies' ESG profiles in making investment or voting decisions. A failure to comply with investor expectations and standards, which are evolving and vary considerably, or the perception that we have not responded appropriately to the growing concern for ESG issues, could result in reputational harm to our business and could have an adverse effect on us. To the extent ESG matters negatively impact our reputation, it may also negatively impact our share price as well as our access to and cost of capital and impede our ability to compete as effectively to attract and retain employees, which may adversely impact our operations.

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

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not yet completed a Section 382 or Section 383 analysis, and therefore, there can be no assurances that any previously experienced ownership changes have not materially limited our utilization of affected net operating loss carryforwards or other tax attributes. We may experience ownership changes in the future as a result of shifts in our stock ownership. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize net operating loss carryforwards associated with any such losses to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Trump administration has proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flows, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the U.S. federal government and by the states and foreign jurisdictions in which we conduct our business. For more information, see the section of this report titled "*Business – Healthcare Laws and Regulations.*"

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that our business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of significant investigations, prosecutions, convictions and settlements in the healthcare industry.

Efforts to ensure that our internal operations and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

If we fail to comply with 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 wastes. 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.

We may be affected by regulatory responses to climate-related issues.

The Biden administration made climate change and the limitation of greenhouse gas ("GHG") emissions one of its primary objectives. Although the Trump administration is expected to reverse such priorities, several states and other geographic regions in the United States have also adopted legislation and regulations to reduce emissions of GHGs.

On March 6, 2024, the SEC finalized new rules for public companies that would require extensive climate-related disclosures and significant analysis of the impact of climate-related issues on our business strategy, results of operations, and financial condition (the "SEC Climate Disclosure Rules"). Following court challenges initiated during the Biden administration and while the SEC was led by former Chairman Gensler that resulted in the indefinite delay in implementation of the SEC Climate Disclosure Rules, on March 27, 2025, the SEC announced that it had voted to end its defense of such rules in court. Nevertheless, if the SEC or state regulatory authorities were to seek to impose such rules in the future, our legal, accounting and other compliance expenses would increase significantly. . We may also be exposed to legal or regulatory action or claims as a result of any such new regulations. All of these risks could have a material adverse effect on our business, financial position, and/or stock price.

Risks Related to Intellectual Property

Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand.

The loss of any procured intellectual property rights in our products could permit our competitors to manufacture their own version of our products. We have attempted to protect our intellectual property rights in our products through a combination of patents, confidentiality agreements, non-compete agreements and other contractual protection mechanisms, and we will continue to do so. While we intend to defend against threats to our intellectual property, our patents or various contractual protections may not adequately protect our intellectual property. In addition, we could be required to expend significant resources to defend our rights to proprietary information, and may not be successful in such defense.

As such, we may not be successful in preventing third parties from infringing, copying or misappropriating our intellectual property. There can also be no assurance that pending patent applications owned by us will result in patents being issued to us, that patents issued to or licensed by us in the past or in the future will not be challenged or circumvented by competitors or that such patents will be found to be valid or sufficiently broad to protect our products or to provide us with any competitive advantage. Third parties could also obtain patents that may require us to negotiate to obtain licenses to conduct our business, and any required licenses may not be available on reasonable terms or at all. We also rely on confidentiality and non-compete agreements with certain employees, independent distributors, consultants and other parties to protect, in part, trade secrets and other proprietary rights. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. We cannot assure investors that any of the currently pending or future patent applications will result in granted patents, nor can we predict how long it will take for such patents to be granted.

Our commercial success will depend in part on us obtaining and maintaining patent protection and trade secret protection of our current and future product candidates, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities and the right under our licensed patents to contest alleged infringement.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our owned or licensed intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid or unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make product candidates or develop a platform similar to, or better than, ours in a way that is not covered by the claims of our licensed or owned patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of patents we own or that are licensed to us;
- we or our prospective licensors or future collaborators might not have been the first to make the inventions covered by any pending patent applications issued patents that we own or license;
- we or our prospective licensors or future collaborators might not have been (or may not be in the future) the first to file patent applications for certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- our pending patent applications may not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable as a result of legal challenges by our competitors or others;
- our competitors might conduct R&D 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;
- any patents that we obtain, or are licensed to us, may not provide us with any competitive advantages or protection against competitors, or may be challenged by third parties;

- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or may in-license in the future will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;

- if we attempt to enforce our patents, a court may hold that our patents are not invalid, unenforceable or not infringed;

- we may not develop additional proprietary technologies that are patentable;

- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

- 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;

- we may be required to change, redesign or stop using trademarks, service marks, domain names, logos, trade names and other identifiers that we own or use to avoid infringing the rights of third parties;

- we may fail to adequately protect and police our trade secrets; or

- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Without patent protection on the composition of matter of our product candidates, our ability to assert our patents to stop others from using or selling our product candidates in a non-pharmaceutically acceptable formulation may be limited.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our product candidates or methods involving these candidates in parent patent applications. We may have to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in parent patent applications.

Moreover, it is possible that our pending patent applications will not result in granted patents, and even if such pending patent applications are granted as patents, they may not provide a basis for intellectual property protection of commercially viable products nor provide us with any competitive advantages. Further, it is possible that, for any of the patents that may be granted in the future, others will design around the patent rights or identify cancer treatment methods that do not concern the rights covered by our patent rights or licenses. Further, we cannot assure investors that other parties will not challenge any patents granted to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We also cannot guarantee that we will be successful in defending challenges made against our patents. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, or to such patents being interpreted narrowly or otherwise in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors may be diminished because of these uncertainties.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors or other third parties. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets may be expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business; we may in the future also license or purchase patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our technology and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

We cannot provide any assurances that any of our current or future patents have or will include claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its earliest U.S. non-provisional filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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 commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, owned by or co-owned with third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our R&D efforts in time to obtain any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our R&D efforts, including for example, our employees, former employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant or *inter partes* review, or interference proceedings or other similar proceedings challenging our patent rights or the patent rights of others in the USPTO or other foreign patent office. An unfavorable 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 products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts, and could increase our costs.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties allege they have patent rights encompassing our product candidates, technologies or methods.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If CER-1236 or another product candidate is cleared/approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any patent claims that could have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or 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 the product candidate unless we were to obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we were to obtain a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent of a third party. A finding of infringement could prevent us from commercializing our product candidates or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom-to-operate search or analysis for any of our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

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

Presently, we have rights to certain intellectual property, under issued patents that we own, including U.S. Patent No. 11,708,423 and EP Patent No. 3,519,441, which relate to CER-1236, as well as additional patents which relate to certain other product candidates. U.S. Patent Application Number 16/646,530 was allowed and later issued on July 25, 2023 as U.S. Patent Number 11,708,423. This patent provides coverage over our CER-1236 product candidate and includes claims directed to a CER comprising, at least in part, a Tim-4 phosphatidylserine binding domain and a TLR signaling domain. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain T cell constructs, we may not be able to obtain intellectual property rights to broader T cell or engineered T cell constructs.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antibodies that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a legal proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put one or more of our pending patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority or provenance of inventions with respect to our patents or patent applications or those of our prospective licensors. An unfavorable outcome could result in a loss of our current patent rights and 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 harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference or derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and patent agencies outside the United States in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents covering our product candidates, our competitors might be able to enter the market, which would harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in-licensed from a third party, any failure on our part to maintain the in-licensed rights could jeopardize our rights under the relevant license and may expose us to liability.

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

We may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

Issued patents covering our product candidates could be found unpatentable, invalid or unenforceable if challenged in court or the USPTO.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *inter partes* review, *ex parte* re-examination and post grant review in the United States, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation, including legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

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

We may not be able to protect our intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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 United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or 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 which we could expand to, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

In addition to seeking patent protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

Because we will rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use and disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint R&D programs may require us to share trade secrets under the terms of our R&D or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may not have sufficient patent lifespan to effectively protect our products and business.

All of our patents are in early stages. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its earliest U.S. non-provisional filing date. 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 the resulting products are commercialized. As a result, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. During the period of patent term extension, the claims of a patent are not enforceable for their full scope but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any comparable foreign regulatory authorities, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. The terms of our patents may also be affected by the filing of terminal disclaimers during prosecution before the USPTO and foreign authorities recognizing similar disclaimer mechanisms. A patent subject to a terminal disclaimer may have its term limited so that its lifespan does not extend beyond the term of a related patent having a shorter term. If any of the foregoing occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise have expected, and our competitors may obtain approval of and launch products earlier than might otherwise have been the case.

The life of patent protection is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly with us after a patent licensed to us expires, which could materially and adversely affect our ability to commercialize our products and technologies.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In Europe, the expiration of an invention patent is 20 years from its filing date. Even if we successfully obtain patent protection for an approved product candidate, it may face competition from biosimilar medications. Manufacturers of other drugs may challenge the scope, validity or enforceability of the patents underlying our technology in court or before a patent office, and the patent holder may not be successful in enforcing or defending those intellectual property rights and, as a result, we may not be able to develop or market the relevant product candidate exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, the patents or pending applications licensed to us may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that the patents involved are eligible for certain (and time-limited) patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to such patents, or may grant more limited extensions than requested. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested. If we are unable to obtain patent term extension or term of any such extension is less than requested, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The patent pending applications for our product candidates are expected to expire on various dates. Upon the expiration, we will not be able to assert such licensed patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Ownership of our Securities

Sales of a substantial number of our securities in the public market by our existing securityholders could cause the price of our Common Stock and Warrants to fall.

Sales of a substantial number of shares of our Common Stock in the public market could occur at any time (after the expiration of any applicable lock-up period, assuming the satisfaction of any applicable vesting conditions and subject to the beneficial ownership and stock exchange limitations described herein). These sales, or the perception in the market that the holders of a large number of shares of our Common Stock intend to sell shares, could increase the volatility of the market price of our Common Stock or result in a significant decline in the public trading price of our Common Stock.

The resale, or expected or potential resale, of a substantial number of shares of our Common Stock in the public market could adversely affect the market price for our Common Stock and make it more difficult for you to sell your holdings at times and prices that you determine are appropriate. Accordingly, the adverse market and price pressures resulting from an offering may continue for an extended period of time. Sales of substantial number of such shares in the public market could adversely affect the market price of our Common Stock.

We have filed (in each case, the share numbers set forth below have been adjusted for the Reverse Stock Split):

- a registration statement with the SEC for purposes of registering the resale from time to time of up to 2,100,000 Shares of Common Stock, which consists of (i) 2,086,357 shares of Common Stock under the New Keystone Purchase Agreement and (ii) 13,643 shares of Common Stock under the Old Keystone Purchase Agreement;

- a registration statement with the SEC for purposes of registering the resale from time to time of up to 266,191 Shares of Common Stock, which consists of (i) 250,000 Keystone Purchase Shares, (ii) 6,191 Keystone Commitment Shares, and (iii) 10,000 Arena Commitment Shares;

- a registration statement with the SEC for purposes of registering (1) the resale from time to time of up to 357,737 shares of Common Stock, which consists of (i) 20,557 shares of Common Stock issued to certain selling securityholders for their portion of the merger consideration in connection with the consummation of the Business Combination in exchange for shares of common stock of Legacy CERo; (ii) 200,800 shares of Common Stock issuable upon the conversion of shares of our Series A Preferred Stock, purchased by certain investors pursuant to the First Securities Purchase Agreement; (iii) 12,520 shares of Common Stock issuable upon the conversion of shares of our Series B Preferred Stock, purchased by certain investors pursuant to the Second Securities Purchase Agreement; (iv) 31,712 shares of Common Stock initially issued to the Sponsor and distributed to its members in a distribution-in-kind immediately prior to the Business Combination; (v) 10,000 shares of Common Stock issued to the Sponsor, which are subject to forfeiture upon the vesting of the Tertiary Earnout Shares; (vi) 1,850 shares of Common Stock issued to investors other than the Sponsor in a private placement concurrently with the Initial Public Offering; (vii) 16,495 shares of our Common Stock issued to certain third-party vendors and service providers; (viii) 3,250 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Common Stock that were converted from Legacy CERo warrants in connection with the Business Combination; (ix) 6,127 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Common Stock sold to certain investors pursuant to the First Securities Purchase Agreement; (x) 50,000 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Series A Preferred Stock sold to certain investors pursuant to the First and Second Securities Purchase Agreement and conversion of the underlying shares of Series A Preferred Stock into Common Stock and (xi) 4,425 shares of Common Stock issuable upon the exercise of Private Placement Warrants to purchase shares of our Common Stock, at an exercise price of $1,150.00 per share, that were originally sold in a private placement concurrently with the Initial Public Offering; and (2) the issuance by us of up to 87,500 shares of Common Stock issuable upon the exercise of public warrants to purchase shares of our Common Stock, at an exercise price of $1,150.00 per share, that were originally issued in the Initial Public Offering;

- a registration statement with the SEC for purposes of registering of the resale from time to time of up to 6,385,638 shares of Common Stock, which consists of (i) 576,710 shares of Common Stock issuable upon the conversion of shares of our Series A Preferred Stock purchased by certain investors pursuant to the First Securities Purchase Agreement; (ii) 91,829 shares of Common Stock issuable upon the conversion of shares of our Series B Preferred Stock purchased by certain investors pursuant to the Second Securities Purchase Agreement; (iii) 707,394 shares of Common Stock issued upon the conversion of shares of our Series A Preferred Stock and Series B Preferred Stock; (iv) 4,366,837 shares of Common Stock issuable upon the conversion of 300% of the number of outstanding shares of our Series C Preferred Stock purchased by certain investors pursuant to the Third Securities Purchase Agreement; (v) 2,500 shares of Common Stock issued to a stockholder in a reallocation of shares in connection with the consummation of the Business Combination; (vi) 81,752 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Common Stock, at an exercise price of $9.80 per share, which warrants were sold to certain investors pursuant to the Third Securities Purchase Agreement (the "Series C Warrants"); and (ii) 558,617 shares of Common Stock issuable upon the conversion of shares of Series A Preferred Stock resulting from the exercise of outstanding Preferred Warrants; and

- a registration statement with the SEC for the purposes of registering the primary issuance by the Company of (i) 300,000 shares of Common Stock (ii) 2,551,020 new common warrants to purchase up to an aggregate of 2,551,020 shares of our Common Stock and an aggregate of 2,551,020 shares of our Common Stock issuable upon exercise of the common warrants and (ii) Pre-Funded Warrants to purchase up to 2,251,020 shares of Common Stock, in lieu of shares of Common Stock.

In addition to any resales pursuant to such registration statements, subject to applicable transfer restrictions and the conditions to the availability of Rule 144 for former shell companies under Rule 144(i), shares of Common Stock held by these stockholders will be eligible for resale, potentially subject to, in the case of stockholders who are our affiliates, volume, manner of sale, and other limitations under Rule 144 promulgated under the Securities Act.

In addition, shares of our Common Stock issuable upon exercise or vesting of incentive awards under our incentive plans are, once issued, eligible for sale in the public market, subject to any lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144. Furthermore, shares of our Common Stock reserved for future issuance under our incentive plan may become available for sale in future.

The market price of shares of our Common Stock could drop significantly if the holders of the shares of Common Stock described above sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of shares of our Common Stock or other securities.

Most of our outstanding Common Warrants are "out-of-the-money." If the trading price of our Common Stock does not increase, the holders thereof will be unlikely to exercise such Common Warrants and we will not receive the proceeds of such exercises.

Holders of our Warrants will be less likely to exercise their Warrants if the exercise prices of their Warrants exceed the market price of our Common Stock. There is no guarantee that our Warrants will continue to be in the money prior to their expiration, and as such, the Warrants may expire worthless. As such, any cash proceeds that we may receive in relation to the exercise of the Warrants overlying shares of Common Stock being offered for sale in this Annual Report will be dependent on the trading price of our Common Stock. There is no assurance that the holders of the Warrants will elect to exercise any or all of such Warrants. As of the date of this Annual Report, (i) all of the Private Placement Warrants and Public Warrants, which have an exercise price of $1,150.00 per share, (ii) December 2024 Common Warrants, which have an exercise price of $5.61 per share, (iii) January 2025 Common Warrants, which have an exercise price of $5.82 per share, (iv) February 2025 Common Warrants to purchase shares of Common Stock, at a current exercise price of $1.96 per share issued by the Company in a public offering on February 7, 2025. and (v) all of the Series A Warrants, which have a current exercise price of $139.00 per share, are "out of the money," meaning the exercise price is higher than the market price of our Common Stock. Holders of such "out of the money" Warrants are not likely to exercise such Warrants. There can be no assurance that such Warrants will be in the money prior to their respective expiration dates, and therefore, we may not receive any cash proceeds from the exercise of such Warrants.

An active trading market for our Common Stock may not be available on a consistent basis to provide stockholders with adequate liquidity. The price of our Common Stock may be extremely volatile, and stockholders could lose all or part of their investment.

The trading price of our Common Stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "*Risk Factors*" section and elsewhere in this Annual Report, these factors include:

- the commencement, enrollment or results of any planned and future preclinical studies and clinical trials of our product candidates or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse results from or delays in preclinical studies and clinical trials of our product candidates, including as a result of clinical holds, safety events, enrollment difficulties, or study protocol amendments;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

- adverse regulatory decisions, including failure to receive regulatory approval of our drug to market for our product candidates;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved drug or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new drugs by our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- any significant change in our management;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC;
- publication of research reports about us or our industry, or microbiome therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- guidance, if any, that we provide to the public, any changes in this guidance or our failure to meet this guidance;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our Common Stock by us or our stockholders, in the future;
- trading volume of our Common Stock;
- investor perceptions of the investment opportunity associated with our Common Stock relative to other investment alternatives;

- actions by institutional or activist stockholders;
- change in accounting standards, policies, guidelines, interpretations or principles;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payments systems;
- issuance of additional shares of our Common Stock to comply with the full ratchet antidilution rights contained in our outstanding Warrants;
- failure to raise additional funds on acceptable terms, or at all;
- changes in business or regulatory conditions, including new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- general political, economic, industry and market conditions, including rising interest rates and inflation; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the markets for special purpose acquisition company post-business combination businesses and healthcare companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Stock, regardless of our actual operating performance. In addition, price volatility may be greater if the public float and trading volume of our Common Stock is low. If the market price of our Common Stock falls, you may not realize any return on your investment and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, higher interest rates and uncertainty about economic stability. For example, the Russia-Ukraine war and the Israel-Hamas war created volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain and energy markets. The imposition of tariffs by the United States on imports from Canada, China and Mexico and retaliatory tariffs or other actions by the governments of such countries have also created economic uncertainty and disruptions in the capital markets. There have also been disruptions to the U.S. banking system due to bank failures in the past several years, including with respect to Silicon Valley Bank, Signature Bank and First Republic Bank. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing its costs, including labor and employee benefit costs. In addition, higher inflation could also increase customers' operating costs, which could result in reduced budgets for customers and potentially less demand for our products, if and when approved. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition.

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our Common Stock. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of the market price (if any) of our stock.

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

We are an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements that are applicable to other public companies that are not emerging growth companies, including being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure, not being required to have its internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act ("Section 404"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until the last day of the fiscal year ending after the fifth anniversary of the consummation of our Initial Public Offering or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues equal or exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period prior to such time. In particular, in this Annual Report, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if it were not an emerging growth company, and it may elect to take advantage of other reduced reporting requirements in future filings. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of its financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this Annual Report may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our Common Stock less attractive as a result of these elections, which may result in a less active trading market for our Common Stock and higher volatility in its share price.

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

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

Our operations to date have been primarily limited to researching and developing our product candidates. We have not yet obtained regulatory approvals for any of its product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict future operating results. From time to time, we may enter into license or collaboration agreements 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. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our drugs, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in operating results from one period to the next.

In addition, our measurement of compensation cost for stock-based awards made to employees, directors and non-employee consultants is based on the fair value of the award on the grant date and we recognize the cost as an expense over the requisite service period or upon the completion of performance-based vesting terms, as applicable. Because the variables that we use as a basis for valuing stock-based awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, 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:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development;
- the timing and cost of, and level of investment in, R&D activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop product candidates;
- expenditures that our will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;

- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize product candidates outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

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

Anti-takeover provisions under our organizational documents and Delaware law could delay or prevent a change of control which could limit the market price of our Common Stock and may prevent or frustrate attempts by our stockholders to replace or remove our then-current management.

Our Charter and Bylaws, contain provisions that could delay or prevent a change of control of our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board of directors will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairperson of our board of directors, our Chief Executive Officer or by a majority of the total number of authorized 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 and subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, upon the approval of not less than two-thirds of all outstanding shares of our 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 or to amend specific provisions of our Charter; and
- the authority of the board of directors to issue preferred stock on terms determined by the 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, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our Charter or Bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our Common Stock to decline.

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

We intend to evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary drugs, 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 and drugs of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, 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 or 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, 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. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our Bylaws provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

The Charter provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us or any of our current or former directors, officers or other employees arising under the DGCL, the Charter, or the Bylaws;
- any action seeking to interpret, apply, enforce or determine the validity of this Charter or our Bylaws;
- any action as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, the Charter further provides that, unless we consent to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of the Charter. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in the Charter to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, or could result in increased costs for a stockholder to bring a claim, particularly if they do not reside in or near Delaware, both of which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in the Charter to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, results of operations, and financial condition.

As a public company, we are subject to the reporting requirements of the Exchange Act, the listing standards of Nasdaq, and other applicable securities rules and regulations. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly, and place significant strain on our personnel, systems and resources. For example, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, results of operations and financial condition. Although we have already hired additional employees to assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our operating expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest substantial resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business operations to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We also expect that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee (the "Audit Committee") and compensation committee, and qualified executive officers.

As a result of disclosure of information in the filings required of a public company, our business and financial condition will become more visible, which may result in an increased risk of threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, results of operations, and financial condition.

We have identified a material weakness in our internal control over financial reporting. If our remediation of such material weaknesses is not effective, or if we identify additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

We are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting. In 2026, five years after our Initial Public Offering, we may be required to comply with auditor attestation requirements, as required by Section 404. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

In preparing our accompanying consolidated financial statements, we identified a material weakness in our system of internal financial and accounting controls and procedures, as defined in the SEC guidelines for public companies. The material weakness identified relates to our conclusion that due to a lack of sufficient and qualified resources, we lack effective processes and controls to ensure the accuracy and completeness of our financial statements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. We continue to evaluate steps to remediate the material weakness. These remediation measures may be time consuming and costly and there is no assurance that these initiatives will ultimately have the intended effects.

Our control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our financial statements are not accurate, investors may not have a complete understanding of our operations. If we do not file financial statements on a timely basis as required by the SEC, we could face severe consequences. If we are unable to conclude that its internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our Common Stock could decline, and we could be subject to sanctions or investigations by the Nasdaq, the SEC or other regulatory authorities. Moreover, responding to such investigations are likely to consume a significant amount of our management resources and cause us to incur significant legal and accounting expenses. Failure to remedy any material weakness in internal control over financial reporting, or to maintain effective control systems, could also restrict our future access to the capital markets. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

As a public reporting company, we are subject to filing deadlines for reports that we file pursuant to the Exchange Act, and our failure to timely file such reports may have material adverse consequences on our business.

Following the consummation of the Business Combination, we failed to timely file our Form 8-K with Form 10 information prior to the "staleness" date (as determined in accordance with the applicable rules and regulations of the SEC) applicable to the financial statements that were required by the applicable accounting requirements and other rules and regulations of the SEC to be included in such filing (including pro forma financial information); thus, we have not remained current in our reporting requirements with the SEC since we became an SEC reporting company on February 14, 2024. Although we have since regained status as a current filer by filing a Form 8-K/A with current financial statements on April 1, 2024, we will not be eligible to use a registration statement on Form S-3 that would allow us to continuously incorporate by reference our SEC reports into the registration statement, or to use "shelf" registration statements to conduct offerings, until approximately one year from the date we regained (and maintain) status as a current filer. Until such time, if we determine to pursue an offering, we would be required to conduct the offering on an exempt basis, such as in accordance with Rule 144A, or file a registration statement on Form S-1. Using a Form S-1 registration statement for a public offering would likely take significantly longer than using a registration statement on Form S-3 and increase our transaction costs, and could, to the extent we are not able to conduct offerings using alternative methods, adversely impact our liquidity, ability to raise capital or complete acquisitions in a timely manner. The use of Form S-1 would also prevent us from conducting offerings on a "shelf basis," limiting our flexibility as to the terms, timing or manner of any such offering.

We cannot guarantee that in the future our reporting will always be timely. If we are unable to satisfy SEC filing deadlines or otherwise provide disclosures of material information on a timely basis, stockholders and potential investors in our Common Stock may have incomplete information about our business and results of operations, which may impact their ability to make an informed investment decision, result in a reduction in the trading price, trading volume or analyst coverage of our Common Stock or expose us to potential liability.

We could be subject to securities class action litigation.

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

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our Common Stock.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities.

On July 19, 2024, we received a letter (the "Bid Price Requirement Letter") from the staff at Nasdaq notifying us that, for the 30 consecutive trading days prior to the date of the Bid Price Requirement Letter, the closing bid price for the Common Stock has been below the minimum $1.00 per share required for continued listing on Nasdaq set forth in Nasdaq Listing Rule 450(a)(1), which is required for continued listing of the Common Stock on Nasdaq (the "Bid Price Requirement"). On October 23, 2024, the trading price for our Common Stock closed under $0.10 and was the tenth consecutive trading day to do so.

On October 24, 2024, we received a letter from the staff at Nasdaq notifying us that, because our Common Stock had a closing bid price of $0.10 or less for ten consecutive trading days, it was no longer eligible to rely upon the 180-day cure period set forth in the Bid Price Requirement Letter. In addition, on October 30, 2024, the Company received a letter from the staff at Nasdaq notifying the Company that it had not regained compliance with the continued listing requirement to maintain a minimum market value of $50,000,000 (the "MVLS Requirement") for its listed securities within the 180-day compliance period granted by Nasdaq in May 2024.

On July 19, 2024, we also received a letter (the "MVPHS Letter") from Nasdaq notifying the Company that the Market Value of Publicly Held Shares (the "MVPHS") of the Common Stock had been below the minimum of $15,000,000 for the last 30 consecutive business days prior to the date of the MVPHS Letter, which is required for continued listing of the Common Stock on Nasdaq (the "MVPHS Requirement").

Each of the Bid Price Requirement and MVLS Requirement (as defined below) deficiencies results in the commencement of delisting proceedings. However, we attended a hearing before a Nasdaq panel (the "Nasdaq Panel") on December 17, 2024, at which we submitted a plan to regain compliance with the listing requirements. On January 17, 2025, the Nasdaq Panel granted the Company's request for an extension of the deadline for regaining compliance with Nasdaq listing requirements to April 22, 2025, subject to certain conditions (the "Nasdaq Conditions"). Pursuant to the Nasdaq Conditions, the Company shall demonstrate compliance with the Bid Price Requirement and apply to transfer its listing to the Nasdaq Capital Market on or prior to January 22, 2025. The Company is also required to satisfy the $2.5 million stockholders' equity requirement of the Nasdaq Capital Market on or prior to April 22, 2025, submit certain plans to Nasdaq and make certain disclosures.

On February 12, 2025, we received a letter from the Nasdaq confirming that we have regained compliance with the Bid Price Requirement and we have been moved to the Nasdaq Capital Market, as required by the Nasdaq Panel.

Regaining compliance with the Bid Price Requirement is one of the conditions set forth by the Nasdaq Panel in its previously disclosed decision granting our request for an extension to regain compliance with certain Nasdaq continued listing requirements until April 22, 2025. We continue to make progress towards satisfaction of the other conditions. Nevertheless, as of the date of this Annual Report, the trading price of our Common Stock is below the Bid Price Requirement and we have not satisfied the $2.5 million stockholder's equity requirement. We cannot assure you that we will obtain compliance with these requirements in a timely manner, or at all.

Nevertheless, if the Company is unable to satisfy the Nasdaq Conditions, it is likely that the Company's securities would be delisted. In addition, if we fail to comply with the Bid Price Requirement at any time prior to the first anniversary of the Reverse Stock Split, we will be ineligible for a 180-day compliance period during which we would otherwise be able to seek to regain compliance by soliciting stockholder approval for another reverse stock split. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, any action taken by us to restore compliance with listing requirements may not allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the Nasdaq minimum share price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from Nasdaq for any reason, and are quoted on the over-the-counter bulletin board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our Common Stock share price and trading volume could decline.

The trading market for our Common Stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If few or no securities or industry analysts cover us, the trading price for our Common Stock would likely be negatively impacted. If one or more of the analysts who cover us downgrade our Common Stock or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Common Stock could decrease, which might cause our share price and trading volume to decline.

Future sales of our Common Stock, or the perception that future sales may occur, may cause the market price of our Common Stock to decline, regardless of our operating performance.

Sales of a substantial number of our shares of Common Stock and/or Public Warrants in the public market by our existing securityholders, or the perception that those sales might occur, could depress the market price of our shares of Common Stock and Public Warrants and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our shares of Common Stock and Public Warrants. Furthermore, the sale of a substantial number of shares of Common Stock pursuant to the registration statements we have filed with the SEC, or the perception that such sale may occur, may materially and adversely affect the prevailing market price of our Common Stock and thus restrict the amount we are able to raise in an equity offering, or require us to issue and sell more Common Stock to generate the same amount of gross proceeds than we would otherwise have had to, which would result in greater dilution to our existing stockholders. We expect that because there is a large number of shares registered pursuant to such registration statements, the holders thereunder will continue to offer the securities covered thereby for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures and constraint on our ability to raise additional capital resulting from the shares registered hereunder may continue for an extended period of time.

Our Warrants are exercisable for Common Stock, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

As of April 11, 2025, there were (i) Series A Warrants to purchase 6,127 shares of Common Stock at an exercise price of $139.00 per share; (ii) Series C Warrants to purchase 81,753 shares of Common Stock at an exercise price of $0.04 per share; (iii) December 2024 and January 2025 Common Warrants to purchase an aggregate of 247,914 shares of Common Stock at an exercise price ranging from $5.61 to $5.82, (iv) February 2025 Common Warrants to purchase an aggregate of 2,551,020 shares of Common Stock at an exercise price of $1.96, (v) Pre-Funded Warrants to purchase an aggregate of 215,740 shares of Common Stock at an exercise price of $0.0001, and (vi) Public Warrants and Private Placement Warrants to purchase an aggregate of 91,925 shares of Common Stock at an exercise price of $1,150.00 per share. To the extent such warrants are exercised, additional shares of our Common Stock will be issued, which will result in dilution to the holders of our Common Stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our Common Stock, the impact of which increases as the value of our stock price increases.

Our Earnout Shares are accounted for as liabilities and the changes in value of such shares could have a material effect on, or cause volatility in, our financial results.

We evaluated the accounting treatment of our Earnout Shares subject to forfeiture if the applicable conditions to transferability thereof are not satisfied and determined to classify such shares as liabilities measured at fair value. The fair value of such shares is remeasured on a quarterly basis over the earn-out period with changes in the estimated fair value recorded in Other income (expense) on the consolidated statement of operations. Due to the recurring fair value measurement, we expect that we will recognize non-cash gains or losses on our Earnout Shares each reporting period and that the amount of such gains or losses could materially impact or cause volatility in our financial results.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have implemented risk management procedures, which include cybersecurity risk management, that are designed to define our corporate risk tolerance and align assumed risks to that tolerance through risk identification, prioritization, assessment, mitigation and planned responses if risk is realized. These elements are applied to cybersecurity as well as other origins of risk.

Our cybersecurity risk management procedures are designed to address four key areas:

- Identification of assets at risk from cybersecurity threats
- Identification of potential sources of cybersecurity threats
- Assessment of the status of protections in place to prevent or mitigate cybersecurity threats
- Given that landscape, how to manage cybersecurity risks

Our risk assessment and mitigation procedures are centered on three key components:

- identification of risks, which involved input from different groups across our company;
- evaluation of the likelihood of the risks manifesting, the severity of the potential consequences and prioritization of different risk items based on, among other things, importance to the business and cost/benefit analysis to fully address; and
- execution - establishment of a program to address.

Our information technology (the "Information Technology Team") is responsible for monitoring our information systems for vulnerabilities and mitigating any issues. It works with others within our company to understand the severity of the potential consequences of a cybersecurity incident and to make decisions about how to prioritize mitigation and other initiatives based on, among other things, materiality to the business. The Information Technology Team has processes designed to keep us apprised of the different threats in the cybersecurity landscape - this includes working with consultants, discussions with peers at other companies, and reviewing government alerts and other news items. The team also regularly monitors our network(s) to identify security risks.

We have an employee education program that is designed to raise awareness of cybersecurity threats to reduce our vulnerability as well as to encourage consideration of cybersecurity risks across functions.

We monitor risks through active (e.g., vulnerability scans) and passive (e.g., end-point protection) methods and addresses system alerts on a constant basis.

As part of the assessment of the protections we have in place to mitigate risks from cybersecurity threats, we engage third parties to conduct risk assessments on our systems.

Before purchasing third-party technology or other solutions that involve exposure to our assets and electronic information, our Information Technology Team performs a review on vendors (evaluating suitability, risk, and impact) before they are approved to work with us.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party vendors have, from time to time, experienced threats and security incidents relating to our and our third-party vendors' information systems. See Item 1A "Risk Factors" in this Annual Report on Form 10-K for more information.

Cybersecurity Governance

Our board of directors has delegated oversight of our enterprise risk management processes, including those relating to cybersecurity risks, to the Audit Committee. Our Chief Financial Officer meets on a periodic basis with the Audit Committee to discuss management's ongoing cybersecurity risk management procedures. Such discussions address, among other things, the sources and nature of cyber-security risks we face, how management assesses likelihood and severity of the impact of such risks, and progress on any active projects as well any current developments in the cybersecurity landscape. At the Audit Committee's discretion, material findings may be escalated to the entire board of directors. The chair of the Audit Committee is a Chief Financial Officer with existing cyber-security and risk management responsibilities at a similar public company.

Item 2. Properties.

We do not own any real estate or other physical properties. We currently maintain our executive office in approximately 12,000 square feet of office and laboratory space in a multi-tenant building at 201 Haskins Way in South San Francisco, California. The lease for our headquarters expires on September 30, 2026. We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. To the knowledge of our management, there is no material litigation, arbitration or governmental proceeding currently pending against us or any members of our management team in their capacity as such.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our Common Stock and Public Warrants are traded on Nasdaq under the symbols "CERO" and "CEROW," respectively.

Stockholders

As of April 11, 2025, the numbers of record holders of our Common Stock and Public Warrants were 131 and 32, respectively, not including beneficial holders whose securities are held in street name.

Dividends

We have never declared or paid cash dividends on our capital stock. We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt, issued preferred securities, or any credit facility agreements.

Securities Authorized for Issuance under Equity Compensation Plans

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

Recent Sales of Unregistered Equity Securities

In February 2024, May 2024 and August 2024, we issued 1,191, 2,504, and 16,139 shares of Common Stock, respectively, to an investor as commitment shares in consideration for entering into an equity line of credit with us. The issuance of these securities was made pursuant to Section 4(a)(2) of the Securities Act, and the rules promulgated thereunder, to an accredited investor. As of the date of this Annual Report, we have issued an aggregate of 744,118 shares of Common Stock to such investor pursuant to the equity line of credit.

In February 2024, we issued an aggregate of 10,039 shares of Series A Preferred Stock, at a price of $1,000 per share, initially convertible into 10,039 shares of Common Stock at $10.00 per share, and 2,500 Preferred Warrants, resulting in aggregate consideration to us of approximately $10.0 million. Such issuance includes 2,185 shares of Series A Preferred Stock, initially convertible into 2,185 shares of Common Stock, that were issued to certain investors in exchange for consideration consisting of approximately $2.16 million aggregate outstanding principal amount, together with accrued and unpaid interest thereon of approximately $0.02 million, of certain convertible promissory notes issued in June 2023 by Legacy CERo and a promissory note issued in December 2022, as amended in December 2023, by PBAX. As additional consideration to certain investors, we also issued 6,127 Series A Warrants as a structuring fee. In March 2024, with the consent of the applicable investors, a portion of the shares of Series A Preferred Stock and Series A Warrants transferred to the purchasers of Series B Preferred Stock described below.

In March 2024, we issued an aggregate of 626 shares of Series B Preferred Stock, at a price of $1,000 per share, initially convertible into 626 shares of Common Stock at $1,000.00 per share, resulting in aggregate gross proceeds to us of approximately $0.5 million.

In May 2024, we issued 3,456 shares of Common Stock to an investor as commitment shares in consideration for entering into an equity line of credit with us. The issuance of these securities was made pursuant to Section 4(a)(2) of the Securities Act, and the rules promulgated thereunder, to an accredited investor.

In September 2024, we issued an aggregate of 2,853 shares of Series C Preferred Stock, at a price of $1,000 per share, and 81,753 shares of Series C Warrants, resulting in aggregate gross proceeds to us of approximately $1.25 million.

In December 2024, we issued warrants to purchase an aggregate of 84,061 shares of Common Stock, with an exercise price of $5.61 per share, which was the closing price of the Common Stock on Nasdaq on December 20, 2024 (as adjusted for the Reverse Stock Split), to certain institutional investors. Such shares were issued in reliance upon the exemption from registration set forth in Section 4(a)(2) of the Securities Act.

The issuance of these securities was made pursuant to 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D, and the rules promulgated thereunder, to accredited investors.

Use of Proceeds from Registered Offerings

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [RESERVED]

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

The following discussion and analysis of CERo's financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the notes related thereto which are included in Item 8 of this Annual Report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under "*Cautionary Note Regarding Forward-Looking Statements*," "*Risk Factors*" and elsewhere in this Annual Report.

Overview

CERo Therapeutics, Inc. (the "Predecessor") was incorporated in Delaware on September 23, 2016, and is based in South San Francisco, California. Predecessor was focused on developing its therapeutic platform to genetically engineer human immune cells to fight cancer and did not begin clinical development or product commercialization. The Company's efforts will focus on continued product development, including clinical development, to support regulatory approval to commercialize and subsequent product commercialization.

On June 4, 2023, Predecessor entered into a Business Combination Agreement (as amended by that certain Amendment No. 1 to the Business Combination Agreement, dated as of February 5, 2024 and Amendment No. 2 to the Business Combination Agreement, dated as of February 13, 2024, the "Business Combination Agreement") by and among PBAX and PBCE Merger Sub, Inc., pursuant to which Merger Sub merged with and into Predecessor, with Predecessor surviving as a wholly-owned subsidiary of PBAX (the "Merger"). In connection with the consummation of the Business Combination on February 14, 2024, PBAX changed its corporate name to "CERo Therapeutics Holdings, Inc."

At the effective time of the Merger, (i) each outstanding share of Predecessor common stock, was cancelled and converted into the right to receive shares of Common Stock; (ii) each outstanding option to purchase Predecessor common stock was converted into an option to purchase shares of Common Stock, par value $0.0001 per share; (iii) each outstanding share of Predecessor preferred stock, was converted into the right to receive shares of Common Stock, and (iv) each outstanding warrant to purchase Predecessor preferred stock was converted into a warrant to acquire shares of Common Stock. In addition, each outstanding Predecessor convertible bridge note was exchanged for shares of Series A Preferred Stock.

In addition, the holders of Predecessor common stock and Predecessor preferred stock have the contingent right to receive the Earnout Shares. At the Closing, the Company issued three pools of shares of Common Stock subject to forfeiture if the applicable conditions to transferability thereof are not satisfied: (i) 12,000 shares of Common Stock (giving retroactive effect to the Reverse Stock Split), which will be fully vested upon the achievement of certain adjusted stock price-based earnout targets or upon a qualifying transaction (ii) 8,750 shares of Common Stock (giving retroactive effect to the Reverse Stock Split), pursuant to a Letter Agreement, dated as of February 14, 2024 which were fully vested at Closing of the Merger and which were issued as an offset to the Sponsor Share Forfeiture Agreement, and (iii) 10,000 shares of Common Stock (giving retroactive effect to the Reverse Stock Split), which were fully vested upon the June 28, 2024 achievement of certain regulatory milestone-based earnout targets.

As consideration for the Merger, the Company issued to Predecessor stockholders an aggregate of 84,483 shares of Common Stock, including 22,000 Earnout Shares and 3,733 shares issuable upon exercise of rollover options or warrants (giving retroactive effect to the Reverse Stock Split).

Going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its R&D activities and meet its obligations on a timely basis. As of December 31, 2024, the Company reported $3.3 million of cash and cash equivalents, with an accumulated deficit of $70.9 million. On February 5, 2025, the Company entered into a securities purchase agreement (the "SPA"), with participation from a member of the Board and a single institutional investor, for the purchase and sale of (i) 2,551,020 shares of Common Stock or Common Stock equivalents in lieu thereof; and (ii) February 2025 Common Warrants to purchase up to 2,551,020 shares of Common Stock at an exercise price of $1.96. In connection with such offering, the Company received net proceeds of approximately $4.5 million. Additionally, since December 31, 2024, the Company received net proceeds from the exercise of the remaining Series A Warrants, the collection of subscriptions receivable and equity line of credit fundings of approximately $2.5 million. Additional funds are necessary to maintain current operations and to continue R&D activities. However, there can be no assurance that sufficient funding will be available to allow the Company to successfully continue its R&D activities and planned regulatory filings with the FDA. If the Company is unable to obtain the necessary funds, significant reductions in spending and the delay or cancellation of planned activities may be necessary. These actions would have a material adverse effect on the Company's business, results of operations, and prospects. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these accompanying financial statements are issued. The accompanying financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Recent Developments

Reverse Stock Split

At 12:01 a.m. Eastern time on January 8, 2025, we effected the Reverse Stock Split pursuant to which each 100 shares of our Common Stock outstanding immediately prior thereto was converted into 1 share of our Common Stock outstanding immediately thereafter.

February 2025 Offering

On February 7, 2025, we closed our reasonable best efforts public offering, with participation from a member of our board of directors and a single institutional investor, for the purchase and sale of (i) 2,551,020 shares of Common Stock or common stock equivalents in lieu thereof; and (ii) February 2025 Common Warrants to purchase up to 2,551,020 shares of common stock, at a combined public offering price of $1.96 per share and warrant. In connection with the offering, on February 5, 2025, we entered into the SPA with the investors. Such transaction is referred to as the "February 2025 Offering." The shares of Common Stock and the Warrants described above and the shares of Common Stock underlying the Warrants were offered pursuant to the Registration Statement on Form S-1 (File No. 333-284007), as amended, which was declared effective by the Securities and Exchange Commission on February 5, 2025. In connection with this offering, we received net proceeds of approximately $4.5 million.

Investigational New Drug Application Submission

On June 28, 2024, the Company submitted an Investigational New Drug Application ("IND") for its product candidate, CER-1236, to FDA. On July 26, 2024, the Company was informed by the FDA that it has placed a clinical hold on the IND. The FDA indicated that the clinical hold has been placed as a result of insufficient data provided with regard to two issues within pharmacology and toxicology of CER-1236. The FDA indicated that, within 30 calendar days, it would provide a detailed official hold letter and requested that the Company hold its response until after receipt of such letter (the "Hold Letter").

The Company received the Hold Letter on July 26, 2024 and submitted a complete response letter to the FDA on October 21, 2024 in which the Company requested a meeting to address the FDA's questions.

On November 15, 2024, the Company received notice from the FDA that the IND for CER-1236 was cleared. The Company currently anticipates beginning clinical trials in the first half of 2025. We submitted a second IND application for the investigation of CER-T cell therapy in NSCLC and ovarian cancer, which was accepted by the FDA on March 27, 2025.

Nasdaq Notices of Non-compliance and Nasdaq Panel Decision

On July 19, 2024, the Company received a letter (the "Bid Price Requirement Letter") from the staff at The Nasdaq Global Market notifying the Company that, for the 30 consecutive trading days prior to the date of the Bid Price Requirement Letter, the closing bid price for the Common Stock had not been in compliance with the Bid Price Requirement. On October 23, 2024, the trading price for CERo common stock closed under $0.10 and was the tenth consecutive trading day to do so. On October 24, 2024, the Company received a letter from the staff at The Nasdaq Global Market notifying the Company that, because its Common Stock had a closing bid price of $0.10 or less for ten consecutive trading days, it was no longer eligible to rely upon the 180-day cure period set forth in the Bid Price Requirement Letter.

On July 19, 2024, the Company also received the MVPHS Letter notifying the Company that, for the 30 consecutive trading days prior to the date of the MVPHS Letter, the Common Stock had not been in compliance with the MVPHS Requirement.

Such letters are in addition to the letter from The Nasdaq Global Market received by the Company on May 2, 2024 (the "MVLS Letter" and, together with the Bid Price Requirement Letter and the MVPHS Letter, the "Letters") notifying the Company that, for the 30 consecutive trading days prior to the date of such MVLS Letter, the Common Stock had traded at a value below the minimum $50,000,000 "Market Value of Listed Securities" ("MVLS") requirement set forth in Nasdaq Listing Rule 5450(b)(2)(A), which is required for continued listing of the Common Stock on The Nasdaq Global Market (the "MVLS Requirement"). On October 30, 2024, the Company received a letter from the staff at The Nasdaq Global Market notifying the Company that it had not regained compliance with the MVLS Requirement within the 180-day compliance period set forth in the MVLS Letter.

Each of the Bid Price Requirement and MVLS Requirement deficiencies results in the commencement of delisting proceedings. However, the Company attended a hearing before the Nasdaq Panel on December 17, 2024, at which the Company submitted a plan for regaining compliance. Notwithstanding that applicable Nasdaq rules provide a 180-day compliance period to regain compliance with the MVPHS Requirement, the plan submitted by the Company in connection with such hearing, as required by applicable Nasdaq requirements, demonstrated a pathway to compliance with all applicable deficiencies.

On January 17, 2025, the Nasdaq Panel granted the Company's request for an extension of the deadline for regaining compliance with Nasdaq listing requirements to April 22, 2025, subject to Nasdaq Conditions. Pursuant to the Nasdaq Conditions, the Company shall demonstrate compliance with the Bid Price Requirement and apply to transfer its listing to the Nasdaq Capital Market on or prior to January 22, 2025. The Company is also required to satisfy the $2.5 million stockholders' equity requirement of the Nasdaq Capital Market on or prior to April 22, 2025, submit certain plans to Nasdaq and make certain disclosures.

On February 12, 2025, we received a letter from Nasdaq confirming that we have regained compliance with the Bid Price Requirement and we have been moved to the Nasdaq Capital Market, as required by the Nasdaq Panel.

Regaining compliance with the Bid Price Requirement is one of the conditions set forth by the Nasdaq Panel in its previously disclosed decision granting our request for an extension to regain compliance with certain Nasdaq continued listing requirements until April 22, 2025. We continue to make progress towards satisfaction of the other conditions. Nevertheless, as of the date of this Annual Report, the trading price of our Common Stock is below the Bid Price Requirement and we have not satisfied the $2.5 million stockholder's equity requirement. We cannot assure you that we will obtain compliance with these requirements in a timely manner, or at all.

Warrant Issuances

On December 23, 2024, the Company issued warrants to purchase an aggregate of 84,061 shares of Common Stock, with an exercise price of $5.61 per share, which was the closing price of the Common Stock on Nasdaq on December 20, 2024, to certain institutional investors as a condition to the exercise of Preferred Warrants held thereby. On January 6, 2025, the Company issued additional warrants to purchase an aggregate of 163,853 shares of Common Stock, with an exercise price of $5.82 per share, which was the closing price of the Common Stock on Nasdaq on January 3, 2025, to an institutional investor as a condition to the exercise of Preferred Warrants held thereby. Such number of shares gives effect to the Reverse Stock Split.

Results of Operations

Revenue

Predecessor and the Company have not recognized any revenue from any sources, including from product sales, and the Company does not expect to generate any revenue from the sale of products in the foreseeable future. If the development efforts for the Company's product candidates, each of which is a specific product and indication combination, are successful and result in regulatory approval, or if the Company executes license agreements with third parties, the Company may generate revenue from R&D services, from the achievement of development milestones or from milestones and royalties related to product sales. However, there can be no assurance as to when any revenues will be generated, if at all.

Operating Expenses

Research and Development Expenses

R&D expenses consist of discovery activities, manufacturing development and production, preclinical and clinical development, and regulatory filing for product candidates. R&D expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in R&D are capitalized until the goods or services are received. Costs incurred in obtaining technology licenses through asset acquisitions, if incurred, will be charged to R&D expense if the licensed technology has not reached technological feasibility and has no alternative future use. R&D expenses include or could include:

- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation and other related costs for those employees involved in R&D efforts;

- external R&D expenses incurred under agreements with preclinical research organizations, clinical research organizations, investigative sites, centralized clinical laboratories, and consultants to conduct preclinical and clinical studies;
- costs related to manufacturing material for preclinical studies and clinical trials, including fees paid to contract development and manufacturing organizations;
- product-liability insurance for clinical development product(s);
- laboratory supplies and research materials;
- software and systems related to R&D activities;
- costs related to regulatory filing and compliance; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, and equipment.

Product candidates in later stages of development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. The Company plans to substantially increase its R&D expenses for the foreseeable future as it continues the development of its product candidates through clinical development. The Company cannot determine with certainty the timing of initiation, the duration or the costs of current or future preclinical studies and clinical trials required for regulatory approval due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. The Company anticipates that it will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and ongoing assessments as to each product candidate's commercial potential. The Company will need to, and plans to, raise substantial additional capital in the future. Future R&D expenses may vary significantly between periods and from current expectations based on factors such as:

- expenses incurred to conduct preclinical studies required to advance product candidates into clinical trials;
- per patient clinical trial costs based on a number of factors, including number of patient clinical visits, clinical laboratory testing, and potential medical imaging;
- the number of clinical trials required for approval, the number of patients who enroll in each clinical trial, and the number and geographic locations of sites included in the clinical trials;
- the length of time required to screen and enroll eligible patients, screen-failure rate, or the discontinuation rates of enrolled patients;
- potential additional safety monitoring requested by regulatory agencies;
- the cost of insurance, including product liability insurance, in connection with clinical trials; and
- suspension or termination of clinical development activities by regulators or institutional review boards for various reasons, including regulatory noncompliance or a finding that the participants are being exposed to unacceptable health risks.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and administrative functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include professional fees for legal, accounting and tax-related services, consulting fees, insurance costs, and investor relations fees.

The Company anticipates that its general and administrative expenses will increase in the future as the Company increases headcount and contracted services for operational support for expanded operations and infrastructure. The Company also anticipates that general and administrative expenses will increase as a result of expenses for accounting, audit, legal and consulting services, as well as costs associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company.

Other Income, Net

Other income, net consists predominantly of interest income from interest bearing bank accounts, interest expense on payables, gains recorded on settlements reached with vendors on payables, and the gain or loss on the revaluation of earnout and derivative liabilities, which represents the change in fair value of earnout liabilities or outstanding warrants between periods.

Results of Operations for the years ended December 31, 2024 and 2023

The Results of Operations for year ended December 31, 2024 are *pro forma* as the period presented in the following table and discussion includes the Predecessor for the period from January 1, 2024 through February 13, 2024 and the Company for the period from February 14, 2024 through December 31, 2024. This pro forma period from January 1, 2024 to December 31, 2024 does not include the Merger transactions that occurred on-the-line.

	For the Years Ended December 31,			
	2024 (*Pro forma*) (Predecessor and Successor)	2023 (Predecessor)	Difference	Percentage Change
Operating expenses:				
Research and development	$ 7,079,744	$ 5,288,580	$ 1,791,164	33.9%
General and administrative	9,118,292	2,386,469	6,731,823	282.1%
Total operating expenses	16,198,036	7,675,049	8,522,987	111.0%
Loss from operations	(16,198,036)	(7,675,049)	(8,522,987)	111.0%
Other income (expense):				
Gain from settlement of liabilities with vendor	3,339,223	8,144	3,331,079	40,902.2%
Other expense	(672,378)	(62,182)	(610,196)	981.3%
Change in fair value of derivative liabilities and earnout liabilities	5,200,117	301,170	4,898,946	1,626.6%
Interest income, net	26,651	138,340	(111,689)	(80.7)%
Total other income, net	7,893,613	385,472	7,508,140	1,947.78%
Net loss	(8,304,423)	(7,289,577)	(1,014,846)	13.9%
Deemed dividend	(2,784,839)	-	(2,784,839)	-
Net loss attributable to common stockholders	$ (11,089,262)	$ (7,289,577)	$ (3,799,686)	52.1%

General and Administrative Expenses

General and administrative expenses were $9.1 million for the year ended December 31, 2024, compared to $2.4 million for the year ended December 31, 2023, reflecting an increase of $6.7 million. The increase in the year ended December 31, 2024, over the year ended December 31, 2023, was partially due to a $1.8 million expense consisting of the remaining underwriting fees from the PBAX initial public offering, which were earned on the consummation of the business combination. Additionally, the hiring of senior management in G&A resulted in an increase of $2.0 million, including recruiting fees. Legal fees increased $1.0 million and business consulting increased $0.8 million in the year ended December 31, 2024, versus the year ended December 31, 2023. Expenses related to services required for SEC compliance, such as printing and transfer agency fees, increased $0.5 million and public company insurance coverage increased insurance expenses $0.5 million in the year ended December 31, 2024, compared to the year ended December 31, 2023. Corporate communications and director fees each increased $0.2 million in the year ended December 31, 2024 compared to the year ended December 31, 2023. The additional expenses are all driven by the increased expenses of operational compliance as a public company.

Research and Development Expenses

Research and development expenses were $7.6 million for the year ended December 31, 2024, compared to $5.3 million for the year ended December 31, 2023, reflecting an increase of $1.8 million. The increase was related to increased R&D activity as the Company prepared and filed the IND for CER-1236, prepared for the clinical trial initiation, and conducted additional experiments in response to the FDA questions related to the IND. Clinical expenses increased $0.2 million, and scientific consulting expenses increased $1.2 million in the year ended December 31, 2024, due to activities related to the preparation of the IND and responses to questions from the FDA, and preparation for the anticipated clinical trial for CER-1236. Additional studies required to address FDA questions increased preclinical study costs by $0.3 million.

The Company anticipates that its R&D expenses will significantly increase in the future as the Company increases headcount, compensation expense, and contracted services for preclinical and clinical development of its product candidates, as well as for manufacturing of clinical product to be used in clinical development.

Other Income, Net

Other income was $7.9 million for the year ended December 31, 2024, compared to $0.4 million for the year ended December 31, 2023, reflecting an increase of $7.5 million. The increase in 2024 as compared to 2023 was primarily due to the $4.8 million positive change in value of the Company's earnout liability and the $0.4 million gain recorded for the change in value of the Predecessor's preferred stock warrant liability in the year ended December 31, 2024. Additionally, settlement of vendor liabilities in 2024 resulted in a $3.3 million increase in other income in 2024. This other income was offset by an increase in other expenses attributable to an increase in registration and other penalties of $0.6 million and a decrease in interest income of $0.1 million.

Net loss and net loss attributable to common stockholders

For the years ended December 31, 2024 and 2023, net loss amounted to $8.3 million and $7.3 million, respectively, an increase of $1.0 million, or 13.9%. During 2024, in connection with our Series A and Series B preferred stock conversions and the repricing of Series A Warrants, we recorded a deemed dividend of $2.8 million. Accordingly, for the years ended December 31, 2024 and 2023, net loss attributable to common stockholders amounted to $11.1 million, or $(19.14) per common share, and $7.3 million, or $(97.90) per common share, respectively.

Liquidity and Capital Resources

Capital Requirements

Predecessor and the Company have not generated any revenue from any source and the Company does not expect to generate revenue for at least the next few years. If the Company fails to complete the timely development of, or fails to obtain regulatory approval for, its product candidates, the ability of the Company to generate future revenue will be adversely affected. The Company does not know when, or if, it will generate any revenue from its product candidates, and does not expect to generate revenue unless and until the Company obtains regulatory approval and commercialization of its product candidates.

The Company expects its expenses to increase significantly in connection with its ongoing activities, particularly as it continues and expands research, preclinical development, and clinical development to support marketing approval for its product candidates. In addition, if the Company obtains approval for any of its product candidates, the Company expects to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, the Company expects to incur additional costs associated with operating as a public company.

The Company, therefore, anticipates that substantial additional funding will be needed in connection with its continuing operations. At December 31, 2024, the Company had $3.3 million in cash and cash equivalents. The Company intends to devote most of the available cash to the preclinical and clinical development of its product candidates and public company compliance costs. Based on current business plans, the Company believes that the cash available at December 31, 2024 will not fund its operations and capital requirements for 12 months after the filing of the audited financial statements for the year ended December 31, 2024. The Company has arranged two equity lines of credit, one providing for the sale of up to 25,000,000 newly issued shares of Common Stock and the other providing for the purchase of up to $25 million of Common Stock on the satisfaction of certain conditions. The Company has no guarantee that the conditions will be satisfied to require the purchase of all, or any additional amount, of the ELOC funds. On February 5, 2025, the Company entered into the SPA, with participation from a member of the Company's Board and a single institutional investor, for the purchase and sale of (i) 2,551,020 shares of our common stock or common stock equivalents in lieu thereof; and (ii) February 2025 Common Warrants to purchase up to 2,551,020 shares of common stock, at a combined public offering price of $1.96 per share and warrant. In connection with this offering, the Company received net proceeds of approximately $4.5 million. Additionally, since December 31, 2024, the Company received net proceeds from the exercise of the remaining Series A Preferred Warrants, the collection of subscriptions receivable and ELOC fundings of approximately $2.5 million. Any estimate as to how long the Company expects the net proceeds from the ELOC funding may fund the Company's operations is based on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than its current expectations. Changing circumstances, some of which may be beyond the Company's control, could result in less cash and cash equivalents available to fund operations or cause the Company to consume capital significantly faster than currently anticipated, and the Company may need to seek additional funds from additional sources sooner than planned.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drug products, the Company is unable to estimate the exact amount of its operating capital requirements. The Company's future funding requirements will depend on many factors, including, but not limited to those listed under "Factors Affecting Our Performance" above.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and the Company may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, the Company's product candidates, if approved, may not achieve commercial success. Commercial revenues, if any, will be derived from sales of product candidates that the Company does not expect to be commercially available in the near term, if at all. Accordingly, the Company will need to continue to rely on additional financing to achieve its business objectives. Adequate additional financing may not be available to the Company on acceptable terms, or at all. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the terms of these equity securities or this debt may restrict the Company's ability to operate. Any future debt financing and equity financing, if available, may involve covenants limiting and restricting the ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If the Company raises additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, it may be required to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to the Company. If the Company is unable to raise capital when needed or on acceptable terms, the Company could be forced to delay, reduce or eliminate its R&D programs or future commercialization efforts.

Cash Flows

	For the Years Ended December 31,		
	2024 (*Pro forma,* Predecessor and Successor)	2023 (Predecessor)	Difference
Net cash used in operating activities	$ (12,915,969)	$ (5,789,987)	$ (7,125,982)
Net cash provided by financing activities:	13,727,634	571,678	13,155,956
Net increase (decrease) in cash and cash equivalents	$ 811,665	$ (5,218,309)	$ 6,029,974

Net cash used in operating activities

Net cash used in operating activities for the year ended December 31, 2024 primarily reflected a net loss of $8.3 million, adjusted for the reconciliation of non-cash items such as a gain on of the settlement of vendor liabilities of $3.3 million, depreciation expense of $0.4 million, stock-based compensation of $0.9 million, amortization of right-of-use asset of $0.7 million and a gain on revaluation of derivative and earnout liabilities of $5.2 million, and changes in operating asset and liabilities primarily consisting of an increase in prepaid expenses and other current assets of $0.1 million, an increase in accounts payable of $0.2 million, an increase in accrued liabilities of $2.3 million, and a decrease in operating lease liabilities of $0.8 million.

Net cash used in operating activities for the year ended December 31, 2023 primarily reflected a net loss of $7.3 million, adjusted for the reconciliation of non-cash items such as depreciation expense of $0.5 million, stock-based compensation of $0.1 million, amortization of right-of-use asset of $0.7 million and a gain on revaluation of the preferred stock warrant liability of $0.3 million, and changes in operating asset and liabilities primarily consisting of an increase in prepaid expenses and other current assets of $0.1 million, an increase in accounts payable of $1.3 million, and a decrease in operating lease liabilities of $0.7 million.

Net cash provided by financing activities

Net cash provided by financing activities for the year ended December 31, 2024 amounted to $13.73 million as compared to $0.6 million for the year ended December 31, 2023.

During the year ended December 31, 2024, net cash provided by financing activities of $13.7 million was primarily attributable to the receipt of net proceeds of $7.2 million from the issuance of Series A and B Preferred Stock, net proceeds of $0.8 million from the issuance of Series C Preferred Stock and associated warrants, net proceeds of $4.8 million for the sale of common stock under the ELOC, and proceeds from the exercise of Series A warrants of $0.9 million.

During the year ended December 31, 2023, net cash provided by financing activities of $0.6 million was primarily attributable to the receipt of net proceeds of $0.6 million from the issuance of convertible notes payable.

Critical Accounting Estimates

Earnout liability - As a result of the Merger in February 2024, the Company recognized an earnout liability of $4.9 million on the merger date. The earnout liability is measured using unobservable (Level 3) inputs and was included in current liabilities on balance sheet. The Company estimated the fair value of the earnout liability by applying a Monte-Carlo simulation method using the Company's projection of future operating results and the estimated probability of achievement of the earnout target metrics. The Monte-Carlo simulation is a generally accepted statistical technique used to generate a defined number of valuation paths in order to develop a reasonable estimate of the fair value of the earnout liability. The liability is remeasured to fair value using the Monte-Carlo simulation method at each reporting period, and the change in fair value is recognized in other income (expense) until the contingency is resolved. During the year ended December 31, 2024, the Company recorded a gain from change of fair value of the earnout liability of $4,880,000, which is included in other income, net on the accompanying consolidated statement of operations.

Stock-based compensation – The Company periodically issues common stock and stock options to officers, directors, and consultants for services rendered. Stock-based compensation accounting requires the recognition of stock-based compensation expense, using a grant date fair value-based method, for costs related to all share-based payments including stock options and restricted stock awards granted to employees and non-employees. Companies are required to estimate the fair value of all share-based payment awards on the date of grant using an option pricing model, and the Company uses a Black-Scholes option pricing model ("Black-Scholes") to estimate option award fair value. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The fair value of restricted stock awards is based upon the estimated share price of the common shares on the date of grant. Forfeitures are accounted for as they occur, and the Company applies the simplified method to estimate expected term of "plain vanilla" options. All options and restricted stock awards granted since inception are expensed on a straight-line basis over the requisite service period, which is usually the vesting period, or upon the completion of certain performance-based vesting terms and the related amounts are recognized in the statements of operations.

The accounting for stock options granted to outside consultants is consistent with the accounting for stock-based payments to officers and directors, as described above, by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as stock-based compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

Recent Accounting Standards

See the section titled in Note 2 to the Company's consolidated financial statements for the year ended December 31, 2024, appearing elsewhere herein.

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

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

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements for the year ended December 31, 2024, together with the reports of our independent registered public accounting firm, appear beginning on page F-1 of this Annual Report.

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

None.

Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures

Disclosure controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time period specified in the SEC's rules and forms. Disclosure controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2024. Based upon their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as a result of the material weakness in internal control over financial reporting as described below, our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective as of December 31, 2024.

(b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with the accounting principles generally accepted in the United States of America ("GAAP"). Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2024. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on our assessments and those criteria, management concluded that our internal control over financial reporting was not effective as of December 31, 2024 as a result of the material weakness in internal control over financial reporting as described below.

Our certifying officers concluded that the Company lacks effective processes and controls to ensure the accuracy and completeness of its financial statements due to the lack of sufficient and qualified resources. This material weakness led to the Company consistently failing to meet contractual deadlines for filing its financial statements. In order to remediate the material weakness, the Company plans to hire additional qualified accounting personnel when the Company has the financial resources to support such expenses, as well as engage consultants and purchase software licenses, if, and to the extent, that the Company has sufficient financial resources for such additional expenses.

Management continues to evaluate its plan to remediate the material weakness, which will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

This Annual Report does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

(c) Changes in Internal Control over Financial Reporting

Other than described above, there were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the year to which this Report relates that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

(d) Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Item 9B. Other Information.

Rule 10b5-1 Plan or non-Rule 10b5-1 Trading Arrangements

During the three-month period ended December 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) adopted, terminated or modified a Rule 10b5-1 trading arrangement or any "non-Rule 10b5-1 trading agreement" (as defined in Item 408(c) of Regulation S-K).

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2024.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2024.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 14. Principal Accountant Fees and Services.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

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

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

(3) Exhibits:

The following list of exhibits includes exhibits submitted with this Annual Report as filed with the SEC and those incorporated by reference to other filings.

Exhibit No.	Description
2.1	Business Combination Agreement, dated as of June 4, 2023, by and among Phoenix Biotech Acquisition Corp., PBCE Merger Sub, Inc. and CERo Therapeutics, Inc., as amended (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Phoenix Biotech Acquisition Corp. with the Securities and Exchange Commission on June 5, 2023).
2.2	Amendment No. 1 to the Business Combination Agreement, dated as of February 5, 2024, by and among Phoenix Biotech Acquisition Corp., PBCE Merger Sub, Inc. and CERo Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Phoenix Biotech Acquisition Corp. with the Securities and Exchange Commission on February 6, 2024).
2.3	Amendment No. 2 to the Business Combination Agreement, dated as of February 13, 2024, by and among Phoenix Biotech Acquisition Corp., PBCE Merger Sub, Inc. and CERo Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Phoenix Biotech Acquisition Corp. with the Securities and Exchange Commission on February 13, 2024).
3.1	Second Amended and Restated Certificate of Incorporation of CERo Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
3.2	Second Amended and Restated Bylaws of CERo Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
3.3	Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
3.4	Certificate of Correction to Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.4 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
3.5	Second Certificate of Correction to Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.5 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).

3.6	Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.6 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).
3.7	Certificate of Designation of Preferences, Rights and Limitations of the Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on October 2, 2024).
4.1	Warrant Agreement, by and between Phoenix Biotech Acquisition Corp. and Continental Stock Transfer & Trust Company, dated October 5, 2021 (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-1 filed by Phoenix Biotech Acquisition Corp. with the Securities and Exchange Commission on September 13, 2021).
4.2	Form of Common Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
4.3	Form of Preferred Warrant (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
4.4	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on September 25, 2024).
4.5*	Description of Securities.
4.6	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 6, 2025).
4.7	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-1/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on January 21, 2025).
10.1+	CERo Therapeutics, Inc. 2016 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-4/A filed by Phoenix Biotech Acquisition Corp. with the Securities and Exchange Commission on June 7, 2023).
10.2+	CERo Therapeutics Holdings, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.3+	First Amendment to the CERo Therapeutics Holdings, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 99.4 to the Registration Statement on Form S-8 filed by CERo Therapeutics Holdings, Inc. with the Securities Exchange Commission on December 9, 2024).
10.4+	Second Amendment to the CERo Therapeutics Holdings, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 99.5 to the Registration Statement on Form S-8 filed by CERo Therapeutics Holdings, Inc. with the Securities Exchange Commission on December 9, 2024).

10.5+	CERo Therapeutics Holdings, Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.6	Form of Indemnification Agreement, by and between Phoenix Biotech Acquisition Corp. and each of its directors and executive officers (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-4/A filed by Phoenix Biotech Acquisition Corp. with the Securities and Exchange Commission on December 18, 2023).
10.7	Investor Rights and Lock-Up Agreement, dated February 14, 2024, by and between Phoenix Biotech Acquisition Corp. and the parties named therein (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.8	Amended and Restated Securities Purchase Agreement, dated as of February 14, 2024, by and between Phoenix Biotech Acquisition Corp., CERo Therapeutics, Inc. and the investors named therein (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.9	Registration Rights Agreement, dated as of February 14, 2024, by and between Phoenix Biotech Acquisition Corp., CERo Therapeutics, Inc. and the investors named therein (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.10	Common Stock Purchase Agreement, dated as of February 14, 2024, by and between CERo Therapeutics Holdings, Inc. and Keystone Capital Partners, LLC (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.11	Registration Rights Agreement, dated as of February 14, 2024, by and between CERo Therapeutics Holdings, Inc. and the Lead Investor (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.12	Form of Share Reallocation Agreement, dated as of February 14, 2024, by and among Phoenix Biotech Acquisition Corp., Phoenix Biotech Sponsor, LLC and the parties named therein (incorporated by reference to Exhibit 10.10 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.13	Letter Agreement, dated as of February 14, 2024, by and between Phoenix Biotech Sponsor, LLC and CERo Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 10.11 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.14	Side Letter, dated as of February 14, 2024, by and between Phoenix Biotech Acquisition Corp. and the Lead Investor (incorporated by reference to Exhibit 10.12 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 27, 2024).
10.15	Securities Purchase Agreement, dated as of March 29, 2024, by and between CERo Therapeutics Holdings, Inc. and the investors named therein (incorporated by reference to Exhibit 10.13 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).

10.16	Registration Rights Agreement, dated as of March 29, 2024, by and between CERo Therapeutics Holdings, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.14 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).
10.17+	Consulting Agreement, dated September 30, 2024, by and between the Company and Kristen Pierce (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on October 2, 2024).
10.18+	Consulting Agreement, dated September 30, 2024, by and between the Company and Andrew Kucharchuk (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on October 2, 2024).
10.19+	Consulting Agreement, dated September 30, 2024, by and between the Company and Brian G. Atwood (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on October 2, 2024).
10.20	Consulting Agreement, dated September 30, 2024, by and between the Company and Chris Ehrlich (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on October 2, 2024).
10.21+	Employment Agreement, dated as of March 28, 2024, by and between CERo Therapeutics Holdings, Inc. and Charles Carter (incorporated by reference to Exhibit 10.16 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).
10.22+	Offer Letter, dated as of March 28, 2024, by and between CERo Therapeutics Holdings, Inc. and Daniel Corey (incorporated by reference to Exhibit 10.17 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).
10.23	Securities Purchase Agreement, dated as of September 25, 2024, by and between CERo Therapeutics Holdings, Inc. and the investors named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on September 25, 2024).
10.24	Registration Rights Agreement, dated as of September 26, 2024, by and between CERo Therapeutics Holdings, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on September 25, 2024).
10.25	Consent and Waiver Agreement, dated as of September 26, 2024, by and between CERo Therapeutics Holdings, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on September 25, 2024).
10.26	Common Stock Purchase Agreement, dated as of November 8, 2024, by and between CERo Therapeutics Holdings, Inc. and Keystone Capital Partners, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on November 12, 2024).

10.27	Registration Rights Agreement, dated as of November 8, 2024, by and between CERo Therapeutics Holdings, Inc. and Keystone Capital Partners, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K/A filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on November 12, 2024).
10.28	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 6, 2025).
10.29	Placement Agency Agreement, dated February 5, 2025, by and between CERo Therapeutics Holdings, Inc., and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on February 6, 2025).
19.1	CERo Therapeutics Holdings Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).
21.1	List of subsidiaries of CERo Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).
23.1*	Consent of Wolf & Company, P.C., independent registered public accounting firm.
24.1	Power of Attorney (included on signature page).
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 and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2022.
97.1	CERo Therapeutics Holdings Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K filed by CERo Therapeutics Holdings, Inc. with the Securities and Exchange Commission on April 2, 2024).
101.INS	Inline XBRL Instance Document (embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.
\+ Indicates management contract or compensatory plan.
\# The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this report and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

CERO THERAPEUTICS HOLDINGS, INC.

Date: April 15, 2025

By: /s/ Chris Ehrlich
Chris Ehrlich
Chairman, Chief Executive Officer and Director
(Principal Executive Officer)

Date: April 15, 2025

By: /s/ Andrew Kucharchuk
Andrew Kucharchuk
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Chris Ehrlich and Andrew Kucharchuk his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Chris Ehrlich Chris Ehrlich	Chairman and Chief Executive Officer and Director *(Principal Executive Officer)*	April 15, 2025
/s/ Andrew Kucharchuk Andrew Kucharchuk	Chief Financial Officer *(Principal Financial and Accounting Officer)*	April 15, 2025
/s/ Brian Atwood Brian Atwood	Director	April 15, 2025
/s/ Michael Byrnes Michael Byrnes	Director	April 15, 2025
/s/ Kathleen LaPorte Kathleen LaPorte	Director	April 15, 2025
/s/ Shami Patel Shami Patel	Director	April 15, 2025
/s/ Lindsey Rolfe Lindsey Rolfe	Director	April 15, 2025

CERO THERAPEUTICS HOLDINGS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2024 and 2023

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of CERo Therapeutics Holdings, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CERo Therapeutics Holdings, Inc. (the Company) as of December 31, 2024 (Successor) and December 31, 2023 (Predecessor), the related statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for the periods from January 1, 2024 through February 13, 2024 (Predecessor), and February 14, 2024 through December 31, 2024 (Successor) and for the year ended December 31, 2023 (Predecessor), and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 (Successor) and December 31, 2023 (Predecessor), and the results of its operations and its cash flows for the periods from January 1, 2024 through February 13, 2024 (Predecessor), and February 14, 2024 through December 31, 2024 (Successor) and for the year ended December 31, 2023 (Predecessor), in conformity with accounting principles generally accepted in the United States of America.

Emphasis of a Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred net losses since its inception, has negative cash flows from operations and will need additional funding to complete planned development efforts. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Wolf & Company, P.C.

We have served as the Company's auditor since 2024.

Boston, MA
April 15, 2025

CERO THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2024 (Successor)	December 31, 2023 (Predecessor)
ASSETS		
Current assets:		
Cash, restricted cash, and cash equivalents	$ 3,327,060	$ 1,601,255
Prepaid expenses and other current assets	274,749	368,780
Deferred offering costs	112,232	-
Total current assets	3,714,041	1,970,035
Deferred offering costs, net of current portion	500,000	-
Operating lease right-of-use assets	1,464,367	2,189,565
Property and equipment, net	528,521	966,702
Total assets	$ 6,206,929	$ 5,126,302
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 4,507,318	$ 1,671,745
Accrued liabilities	1,913,175	144,633
Common stock subscription deposit	-	1,875
Operating lease liability	876,392	769,092
Short-term notes payable, net	-	599,692
Earnout liability	20,000	-
Deemed dividend – common stock liability, 13,835 shares	85,500	-
Preferred stock warrant liability	-	320,117
Total current liabilities	7,402,385	3,507,154
Operating lease liability, net of current portion	699,107	1,575,499
Total liabilities	8,101,492	5,082,653
Commitments and contingencies		
Convertible preferred stock, $0.0001 par value per share, issuable in series:		
Series Seed: 5,155,703 shares authorized, issued and outstanding at December 31, 2023	-	4,077,560
Series A: 24,614,402 shares authorized, 22,764,764 shares issued and outstanding at December 31, 2023	-	38,023,784
Total convertible preferred stock	-	42,101,344
Stockholders' deficit:		
Series C convertible preferred stock, $0.0001 par value;2,853 shares authorized; 2,853 issued and outstanding at December 31, 2024; liquidation preference of $2,853,000	1,249,999	-
Series A convertible preferred stock, $0.0001 par value; 12,580 shares authorized; 1,894 issued and outstanding at December 31, 2024; liquidation preference of $1,894,000	1,708,396	-
Series B convertible preferred stock, $0.0001 par value; 626 shares authorized; 273 issued and outstanding at December 31, 2024; liquidation preference of $273,000	218,051	-
Class A common stock; $0.0001 par value; 1,000,000,000 shares authorized; 2,415,883 shares issued and outstanding at December 31, 2024	242	-
Common stock, $0.0001 par value, 45,350,000 shares authorized, 5,845 shares issued and outstanding at December 31, 2023	-	1
Additional paid-in capital	67,142,046	1,032,125
Stock subscription receivable	(1,295,444)	-
Accumulated deficit	(70,917,853)	(43,089,821)
Total stockholders' deficit	(1,894,563)	(42,057,695)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 6,206,929	$ 5,126,302

See accompanying notes to the consolidated financial statements

Reflects a 1-for-100 reverse stock split effective January 8, 2025

CERO THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the period from February 14, 2024 through December 31, 2024 (Successor)	For the period from January 1, 2024 through February 13, 2024 (Predecessor)	For the year ended December 31, 2023 (Predecessor)
Operating expenses:			
Research and development	$ 6,315,552	$ 764,192	$ 5,288,580
General and administrative	8,985,351	132,941	2,386,469
Total operating expenses	15,300,903	897,133	7,675,049
Loss from operations	(15,300,903)	(897,133)	(7,675,049)
Other income (expenses):			
Gain from settlement of liabilities with vendors	3,339,223	-	8,144
Other expenses	(672,378)	-	(62,182)
Change in fair value of earnout and derivative liabilities	4,880,000	320,117	301,170
Interest income, net	21,846	4,805	138,340
Total other income, net	7,568,691	324,922	385,472
Net loss	(7,732,212)	(572,211)	(7,289,577)
Deemed dividend - preferred stock conversions	(2,508,000)	-	-
Deemed dividend – warrant repricing	(276,839)	-	-
Net loss attributable to common shareholders	$ (10,517,051)	$ (572,211)	$ (7,289,577)
Net loss per common share:			
Basic and diluted	$ (18.15)	$ (97.90)	$ (1,248.64)
Weighted average common shares outstanding:			
Basic and diluted	579,432	5,845	5,838

See accompanying notes to the consolidated financial statements

Reflects a 1-for-100 reverse stock split effective January 8, 2025

CERO THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

	Convertible Preferred Stock								Additional	Stock		Total
	Series A		Series B		Series C		Series A Common Stock		Paid-in	Subscriptions	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Deficit
Balance at 2/14/2024 (Successor)	10,089	$ 8,937,852	-	$ -	-	$ -	145,318	$ 15	$53,899,871	$ (2,000,000)	$(63,185,641)	$ (2,347,903)
Issuance of shares of Series A Preferred Stock upon exercise of Series A Preferred Warrants, net of issuance costs of $14,693	1,875	1,529,493	-	-	-	-	-	-	(1,507,600)	1,507,600	-	1,529,493
Issuance of Series B shares sold to investors for cash, net of issuance costs of $81,684	-	-	626	500,000					(81,684)	-		418,316
Issuance of Series A shares for rounding purchases	3	1,875	-	-			-	-	130	-		2,005
Issuance of common stock for Arena Equity Line of Credit (ELOC) commitment fee	-	-	-	-			3,456	-	500,000	-		500,000
Issuance of shares of Common Stock for Keystone ELOC commitment fee	-	-	-	-	-	-	18,644	2	(2)	-	-	-
Purchases of shares of Common Stock under Keystone ELOC, net of issuance costs of $130,321	-	-	-	-	-	-	453,500	46	4,809,657	(716,694)	-	4,093,009
Issuance of shares of Common Stock upon conversion of Series A Preferred Stock	(10,073)	(8,760,824)	-	-	-	-	1,723,880	172	8,760,652	-	-	-
Issuance of shares of Common Stock upon conversion of Series B Preferred Stock	-	-	(353)	(281,949)	-	-	53,815	5	281,944	-	-	-
Issuance of shares of Series C Preferred Stock sold to investors, net of issuance costs of $446,438	-	-	-	-	2,853	1,249,999	-	-	(446,438)	-	-	803,561
Subscription receivable for share issued in advance	-	-	-	-	-	-	17,270	2	86,348	(86,350)	-	-
Deemed dividend – common stock liability, 13,835 shares	-	-	-	-	-	-	-	-	(85,500)	-	-	(85,500)
Stock-based compensation	-	-	-	-	-	-	-	-	924,668	-	-	924,668
Net loss	-	-	-	-	-	-	-	-	-	-	(7,732,212)	(7,732,212)
Balance at 12/31/2024 (Successor)	1,894	$ 1,708,396	273	$ 218,051	2,853	$1,249,999	2,415,883	$ 242	$67,142,046	$ (1,295,444)	$(70,917,853)	$ (1,894,563)

	Convertible Preferred Stock						Additional		Total
	Series Seed		Series A		Common Stock		Paid-in	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at January 1, 2023 (Predecessor)	5,155,703	4,077,560	22,764,764	38,023,784	5,830	1	929,463	(35,800,244)	(34,870,780)
Issuance of common stock from exercise of stock options	-	-	-	-	15	-	5,766	-	5,766
Stock based compensation expense	-	-	-	-	-	-	96,896	-	96,896
Net loss	-	-	-	-	-	-	-	(7,289,577)	(7,289,577)
Balance at December 31, 2023 (Predecessor)	5,155,703	4,077,560	22,764,764	38,023,784	5,845	1	1,032,125	(43,089,821)	(42,057,695)
Stock based compensation expense	-	-	-	-	-	-	4,431	-	4,431
Net loss	-	-	-	-	-	-	-	(572,211)	(572,211)
Balance at February 13, 2024 (Predecessor)	5,155,703	$ 4,077,560	22,764,764	$ 38,023,784	5,845	$ 1	$ 1,036,556	$ (43,662,032)	$ (42,625,475)

See accompanying notes to the consolidated financial statements

Reflects a 1-for-100 reverse stock split effective January 8, 2025

CERO THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOW

	For the period from February 14, 2024 through December 31, 2024 (Successor)	For the period from January 1, 2024 through February 13, 2024 (Predecessor)	For the year ended December 31, 2023 (Predecessor)
Cash flows from operating activities:			
Net loss	$ (7,732,212)	$ (572,211)	$ (7,289,577)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain from settlement of liabilities with vendors	(3,339,223)	-	-
Depreciation expense	400,825	37,356	460,722
Stock-based compensation	924,668	4,431	96,896
Amortization of right-to-use operating lease asset	609,339	115,859	656,476
Amortization of debt discount	-	(1,875)	-
Non-cash interest expense	-	-	35,655
Gain on revaluation of earnout and derivative liabilities	(4,880,000)	(320,117)	(290,264)
Change in assets and liabilities:			
Prepaid expenses and other current assets	(87,088)	142,687	(112,321)
Accounts payable	130,032	128,429	1,280,560
Accrued liabilities	2,342,593	(50,370)	44,239
Operating lease liability	(647,503)	(121,589)	(672,373)
Net cash used in operating activities	(12,278,569)	(637,400)	(5,789,987)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes	-	-	605,230
Issuance costs for convertible notes	-	-	(41,193)
Common stock subscription deposit	-	-	1,875
Cash proceeds from exercise of common stock options	-	-	5,766
Proceeds from issuance of Series A Preferred Stock, net of issuance costs	6,757,700	-	-
Advances from shareholder	13,731	-	-
Payment of sponsor loans	(19,715)	-	
Payments for short term borrowings	(402,514)	-	
Proceeds from short-term borrowings, net	408,052	-	-
Proceeds from share purchases under ELOC, net of issuance costs	4,809,703	-	-
Proceeds received from sale of Series B Preferred Stock, net of issuance costs	418,316	-	-
Proceeds received from sale of Series C Preferred Stock, net of issuance costs	803,561	-	-
Proceeds from Series A preferred warrant exercises	938,800	-	-
Net cash provided by financing activities	13,727,634	-	571,678
Net increase (decrease) in cash and cash equivalents	1,449,065	(637,400)	(5,218,309)
Cash, restricted cash and cash equivalents at beginning of period	1,877,995	1,601,255	6,819,564
Cash, restricted cash and cash equivalents at end of period	$ 3,327,060	$ 963,855	$ 1,601,255
SUPPLEMENTAL CASH FLOW INFORMATION:			
Cash and cash equivalents	$ 3,252,304	$ 884,099	$ 1,521,499
Restricted cash	74,756	79,756	79,756
Cash, restricted cash and cash equivalents	$ 3,327,060	$ 963,855	$ 1,601,255
NON-CASH FINANCING ACTIVITIES:			
Issuance of common shares to Keystone Capital LLC for equity line of credit	$ 500,000	-	$ -
Issuance of common shares to Arena Capital Partners for equity line of credit	$ 500,000	$ -	$ -
Conversion of Series A and Series B preferred stock to common stock	$ 9,037,773	$ -	$ -
Stock subscription receivables	$ 803,044	$ -	$ -
Increase in deferred offering costs and accounts payable	$ 112,232	$ -	$ -
Exercise of warrants for Series A Preferred Stock through extinguishment of accrued expenses	$ 568,400	$ -	$ -
Deemed dividend – common stock liability, 13,835 shares	$ 85,500	$ -	$ -

See accompanying notes to the consolidated financial statements

NOTE 1 – ORGANIZATION AND DESCRIPTION OF THE BUSINESS

Nature of Operations – CERo Therapeutics Holdings, Inc. (NASDAQ: CERO), F/K/A Phoenix Biotech Acquisition Corp. ("PBAX") was incorporated in Delaware on June 8, 2021. PBAX was formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, or similar business combination with one or more businesses (a "business combination").

Reverse Stock Split – On January 8, 2025, we effected a reverse stock split of our shares of common stock at a ratio of 1-for-100 (the "Reverse Stock Split"). The Company's common stock continued to trade on Nasdaq on a post-split basis under the Company's existing trading symbol, "CERO".

All of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect the Reverse Stock Split.

Business Combination Agreement - On June 6, 2023, CERo Therapeutics, Inc. ("Predecessor"), which was incorporated in Delaware on September 23, 2016, and based in South San Francisco, California, entered into a Business Combination Agreement and Plan of Reorganization (the "BCA") with PBCE Merger Sub, Inc., a wholly-owned subsidiary of PBAX, and PBAX, with the surviving operating entity being named CERo Therapeutics Holdings, Inc. ("Successor" or the "Company"), and such transaction, the "Business Combination" or "Merger".

The Company is an innovative immunotherapy company advancing the development of next generation engineered T cell therapeutics for the treatment of cancer. The Company's proprietary approach to T cell engineering, which enables it to integrate certain desirable characteristics of both innate and adaptive immunity into a single therapeutic construct, is designed to engage the body's full immune repertoire to achieve optimized cancer therapy. The Company has not yet begun clinical development or product commercialization. The Company's efforts will focus on continued product development, including clinical development, to support regulatory approval to commercialize and subsequent product commercialization.

In November 2024, the U.S. Food and Drug Administration ("FDA") cleared the Company's Investigational New Drug Application for Phase 1 clinical trials of its lead compound, CER-1236, in acute myelogenous leukemia.

Going concern – The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its research and development ("R&D") activities and meet its obligations on a timely basis. As of December 31, 2024, the Company reported $3.3 million of cash and cash equivalents, with an accumulated deficit of $70.9 million. On February 5, 2025, we entered into a securities purchase agreement (the "SPA"), with participation from a member of the Company's board of directors and a single institutional investor, for the purchase and sale of (i) 2,551,020 shares of our common stock or common stock equivalents in lieu thereof; and (ii) common warrants to purchase up to 2,551,020 shares of common stock, at a combined public offering price of $1.96 per share and Warrant. In connection with this offering, we received net proceeds of approximately $4.5 million. Additionally, since December 31, 2024, we received net proceeds from the exercise of the remaining Series A Preferred Warrants, the collection of subscriptions receivable and ELOC fundings of approximately $2.5 million. Additional funds are necessary to maintain current operations and to continue R&D activities. However, there can be no assurance that sufficient funding will be available to allow the Company to successfully continue its R&D activities and planned regulatory filings with the FDA. If the Company is unable to obtain the necessary funds, significant reductions in spending and the delay or cancellation of planned activities may be necessary. These actions would have a material adverse effect on the Company's business, results of operations, and prospects. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these financial statements are issued. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Risks and uncertainties – The Company is subject to all of the risks inherent in an early-stage biotechnology company. These risks include, but are not limited to, limited management resources, intense competition, and dependence upon the availability of cash to sustain operations. The Company's operating results may be materially affected by the foregoing factors.

The Company's research also requires approvals from the FDA prior to beginning clinical trials and prior to product commercialization. There can be no assurance that the Company's current ongoing research and future clinical development will result in the granting of these required approvals. If the Company is denied such approvals or such approvals are substantially delayed, they could have a material adverse effect upon the Company's future financial results and cash flows.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation – The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the applicable rules and regulations of the SEC. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of a normal recurring nature, which are necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented.

On February 14, 2024, the Company completed the Merger with CERo Therapeutics, Inc., with CERo Therapeutics, Inc. surviving the Merger as a wholly-owned subsidiary of the Company, the accounting acquirer. The transaction was accounted for as a forward Merger asset acquisition.

Unless the context otherwise requires, the "Company," for periods prior to the Closing, refers to CERo Therapeutics, Inc. ("Predecessor"), and for the periods after the Closing, refers to CERo Therapeutics Holdings, Inc. ("Successor" or the "Company"). As a result of the Merger, the results of operations, financial position and cash flows of the Predecessor and the Company are not directly comparable. CERo Therapeutics, Inc. was deemed to be the Predecessor entity. Accordingly, the historical financial statements of CERo Therapeutics, Inc. became the historical financial statements of the combined Company, upon the consummation of the Merger. As a result, the financial statements included in this report reflect (i) the historical operating results of CERo Therapeutics, Inc. prior to the Merger and (ii) the combined results of the Company, CERo Therapeutics Holdings, Inc., following the Merger. The accompanying consolidated financial statements include a Predecessor period, which includes the period from January 1, 2024 to February 13, 2024 concurrent with the Merger, and a Successor period from February 14, 2024 through December 31, 2024. A black line between the Successor and Predecessor periods has been placed in the consolidated financial statements and in the tables to the notes to the consolidated financial statements to highlight the lack of comparability between these two periods.

Use of estimates – The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses incurred during the reporting period. Items subject to such estimates and assumptions include the estimates of the fair values of convertible preferred stock, common stock, and preferred stock warrant liability, stock-based compensation expense, the present value of right-to-use assets and lease liabilities, the valuation of earnout liability, and the valuation allowance associated with deferred tax assets. Actual results could differ from those estimates.

Cash, restricted cash, and cash equivalents – The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents. As of December 31, 2024 and 2023, cash and cash equivalents consist of cash deposited with banks, including a money market sweep account. Restricted cash consists of $74,756 and $79,756, respectively, held on account by a financial institution as collateral for a demand letter of credit issued as a real estate security deposit.

Concentration of credit risk – Financial instruments that potentially subject the Company to credit risk consist primarily of cash, restricted cash, and cash equivalents. The Company's cash, restricted cash, and cash equivalents are on deposit with two financial institutions that management believe are of sufficiently high credit quality. Deposits at any of the Company's financial institutions may, at times, exceed federal insured limits.

Property and equipment – Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years or the remaining lease term for leasehold improvements, if shorter. Expenditures for repairs and maintenance are charged to expense as incurred. Upon disposition, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is reflected in the consolidated statements of operations.

Impairment of long-lived assets – The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. Through December 31, 2024, the Company has not experienced any impairment losses on its long-lived assets.

Leases – The Company determines if an arrangement contains a lease at inception. A lease is an operating or financing contract, or part of a contract, that conveys the right to control the use of an identified tangible asset for a period of time in exchange for consideration.

At lease inception, the Company recognizes a lease liability equal to the present value of the remaining lease payments, and a right of use asset equal to the lease liability, subject to certain adjustments, such as for lease incentives. In determining the present value of the lease payments, the Company uses its incremental borrowing rate, determined by estimating the Company's applicable, fully collateralized borrowing rate, with adjustment as appropriate for lease term. The lease term at the lease commencement date is determined based on the non-cancellable period for which the Company has the right to use the underlying asset, together with any periods covered by an extension option if the Company is reasonably certain to exercise that option.

Right-of-use assets and obligations for leases with an initial term of 12 months or less are considered short term and are (a) not recognized in the balance sheet and (b) recognized as an expense on a straight-line basis over the lease term. The Company does not sublease any of its leased assets to third parties and the Company's lease agreements do not contain any residual value guarantees or restrictive covenants.

The accounting for leases includes a number of reassessment and re-measurement requirements for lessees based on certain triggering events or impairment conditions. There were no impairment indicators identified during the years ended December 31, 2024 or 2023 that would require impairment testing of the Company's right-of-use assets.

Certain of the Company's leases include variable lease costs to reimburse the lessor for real estate tax and insurance expenses, and certain non-lease components that transfer a distinct service to the Company, such as common area maintenance services. The Company has elected to separate the accounting for fixed lease components and variable and non-lease components for real estate and equipment leases. The variable lease costs are recorded on the statement of operations as rent expense, within general and administrative expenses. The Company does not have any financing leases at December 31, 2024 or 2023.

Derivative financial instruments – The Company evaluates financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, "Derivatives and Hedging". Derivative instruments are initially recorded at fair value on the grant date and re-valued at each reporting date, with changes in the fair value reported in the statements of operations. Derivative assets and liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date.

Convertible preferred stock – The Predecessor's convertible preferred stock was redeemable upon the liquidation or winding up of the Company, a change in control, or a deemed liquidation event related to the sale of substantially all the assets of the Company. Based on the ownership of the Company's equity and associated board of director control, deemed liquidation events were not solely within the control of the Company. As a result, the shares of the Predecessor's convertible preferred stock were considered contingently redeemable. The Company had elected to present it's the Predecessor's convertible preferred stock as mezzanine equity in its balance sheet. Further, the Company elected not to adjust the carrying values of the Predecessor's convertible preferred stock to the redemption value of such shares, since it was uncertain whether or when a redemption event would occur. Subsequent adjustments to increase the carrying values to the redemption values were to be made when it became probable that such redemption would occur. The Company has not included the effect of the Predecessor's convertible preferred stock in the calculation of diluted loss per share, since the inclusion of such convertible preferred stock would be anti-dilutive.

Preferred stock warrant liability – Warrant accounting requires liability classification of warrants when the warrants include a conditional obligation, once the warrant is exercised, that would require the Company to redeem its equity shares. As stated above, the shares of the predecessor Company's convertible preferred stock are considered contingently redeemable and therefore, any preferred stock warrants to purchase preferred shares was classified as a liability in the Company's balance sheets. The warrants are analyzed to determine whether the warrant is a freestanding instrument and if so, whether the warrant was issued in a transaction with other instrument(s). If a freestanding warrant is issued with other instruments in a single transaction, then the proceeds of the transaction are allocated first to the fair value of the warrant, with the remainder being allocated to the other instruments. The warrants are remeasured as of each reporting period end, with any changes in fair value recognized as interest and other income, net in the statement of operations. The Company has determined that the warrant liability is a Level 3 instrument in the fair value measurements hierarchy. The Company has not included the effect of the preferred stock warrants in the calculation of diluted loss per share since the inclusion of such warrants would be anti-dilutive.

Earnout liability - As a result of the Merger in February 2024, the Company recognized an earnout liability of $4.9 million on the merger date. The earnout liability is measured using unobservable (Level 3) inputs and is included in current liabilities on accompanying balance sheet. The Company estimated the fair value of the earnout liability by applying a Monte-Carlo simulation method using the Company's projection of future operating results and the estimated probability of achievement of the earnout target metrics. The Monte-Carlo simulation is a generally accepted statistical technique used to generate a defined number of valuation paths in order to develop a reasonable estimate of the fair value of the earnout liability. The liability is remeasured to fair value using the Monte-Carlo simulation method at each reporting period, and the change in fair value is recognized in other income (expense) until the contingency is resolved. During the year ended December 31, 2024, the Company recorded a gain from change of fair value of the earnout liability of $4,880,000, which is included in other income, net on the accompanying consolidated statement of operations.

Fair value measurements – The Company's assets and liabilities are carried at fair value. Fair value is the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. In determining fair value, the assumptions that market participants would use in pricing an asset or liability (the inputs) are based on a tiered fair value hierarchy consisting of three levels, 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.

Level 3 – Unobservable inputs for which there is little or no market data and which require the Company to develop its own assumptions about how market participants would price the asset or liability. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Carrying amounts of certain of the Company's financial instruments, including cash, restricted cash, and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued liabilities, and short-term notes payable approximate fair value due to their relatively short maturities.

Non-financial assets such as property and equipment are evaluated for impairment and adjusted to fair value using Level 3 inputs only when impairment is recognized. Fair values are considered Level 3 when management makes significant assumptions in developing a discounted cash flow model based upon a number of considerations including projections of revenues, earnings, and a discount rate. To date, the Company has not recorded any adjustments to fair value related to impairment on property and equipment. At December 31, 2024 and 2023, the fair value of the Company's earnout liability and preferred stock warrant liability (see Note 10 for details) was classified as follows:

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Earnout liability	$ -	$ -	$ 20,000	$ 20,000

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Preferred stock warrant liability	$ -	$ -	$ 320,117	$ 320,117

The change in the fair value measurement using significant inputs (Level 3) is summarized below:

Preferred stock warrant liability (Predecessor):	
Balance at January 1, 2023	$ 610,381
Gain on revaluation of warrant liability	(290,264)
Balance at December 31, 2023	320,117
Gain on revaluation of warrant liability	(320,117)
Balance at February 14, 2024	$ -
Earnout liability (Successor):	
Balance at February 14, 2024	$ 4,900,000
Gain on revaluation of earnout liability	(4,880,000)
Balance at December 31, 2024	$ 20,000

Research and development – R&D costs consist primarily of salaries and benefits, including stock-based compensation, occupancy, materials and supplies, contracted research, consulting arrangements, and other expenses incurred in the pursuit of the Company's R&D programs. R&D costs are expensed as incurred.

Stock-based compensation – The Company periodically issues common stock and stock options to officers, directors, and consultants for services rendered. Stock-based compensation accounting requires the recognition of stock-based compensation expense, using a grant date fair value-based method, for costs related to all share-based payments including stock options and restricted stock awards granted to employees and non-employees. Companies are required to estimate the fair value of all share-based payment awards on the date of grant using an option pricing model, and the Company uses a Black-Scholes option pricing model ("Black-Scholes") to estimate option award fair value. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The fair value of restricted stock awards is based upon the estimated share price of the common shares on the date of grant. Forfeitures are accounted for as they occur, and the Company applies the simplified method to estimate expected term of "plain vanilla" options. All options and restricted stock awards granted since inception are expensed on a straight-line basis over the requisite service period, which is usually the vesting period, or upon the completion of certain performance-based vesting terms and the related amounts are recognized in the consolidated statements of operations.

The accounting for stock options granted to outside consultants is consistent with the accounting for stock-based payments to officers and directors, as described above, by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as stock-based compensation expense on the straight-line basis in the Company's consolidated financial statements over the vesting period of the awards.

Income taxes – The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company follows tax accounting requirements for the recognition, measurement, presentation, and disclosure in the financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded in the financial statements. It is the Company's policy to include penalties and interest expense related to income taxes as a component of income tax expense, as necessary. The Company has not recorded any interest or penalties associated with income tax since inception. Tax years subsequent to 2021 are subject to examination by federal and state authorities.

Earnings per share – The Company reports both basic and diluted earnings per share. Basic earnings per share is calculated based on the weighted average number of shares of common stock outstanding and excludes the dilutive effect of convertible preferred stock, convertible preferred stock warrants, stock options or any other type of convertible securities. Diluted earnings per share is calculated based on the weighted average number of shares of common stock outstanding and when the effect of stock options, warrants and other types of convertible securities is dilutive, they are included in the calculation. Dilutive securities are excluded from the diluted earnings per share calculation if their effect is anti-dilutive, such as in periods where the Company reports a net loss.

Segment reporting - Operating segments are defined as components of a business for which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company operates as a single operating and reporting segment, reflecting our sole focus in developing next generation engineered T cell therapeutics for the treatment of cancer. Our Chief Executive Officer serves as the Chief Operating Decision Maker (CODM), responsible for assessing the Company's performance and making resource allocation decisions. The CODM evaluates financial information on a consolidated basis, focusing on key metrics such as research and development expense, general and administrative expenses, and other income/expenses, which is reflected on the face of the Company's consolidated statement of operations. The CODM allocates resources based on the Company's available cash resources, forecasted cash flow, and expenditures on a consolidated basis, as well as an assessment of the probability of success of its research and development activities. Resource allocation decisions are informed by budgeted and forecasted expense information, along with actual expenses incurred to date. The measure of segment assets is reported on the balance sheet as total assets. Disaggregated profit or loss information at the program or functional level is *not* regularly provided to or relied upon by the CODM, as our integrated operating model emphasizes shared resources and centralized decision-making.

Recently adopted accounting standards

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires that an entity report segment information in accordance with Topic 280, Segment Reporting. The amendment in the ASU is intended to improve reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The Company adopted ASU 2023-07 for the year ended December 31, 2024 retrospectively to all periods presented in the consolidated financial statements. The adoption of this ASU had no impact on reportable segments identified and had no effect on the Company's consolidated financial position, results of operations, or cash flows.

Accounting standards not yet adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. This pronouncement is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently assessing this ASU to determine the impact on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), which requires entities to provide more detailed disaggregation of expenses in the income statement, focusing on the nature of the expenses rather than their function. The new disclosures will require entities to separately present expenses for significant line items, including but not limited to, depreciation, amortization, and employee compensation. Entities will also be required to provide a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively, disclose the total amount of selling expenses and, in annual reporting periods, provide a definition of what constitutes selling expenses. This pronouncement is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently assessing this ASU to determine the impact on its consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the Company's consolidated financial statements.

NOTE 3 – BUSINESS COMBINATION

Business Combination Agreement - On June 6, 2023, CERo Therapeutics, Inc. ("Predecessor"), which was incorporated in Delaware on September 23, 2016, and based in South San Francisco, California, entered into a Business Combination Agreement and Plan of Reorganization (the "BCA") with PBCE Merger Sub, Inc., a wholly-owned subsidiary of PBAX, and PBAX, with the surviving operating entity being named CERo Therapeutics Holdings, Inc. ("Successor" or the "Company"), and such transaction, the "Business Combination" or "Merger".

The Company is focused on genetically engineering human immune cells to fight cancer. The Predecessor focused on developing the CERo therapeutic platform and had not yet begun clinical development or product commercialization. The Company's efforts will focus on continued product development, including clinical development, to support regulatory approval to commercialize and subsequent product commercialization.

The BCA was amended on February 5, 2024 and again on February 13, 2024. The Merger closed on February 14, 2024 (the "Closing"), at which time the following occurred:

1. The outstanding shares of Predecessor's Preferred Stock were converted into 44,155 shares of Common Stock, par value $0.0001 per share (the "Common Stock"), valued at $21,635,926.

2. The outstanding shares of Predecessor's common stock were converted into 5,845 shares of Common Stock, valued at $2,864,074.

3. Each holder of Predecessor's common stock received a pro rata portion of up to 12,000 earnout shares of restricted Common Stock (the "BCA Earnout Shares"), valued at $5,880,000, 10,000 of which are subject to vesting upon the achievement of certain stock price-based earnout targets and 2,000 of which are subject to vesting upon a change of control, respectively.

4. Certain holders of Predecessor's common stock received a pro rata portion of 8,750 earnout shares of Common Stock (the "Reallocation Shares"), valued at $4.29 million, which became fully vested upon the Closing.

5. Certain holders of Predecessor's common stock and convertible bridge notes received a pro rata portion of 10,000 earnout shares (the "IND Earnout shares") of restricted Common Stock, valued at $4,900,000, which vested when the Company filed an investigational new drug ("IND") application with the Food and Drug Administration ("FDA"). The earning of these shares was accompanied by a forfeiture of 10,000 restricted shares of Common Stock held by the sponsor following receipt of an acknowledgement notice by the Sponsor.

6. Each outstanding Predecessor option was converted into an option to purchase a number of shares of Common Stock, equal to the Predecessor's common stock underlying the option multiplied by the Exchange Ratio factor of 0.064452, at an exercise price per share equal to the Predecessor option exercise price divided by the Exchange Ratio factor.

7. Each warrant to purchase the Predecessor's preferred stock was converted into a warrant to acquire a number of shares of Common Stock obtained by dividing the warrant as-if-exercised liquidation preference by $1,000.00, with the exercise price equal to the total Predecessor warrant exercise amount divided by the number of shares of Common Stock issuable upon exercise.

8. The Predecessor's bridge notes automatically converted into shares of the Company's Series A Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"), at a conversion price equal to $750 per share of Series A Preferred Stock.

The Company issued, transferred from the Sponsor, or reserved for issuance an aggregate of 84,000 shares of Common Stock to the holders of Predecessor common stock and Predecessor preferred stock or reserved for issuance upon exercise of rollover (from Predecessor to Successor) options and warrants as consideration in the Merger.

Asset Acquisition Method of Accounting - The Merger was accounted for using the asset acquisition method in accordance with GAAP. Under this method of accounting, PBAX was considered to be the accounting acquirer based on the terms of the Merger. Upon consummation of the Merger, the cash on hand resulted in the equity at risk being considered insufficient for Predecessor to finance its activities without additional subordinated financial support. Therefore, Predecessor was considered a Variable Interest Entity ("VIE") and the primary beneficiary of Predecessor was treated as the accounting acquirer. PBAX holds a variable interest in Predecessor and owns 100% of Predecessor's equity. PBAX was considered the primary beneficiary as it has the decision-making rights that gives it the power to direct the most significant activities. Also, PBAX retained the obligation to absorb the losses and/or receive the benefits of Predecessor that could have potentially been significant to Predecessor. The Merger was accounted for as an asset acquisition as substantially all of the fair value was concentrated in IPR&D, an intangible asset. Predecessor's assets (except for cash) and liabilities were measured at fair value as of the transaction date. Consistent with authoritative guidance on the consolidation of a VIE that is not considered a business, differences in the total purchase price and fair value of assets and liabilities are recorded as a gain or loss to the consolidated statement of operations. The loss reflected below on the consolidation of the VIE is reflected "on the line" (defined below) in the Company's opening accumulated deficit.

Costs incurred in obtaining technology licenses are charged to research and development expense as IPR&D if the technology licensed has not reached technological feasibility and has no alternative future use. The IPR&D recorded at the Closing of $45.6 million is reflected "on the line" in the Company's opening accumulated deficit. To estimate the value of the acquired IPR&D, the Company used the avoided cost method, which calculates a present value of a 45% return on research and development effort applied to research and development expenditures over the life of the Predecessor. The determination of the fair value requires management to make a significant estimate of the return on research and development expenditures. Changes in these assumptions could have a significant impact on the fair value of the IPR&D. The estimate of the return on research and development expenditures was based on multiple published studies analyzing actual returns of research and development expenditures.

The following is a summary of the purchase price calculation:

Number of shares of Common Stock		50,000
Multiplied by PBAX's share price, as of the Closing	$	585.00
Total	$	29,250,000
Fair value of PBAX founder's shares converted to shares of Common Stock and transferred to Predecessor stockholders	$	5,118,750
Fair value of contingent Common Stock consideration	$	12,870,000
Total Common Stock consideration	$	47,238,750
Assumed liabilities		3,311,153
Total purchase price	$	50,549,903

The allocation of the purchase price was as follows:

Cash	$	963,855
Net working capital deficit (excluding cash and cash equivalents)		(1,819,514)
Fixed assets		929,346
Acquired in-process research and development		45,640,000
Net assets acquired		45,713,687
Loss on consolidation of VIE		4,836,216
Total purchase price	$	50,549,903

In connection with the Merger, the transactions that occurred concurrently with the closing date of the Merger were reflected "on the line". "On the line" describes those transactions triggered by the consummation of the Merger that are not recognized in the consolidated financial statements of the Predecessor nor the Company as they are not directly attributable to either period but instead were contingent on the Merger. The opening cash balance in the consolidated statement of cash flow of $1.88 million consists of $0.92 million from PBAX and $0.96 million from Predecessor. The number of shares of Common Stock issued and amounts recorded on the line within stockholders' deficit are reflected below to arrive at the opening consolidated balance sheet of the Company.

	Convertible Preferred Stock Series A		Series A Common Stock		Additional Paid-in	Stock Subscription	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Total
PBAX Closing Equity as of February 13, 2024	-	$ -	54,812	$ 6	$ 541	$ -	$(12,709,426)	$(12,708,879)
Forfeiture of founders shares	-	-	(8,750)	(1)	1	-	-	-
Adjusted shares outstanding	-	-	46,062	5	542	-	(12,709,426)	(12,708,879)
Shares issued as consideration in the Merger	-	-	80,750	8	47,238,742	-	-	47,238,750
Loss on VIE consolidation	-	-	-	-	-	-	(4,836,216)	(4,836,216)
Expense IPR&D	-	-	-	-	-	-	(45,640,000)	(45,640,000)
Reclassification of public shares	-	-	820	-	911,358	-	-	911,358
Issuance of common stock as payment to vendors	-	-	16,495	2	3,182,548	-	-	3,182,550
Elimination of deferred underwriting fees	-	-	-	-	5,690,000	-	-	5,690,000
Reclassification of earnout liability	-	-	-	-	(4,900,000)	-	-	(4,900,000)
Conversion of CERo bridge notes and accrued interest into Series A preferred stock	630	627,154	-	-	-	-	-	627,154
Conversion of working capital loan into Series A preferred stock	1,605	1,555,000	-	-	-	-	-	1,555,000
Issuance of Series A shares sold to investors, net	7,854	6,755,698	-	-	(856,663)	-	-	5,899,035
Issuance of Series A Preferred Warrants	-	-	-	-	2,000,000	(2,000,000)	-	-
Issuance of common shares to Keystone Capital LLC for equity line of credit	-	-	1,191	-	633,345	-	-	633,345
Opening Equity at February 14, 2024 (Successor)	10,089	$ 8,937,852	145,318	$ 15	$53,899,871	$ (2,000,000)	$(63,185,641)	$ (2,347,903)

NOTE 4 – NET LOSS PER SHARE OF COMMON STOCK

The accounting standards require the presentation of both basic and diluted earnings per share on the face of the statements of operations. The Company's basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period. If there are dilutive securities, diluted income per share is computed by including common stock equivalents which includes shares issuable upon the exercise of stock options into shares of common stock, exercise of preferred warrants into shares of preferred stock, and conversion of preferred stock into shares of common stock, net of any shares assumed to have been purchased with the proceeds, using the treasury stock method. In periods for which the Company reports a net loss, the common stock equivalents are not included, as they would be anti-dilutive.

The following table summarizes the number of shares of Common Stock issuable upon conversion or exercise, as applicable, of convertible securities, stock options, and warrants that were not included in the calculation of diluted net loss per share because such shares are anti-dilutive:

	December 31, 2024 (Successor)	December 31, 2023 (Predecessor)
Conversion of convertible preferred stock issued and outstanding	1,074,790	17,995
Conversion of convertible preferred stock underlying convertible preferred stock warrants	163,704	1,192
Exercise of public warrants and common warrants into common stock	263,866	-
Common stock underlying outstanding options (2024 Plan)	64,948	504
	1,567,308	19,691

Restricted common stock can be issued to directors, executives or employees of the Company and are subject to time-based vesting. These potential shares are excluded from the computation of basic loss per share as these shares are not considered outstanding until vested. No unvested restricted common stock awards were issued or outstanding during the years ended December 31, 2024 or 2023.

NOTE 5 – PROPERTY AND EQUIPMENT

Property and equipment, net, consisted of the following as of December 31, 2024 and 2023:

	December 31, 2024 (Successor)	December 31, 2023 (Predecessor)
Laboratory equipment	$ 2,507,839	$ 2,507,839
Computers	38,323	38,323
Furniture	8,429	8,429
Total cost	2,554,591	2,554,591
Less: accumulated depreciation	(2,026,070)	(1,587,889)
Property and equipment, net	$ 528,521	$ 966,702

Depreciation expense for the period from February 14, 2024 through December 31, 2024 for Successor was $400,825. Predecessor depreciation expense for the period January 1, 2024 through February 13, 2024 and for the year ended December 31, 2023 was $37,356 and $460,722, respectively.

NOTE 6 – ACCRUED LIABILITIES

Accrued liabilities consisted of the following as of December 31, 2024 and 2023:

	December 31, 2024 (Successor)	December 31, 2023 (Predecessor)
Employee-related liabilities	$ 244,302	$ 68,697
Accrued franchise taxes	78,448	-
Accrued legal expenses	593,825	46,466
Accrued interest	-	27,637
Penalty for late S-1 filing and effectiveness	55,000	-
Accrued consulting and professional services	941,600	-
Other accrued expenses	-	1,833
	$ 1,913,175	$ 144,633

NOTE 7 – LEASES

As of December 31, 2024 and 2023, the Company holds a five-year lease for laboratory and office space. The lease has escalating contractual rent and variable rent components and the Company elected to separate the contractual and variable elements for valuing the operating lease liability and right-to-use asset. The lease does not have any options for extension or expansion. The Company recorded the following lease costs:

	For the period from February 14, 2024 through December 31, 2024 (Successor)	For the period from January 1, 2024 through February 13, 2024 (Predecessor)	For the year ended December 31, 2023 (Predecessor)
Operating leases:			
Operating lease cost	$ 762,057	$ 152,887	$ 930,913
Variable operating lease cost	581,860	116,371	637,016
Total lease cost	$ 1,343,917	$ 269,258	$ 1,567,929

The right-of-use asset, net for the operating lease was recorded in the consolidated balance sheets as follows:

	December 31, 2024 (Successor)	December 31, 2023 (Predecessor)
Right-of-use assets, net	$ 1,464,367	$ 2,189,565

The operating lease liability for the operating lease was recorded in the consolidated balance sheets as follows:

	December 31, 2024 (Successor)	December 31, 2023 (Predecessor)
Operating lease liabilities, current	$ 876,392	$ 769,092
Operating lease liabilities, non-current	699,107	1,575,499
Total operating lease liabilities	$ 1,575,499	$ 2,344,591
Weighted-average remaining lease term of operating leases (in years)	1.75	2.75
Weighted-average discount rate for operating leases	9.60%	9.60%

The following table reconciles the undiscounted future minimum lease payments under the non-cancelable operating lease with terms of more than one year to the total operating lease liabilities recognized on the Company's balance sheet as of December 31, 2024:

Maturity of the Company's lease liabilities as of December 31, 2024 is as follows:

2025	$ 990,055
2026	726,394
Total lease payments	1,716,449
Less: imputed interest	(140,950)
Total lease liabilities	$ 1,575,499

NOTE 8 – STOCKHOLDERS' DEFICIT

Successor Series A Convertible Preferred Stock

The Company designated 12,580 shares of its authorized preferred stock as the Series A Preferred Stock and the rights, preferences and privileges of the Series A Preferred Stock are summarized below.

Each share of Series A Preferred Stock has a stated value of $1,000 per share and, when issued, the Series A Preferred Stock was fully paid and non-assessable. The Series A Preferred Stock, ranks senior to all other Company capital stock unless required holder votes are obtained to create a class of stock senior to Series A Preferred Stock. The requisite holders of Series A Preferred Stock consented to the issuance of the Series C Preferred Stock described below, which ranks senior to the Series A Preferred Stock and Series B Preferred Stock.

Dividend and Participation Rights: The holders of Series A Preferred Stock will be entitled to dividends, on an as-if converted basis, equal to and in the same form as dividends actually paid on shares of Common Stock, when and if actually paid. Series A Preferred Stockholders will be entitled to participate pro rata in any purchase rights extended to holders of Common Stock on an as-converted basis.

Conversion: Each holder of Series A Preferred Stock may convert at any time, all, or any part, of the outstanding Series A Preferred Stock into shares of the Common Stock at the initial "Conversion Price" of $1,000, which is subject to customary adjustments for stock splits. The Company's Board of Directors has the right, at any time, with the written consent of the Required Holders (as defined in the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Preferred Stock (the "Series A Certificate of Designations")), to lower the fixed conversion price to any amount and for any period of time. If 90 days or 180 days following the occurrence of the effective date of the registration statement filed pursuant to the First PIPE Registration Rights Agreement, the Conversion Price then in effect is greater than the greater of $100.00 and the Market Price (as defined in the Series A Certificate of Designations) then in effect (the "Adjustment Price"), the Conversion Price shall automatically lower to the Adjustment Price. In connection with such adjustment provisions, the Conversion Price was reset to $100.00.

Alternate Conversion: Following the occurrence and during the continuance of a Trigger Event (as defined below), each holder may alternatively elect to convert the Series A Preferred Stock at the "Alternate Conversion Price" equal to the lesser of the Conversion Price and the greater of $100.00 (the "Series A Conversion Price Floor") or 80% of the 5-day volume weighted average price of a share of Common Stock. Trigger Events include customary terms related to exchange listing, registration rights, failure to deliver shares on conversion or exercise of derivative instruments, or insolvency. Notwithstanding the Series A Conversion Price Floor, if the Series A Conversion Price Floor is greater than 80% of the 5-day volume weighted average price of a share of Common Stock, then the Conversion Amount (as defined in the Certificates of Designations) is increased by a multiplier resulting in the convertibility of the shares of Series A Preferred Stock into the number of shares of Common Stock that would have been issuable if the Alternate Conversion Price had been equal to such lower volume weighted average price. Such multiplier was in effect from when the registration statement for the resale of shares of Common Stock issuable upon conversion of the Series A Preferred Stock was declared effective on July 5, 2024 because such effectiveness was after the applicable deadline therefore and, as a result of such multiplier, such registration statement registered fewer than the maximum number of shares of Common Stock issuable upon such conversion. Such multiplier ceased to apply on January 6, 2025, the 20th trading day after the effectiveness of the additional registration statement registering the resale of additional shares of Common Stock issuable upon conversion of the Series A Preferred Stock resulting from such shortfall, which additional registration statement was declared effective on December 5, 2024.

Redemptions: Upon bankruptcy or liquidation, Series A Preferred Stock will be redeemed at a 25% premium (or at 50% premium 180 days after issuance) to the greater of the conversion amount or the number of shares multiplied by the highest closing price within the preceding 20 days. Additionally, the Company may voluntarily redeem the Series A Preferred Stock at a 20% premium to the greater of the conversion amount or the number of shares multiplied by the highest closing price within the preceding 20 days.

The holders of the Series A Preferred Stock have no voting rights.

In February 2024, the Company consummated a private placement (the "Series A PIPE Financing") of 10,039 shares of Series A Preferred Stock, warrants to purchase 6,127 shares of Common Stock (the "February 2024 PIPE Common Warrants") and warrants to purchase 2,500 shares of Series A Preferred Stock (the "Preferred Warrants") (See Note 9 below), pursuant to the Amended and Restated Securities Purchase Agreement, dated February 14, 2024, by and among the Company, PBAX and certain accredited investors (the "Initial Investors") for aggregate cash proceeds to the Company of approximately $10.0 million, including cash previously received for bridge loan proceeds.

A portion of such Series A Preferred Stock was issued as consideration for the cancellation of outstanding indebtedness, including a promissory note of PBAX amounting to $1,555,000 and the Predecessor's convertible notes amounting to $627,154.

The Company accounts for preferred stock as either equity or debt-like securities based on an assessment of the Preferred Stock rights and preferences and applicable authoritative guidance in ASC 480 and ASC 815, Derivatives and Hedging. The Company has concluded that the Series A, Series B Preferred Stock and Series C Preferred Stock, which have no cash redemption features outside of the Company's control are treated as equity. The Company has also concluded that the Series A Common Warrants and Series C Common Warrants do not possess redemption features outside of the Company's control and are treated as equity.

Due to delayed filing and declaration of effectiveness relative to the deadlines defined in the Registration Rights Agreement, on June 30, 2024, the Company accrued a registration rights penalty amounting to $645.693, which was payable in cash to the holders of Series A Preferred Stock. On March 27, 2025, the Company entered into a Waiver of Registration Rights Penalties whereby the Investor agreed to waive registration rights penalty amounting to $568,400 in exchange for the Company's forgiveness of the $600,000 Series A warrants exercise price shortfall. In December 2024, the Investor exercised its Series A Preferred Warrants to purchase shares of Series A Preferred stock of the Company for which the Investor remitted a partial exercise price amount of $100,000 instead of the exercise price of $700,000.

During the year ended December 31, 2024, 10,023 shares of Series A Preferred Stock were converted into 1,723,880 shares of Common Stock. The conversion ratio was based on the Series A Certificate of Designations and reflected the application of the Alternate Conversion Price described above, applicable as of each date of conversion plus a 25% premium for penalties due. As a result of the 25% premium, the Company recorded a deemed dividend of $2,419,750 which represents the fair value of excess common shares transferred to the preferred shareholders based on an average per share common share price of $7.10, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended December 31, 2024. Additionally, certain investors are owed an aggregate of 13,835 shares of Common Stock of the Company due to shortfall in number of shares issued upon conversion, which represents the 25% premium not received. Accordingly, the Company reduced additional paid-in capital by $85,500 and recorded a liability of $85,500, which is reflected on the accompanying consolidated balance sheet as deemed dividend - common stock liability. As of December 31, 2024, there were 1,894 remaining shares of Series A Preferred Stock, which were convertible into 473,500 shares of Common Stock.

Successor Series B Convertible Preferred Stock

The Company designated 626 shares of its authorized preferred stock as Series B Preferred Stock and established the rights, preferences and privileges of the Series B Preferred Stock pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock (the "Series B Certificate of Designations" and, together with the Series A Certificate of Designations, the "Certificates of Designations"), as summarized below. Except as set forth below, the Series B Preferred Stock has terms and provisions that are identical to those of the Series A Preferred Stock.

On April 1, 2024, we consummated a private placement of 626 shares of the Company's Series B Preferred Stock, pursuant to the Securities Purchase Agreement, dated March 28, 2024, by and among us and certain accredited investors (the "Additional Investors" and, together with the Initial Investors, the "PIPE Investors"), for aggregate cash proceeds to us of approximately $0.5 million. Such private placement closed on April 1, 2024.

The holders of the Series B Preferred Stock have no voting rights.

The Series B Preferred Stock ranks pari passu with the Series A Preferred Stock.

Due to delayed filing and declaration of effectiveness relative to the deadlines defined in the Registration Rights Agreement, through December 31, 2024, the Company accrued a registration rights penalty amounting to $55,000, which is payable in cash to the holders of Series B Preferred Stock and included in accrued liabilities on the accompanying consolidated balance sheet as of December 31, 2024.

During the year ended December 31, 2024, 353 shares of Series B Preferred Stock were converted into 53,815 shares of Common Stock. The conversion ratio was based on the Series B Certificate of Designations and included the 25% premium to the greater of the conversion amount or the number of shares multiplied by the highest closing price within the preceding 20 days. As a result of the 25% premium, the Company recorded a deemed dividend of $88,250 which represents the fair value of excess common shares transferred to the preferred shareholders based on an average per share common share price of $7.30, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended December 31, 2024. As of December 31, 2024, there were 273 remaining shares of Series B Preferred Stock, which were convertible into 111,084 shares of Common Stock.

Successor Series C Convertible Preferred Stock

The Company designated 2,853 shares of its authorized preferred stock as the Series C Preferred Stock and the rights, preferences and privileges of the Series C Preferred Stock are summarized below.

Each share of Series C Preferred Stock has a stated value of $1,000 per share and, when issued, the Series C Preferred Stock was fully paid and non-assessable. The Series C Preferred Stock, ranks senior to all other Company capital stock unless required holder votes are obtained to create a class of stock senior to Series C Preferred Stock.

Ranking: The Series C Preferred Stock are senior in rank with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company to the Series A Convertible Preferred Stock, the Series B Convertible Preferred Stock, and Common Stock. The Company shall not, without the consent of the Required Holders, authorize or issue any shares of senior rank with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company, shares of pari passu rank with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company, or shares of junior ranking stock that have a maturity or redemption date prior to the first anniversary of the Series C Preferred Stock issuance date.

Dividend and Participation Rights: The holders of Series C Preferred Stock will be entitled to dividends, on an as-if converted basis, equal to and in the same form as dividends actually paid on shares of Common Stock, when and if actually paid. Series C Preferred Stockholders will be entitled to participate pro rata in any purchase rights extended to holders of Common Stock on an as-converted basis.

Conversion: Each holder of Series C Preferred Stock may convert at any time, all, or any part, of the outstanding Series C Preferred Stock into shares of the Common Stock at the initial "Conversion Price" of $22.40, which is subject to customary adjustments for stock splits.

Alternate Conversion: Following the occurrence and during the continuance of a Trigger Event (as defined below), each holder may alternatively elect to convert the Series C Preferred Stock at the "Alternate Conversion Price" equal to the lesser of the then current Conversion Price and the greater of $1.96 (the "Series C Conversion Price Floor") or 80% of the trailing 5-day daily volume weighted average price of a share of Common Stock. Trigger Events include customary terms related to exchange listing, registration rights, failure to deliver shares on conversion or exercise of derivative instruments, or insolvency. Notwithstanding the Series C Conversion Price Floor, if the Series C Conversion Price Floor is greater than 80% of the 5-day volume weighted average price of a share of Common Stock, then the Conversion Amount (as defined in the Series C Certificate of Designation) for such Series C Preferred Stock is increased by a multiplier resulting in the convertibility of the shares of Series C Preferred Stock into the number of shares of Common Stock that would have been issuable if the Alternate Conversion Price had been equal to such lower volume weighted average price.

Redemptions: Upon bankruptcy or liquidation, Series C Preferred Stock will be redeemed at a 25% premium to the conversion amount multiplied by the highest Alternative Conversion Price within the preceding 20 days multiplied by 125% of the greatest closing sale price of the Common Stock on any day immediately following public announcement of insolvency and the date the entire redemption payment has been made. Additionally, the Company may voluntarily redeem the Series C Preferred Stock as at 25% premium to the greater of the conversion amount or the number of shares multiplied by the highest closing price within the preceding 20 days.

The holders of the Series C Preferred Stock have no voting rights.

In September 2024, the Company consummated a private placement (the "Series C PIPE Financing") of 2,853 shares of Series C Preferred Stock and warrants to purchase 81,752 shares of Common Stock (the "September 2024 PIPE Common Warrants") (See Note 9 below), pursuant to the Securities Purchase Agreement, dated September 25, 2024, by and among the Company and certain accredited investors for aggregate gross cash proceeds to the Company of approximately $1.25 million.

The Company accounts for preferred stock as either equity or debt-like securities based on an assessment of the Preferred Stock rights and preferences and applicable authoritative guidance in ASC 480 and ASC 815, Derivatives and Hedging. The Company has concluded that the Series C Preferred Stock, which has no cash redemption features outside of the Company's control are treated as equity. The Company has also concluded that the Series C Common Warrants do not possess redemption features outside of the Company's control and are treated as equity.

As of December 31, 2024, there were 2,853 remaining shares of Series C Preferred Stock, which were convertible into 490,206 shares of Common Stock.

Predecessor Preferred Stock Conversion to Common Stock

At December 31, 2023, Predecessor had 75,120,105 shares of capital stock authorized, consisting of 45,350,000 shares of Predecessor common stock and 29,770,105 shares of Predecessor convertible preferred stock. All classes of the Predecessor's stock had a par value of $0.0001. On February 14, 2024, on the close of the Merger, the Predecessor's outstanding convertible preferred stock converted to Common Stock at a conversion ratio of 0.0806 and 0.01757 shares of Common Stock for each share of Predecessor Series Seed Convertible Preferred Stock and Predecessor Series A Convertible Preferred Stock, respectively. This resulted in the issuance of 4,155 and 40,000 shares of Common Stock for the Predecessor's Series Seed Preferred Stock and Predecessor Series A Preferred Stock, respectively.

Predecessor's Series Seed and Series A Preferred Stock had cash redemption features outside of its control, and therefore were classified in a mezzanine section presented on the balance sheets between liabilities and stockholders' deficit.

Purchase of Common Stock by Keystone Capital Partners under the Equity Line of Credit ("ELOC")

On February 14, 2024, in conjunction with, and as a condition to the closing of the Series A PIPE Financing, the Company entered into a common stock purchase agreement (the "Old Keystone Purchase Agreement") with Keystone Capital Partners, L.P. ("Keystone"), pursuant to which we may sell and issue, and Keystone is obligated to purchase, up to 250,000 shares subject to the Company obtaining all necessary stockholder approvals to issue the shares to Keystone. The price of the shares purchased by Keystone under the ELOC is 90% of various volume-weighted average price ("VWAP") and closing price-based formulae, and requires a waiver, should the selling price be below $100.00 per share. As consideration for Keystone's commitment to purchase shares of Common Stock pursuant to the Old Keystone Purchase Agreement, we issued an aggregate of 18,643 shares of Common Stock to Keystone.

On November 8, 2024, the Company consummated a purchase agreement with Keystone (the "New Keystone Purchase Agreement") pursuant to which we may sell and issue, and Keystone is obligated to purchase, up to $20.6 million of shares of Common Stock, constituting the remaining unsold balance under the original Keystone Purchase Agreement, subject to certain market conditions. The price of the shares purchased by Keystone under the ELOC is 90% of various volume-weighted average price ("VWAP") and closing price-based formulae, and requires a waiver, should the selling price be below $1.00 per share.

For the period from February 14, 2024 through December 31, 2024, the Company sold 453,500 common shares of the Company for gross proceeds of approximately $4.9 million under the Keystone ELOC. The Company received net proceeds of approximately $4.1 million, and as of December 31, 2024, the Company had a stock subscription receivable of $716,694, which was collected in January 2025. The Company sought and received a waiver to sell the shares below the applicable minimum price in the agreement. The Company also issued 18,644 shares of common stock to Keystone as consideration for the ELOC in the period from February 14, 2024 to December 31, 2024, respectively.

Issuance of Common Stock to Arena Business Solutions Global SPC II, Ltd. ("Arena") for the Arena ELOC

On February 23, 2024, the Company entered into a common stock purchase agreement (the "Arena Purchase Agreement") with Arena, pursuant to which we may sell and issue, and Arena is obligated to purchase, up to $25,000,000 of Common Stock. The price of the shares purchased by Arena under the ELOC is 90% of various VWAP and closing price-based formulae, and requires a waiver, should the selling price be below $25.00 per share. As consideration for Arena commitment to purchase shares of Common Stock pursuant to the Arena Purchase Agreement, in May 2024, the Company issued 3,456 shares of Common Stock to Arena during the period from February 14, 2024 through December 31, 2024 valued at $500,000, which is reflected as deferred offering costs on the accompanying consolidated balance sheet as of December 31, 2024. The Company has sold no shares of Common Stock to Arena under the Arena ELOC during the period ended December 31, 2024.

NOTE 9 – WARRANTS

Accounting for warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the instruments' specific terms and applicable authoritative guidance in ASC 480 and ASC 815, Derivatives and Hedging. The assessment considers whether the instruments are free standing financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the instruments meet all of the requirements for equity classification under ASC 815, including whether the instruments are indexed to the Company's own common stock and whether the instrument holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, was conducted at the time of warrant issuance and as of each subsequent period end date while the instruments are outstanding.

Public and Private Placement Warrants (Successor)

At December 31, 2024, there were 91,925 Public and Private Placement Warrants outstanding, each with a right to purchase one share of Common Stock for $1,150. The Public and Private Placement Warrants became exercisable 30 days after the Merger. No warrants will be exercisable for cash unless the Company has an effective and current registration statement covering the Common Stock issuable upon exercise of the warrants and a current prospectus relating to such Common Stock. The Public and Private Placement Warrants were registered under a resale registration statement on Form S-1 (File No. 333-279156), which was declared effective by the Securities and Exchange Commission on July 5, 2024.

Notwithstanding the foregoing, Public and Private Placement Warrant holders may, during any period when the Company shall have failed to maintain an effective registration statement, exercise warrants on a cashless basis pursuant to the exemption provided by Section 3(a)(9) of the Securities Act, provided that such exemption is available. If that exemption, or another exemption, is not available, holders will not be able to exercise their warrants on a cashless basis. The Public and Private Placement Warrants will expire five years after the Merger or earlier upon redemption or liquidation.

Once the warrants became exercisable, the Company may, with 30 days prior notice, redeem the Public Warrants in whole and not in part, at a price of $0.01 per warrant if the shares underlying the warrants are registered and if the closing price of Common Stock equals or exceeds $1,800.00 for 20 of the prior 30 trading days. If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement.

The exercise price and number of shares of Common Stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary dividend or recapitalization, reorganization, merger, or consolidation. However, the warrants will not be adjusted for issuances of Common Stock at a price below their respective exercise prices. Additionally, in no event will the Company be required to net cash settle the warrants.

As discussed above, the Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the instruments' specific terms and applicable authoritative guidance in ASC 480 and ASC 815, Derivatives and Hedging. Management has concluded that the Public Warrants issued pursuant to the warrant agreement qualify for equity accounting treatment.

Conversion Warrants

On November 14, 2019, Predecessor issued warrants to purchase a total of 1,849,638 shares of Predecessor Series A Preferred Stock at a price of $1.7571 per share. The warrants were exercisable into shares of Predecessor Series A Preferred Stock at the discretion of the holder, at any time in the five years after issuance. The warrants were analyzed and determined to be freestanding instruments issued in a transaction including the conversion or sale of the Series A Preferred Stock. A warrant to purchase up to 426,839 shares of Series A Preferred Stock was issued in a transaction that included the conversion of 100 shares of Series 1 Preferred Stock into 2,845,597 shares of Predecessor Series A Preferred Stock. Another warrant to purchase up to 1,422,799 shares of Series A Preferred Stock was issued concurrent with the purchase of 2,845,597 shares of Series A Preferred Stock. These warrants are collectively referred to as the "Predecessor Preferred Stock Warrants." On February 14, 2024, the Predecessor Preferred Stock Warrants were converted into warrants to purchase up to 3,250 shares of Common Stock ("Conversion Warrants").

The Conversion Warrants were exercisable for Common Stock at an exercise price equal to $1,000. The exercise price was subject to adjustment for stock splits, combinations and similar events, and, in the event of stock dividends and splits, the number of shares of Common Stock issuable upon the exercise of the Conversion Warrant will also be adjusted so that the aggregate exercise price shall be the same immediately before and immediately after any such adjustment.

The Conversion Warrants expired five years after the original Predecessor Preferred Stock Warrants were issued, or November 14, 2024.

As discussed above, Predecessor accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the instruments' specific terms and applicable authoritative guidance in ASC 480 and ASC 815, Derivatives and Hedging. Based on the exercisability of the Predecessor Preferred Stock Warrants into Series A Preferred Stock, which had a cash redemption feature outside of the control of Predecessor, the Predecessor Preferred Stock Warrants were recorded as a derivative liability and were revalued at each reporting period, with the change in value being recorded on the statement of operations.

Series A Common Warrants (Successor) - February 2024

The Company's 6,127 Series A Common Warrants are initially exercisable for cash at an exercise price equal to the greater of (x) $920 (as adjusted for stock splits, stock dividends, stock combinations, recapitalizations and similar events) and (y) the closing price of the Common Stock on the trading day immediately prior to the Subscription Date (as defined in the Series A Common Warrant Agreement). The exercise price is subject to adjustment for stock splits, combinations and similar events, and, in the event of stock dividends and splits, the number of shares of Common Stock issuable upon the exercise of the February 2024 PIPE Common Warrants will also be adjusted so that the aggregate exercise price shall be the same immediately before and immediately after any such adjustment. On stockholder approval for the issuance of shares underlying the warrants, granted April 30, 2024, the exercise price of the Series A Common Warrants was adjusted to $139 per share, per the terms of the Securities Purchase Agreement. On April 30, 2024, the Company calculated the total fair value of the consideration for the modification of the Series A Common Warrants, which includes the incremental fair value of the Series A Common Warrants (determined by comparing the fair values immediately prior to and immediately after the modification). The incremental fair value was calculated using the Black-Scholes option-pricing model and amounted to $276,839, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended December 31, 2024. In calculating the incremental fair value om April 30, 2024, the Company used the following assumptions: risk-free interest rate

Risk-free interest rate	4.72%
Expected life (in years)	4.80
Expected dividend yield	0%
Expected volatility	90%

The Series A Common Warrants will be exercisable beginning six months after the issuance date (the "Initial Exercisability Date") and expiring on the third anniversary of the Initial Exercisability Date. The Series A Common Warrants require "buy-in" payments to be made by us for failure to deliver any shares of Common Stock issuable upon exercise.

If at the time of exercise of the Series A Common Warrants, there is no effective registration statement registering the shares of the Common Stock underlying the Series A Common Warrants, such warrants may be exercised on a cashless basis pursuant to their terms.

If we issue options, convertible securities, warrants, shares, or similar securities to holders of Common Stock, each holder of February 2024 PIPE Common Warrants has the right to acquire the same as if the holder had exercised its Series A Common Warrants. The holders of Series A Common Warrants are entitled to receive any dividends paid or distributions made to our holders of Common Stock on an "as if converted" basis.

The Series A Common Warrants prohibit us from entering into specified fundamental transactions unless the Successor entity assumes all of our obligations under the Series A Common Warrants under a written agreement before the transaction is completed. Upon specified corporate events, a holder of Series A Common Warrants will thereafter have the right to receive upon an exercise such shares, securities, cash, assets or any other property whatsoever which the holder would have been entitled to receive upon the happening of the applicable corporate event had the Series A Common Warrants been exercised immediately prior to the applicable corporate event. When there is a transaction involving specified changes of control, a holder of Series A Common Warrants can request the Company to exchange the then unexercised portion of their Series A Common Warrants for consideration equal to the Black-Scholes value thereof, which shall be settled, at the option of the Company in either (i) the form of rights convertible into the consideration receivable by holders of the underlying shares of common stock, based upon the value of the shares of the successor entity over a specified period or (ii) cash in an amount equal to the Black-Scholes value.

The Company's Series A Common Warrants are exercisable into Common Stock and are recorded as equity.

September 2024 Series C Common Warrants (Successor)

The Company's 81,753 September 2024 Series C Common Warrants are initially exercisable for cash at an initial exercise price equal to $9.80 (as adjusted for stock splits, stock dividends, stock combinations, recapitalizations and similar events). The exercise price is also subject to adjustment for the sale of Common Stock, or issuance or modification of options to result in the purchase of one share of Common Stock at an effective price per share lower than the then current Series C Common Warrant exercise price. Additionally, should the Company issue any variable priced convertible securities, the holders may elect an alternative exercise price that allows exercise at the effective purchase price applicable to the convertible security.

The September 2024 PIPE Common Warrants are exercisable beginning six months after the issuance date (the "Initial Exercisability Date") and expiring on the third anniversary of the Initial Exercisability Date. The Series C Common Warrants require "buy-in" payments to be made by us for failure to deliver any shares of Common Stock issuable upon exercise.

If at the time of exercise of the Series C Common Warrants, there is no effective registration statement registering the shares of the Common Stock underlying the Series C Common Warrants, such warrants may be exercised on a cashless basis pursuant to their terms.

If we issue options, convertible securities, warrants, shares, or similar securities to holders of Common Stock, each holder of Series C Common Warrants has the right to acquire the same as if the holder had exercised its Series C Common Warrants. The holders of Series C Common Warrants are entitled to receive any dividends paid or distributions made to our holders of Common Stock on an "as if converted" basis.

The Series C Common Warrants prohibit us from entering into specified fundamental transactions unless the successor entity assumes all of our obligations under the Series C Common Warrants under a written agreement before the transaction is completed. Upon specified corporate events, a holder of Series C Common Warrants will thereafter have the right to receive upon an exercise such shares, securities, cash, assets or any other property whatsoever which the holder would have been entitled to receive upon the happening of the applicable corporate event had the Series C Common Warrants been exercised immediately prior to the applicable corporate event. When there is a transaction involving specified changes of control, a holder of Series C Common Warrants can request the Company to exchange the then unexercised portion of their Series C Common Warrants for consideration equal to the Black-Scholes value thereof, which shall be settled, at the option of the Company in either (i) the form of rights convertible into the consideration receivable by holders of the underlying shares of common stock, based upon the value of the shares of the successor entity over a specified period or (ii) cash in an amount equal to the Black-Scholes value.

The Company's Series C Common Warrants are exercisable into Common Stock and are recorded as equity.

December 2024 Common Warrants (Successor)

On December 23, 2024, the Company issued warrants to purchase an aggregate of 84,061 shares of Common Stock to certain investors affiliated with each other to induce investors to exercise their Series A Preferred Warrants for cash (the "December 2024 Common Warrants"). The December 2024 Common Warrants are initially exercisable for cash at an initial exercise price equal to $5.61 (as adjusted for stock splits, stock dividends, stock combinations, recapitalizations and similar events).

The December 2024 Common Warrants are exercisable beginning six months after the issuance date (the "Initial Exercisability Date") and expiring on the third anniversary of the Initial Exercisability Date. The December 2024 Common Warrants require "buy-in" payments to be made by us for failure to deliver any shares of Common Stock issuable upon exercise.

If at the time of exercise of the December 2024 Common Warrants, there is no effective registration statement registering the shares of the Common Stock underlying the December 2024 Common Warrants, such warrants may be exercised on a cashless basis pursuant to their terms.

If we issue options, convertible securities, warrants, shares, or similar securities to holders of Common Stock, each holder of December 2024 Common Warrants has the right to acquire the same as if the holder had exercised its December 2024 Common Warrants. The holders of December 2024 Common Warrants are entitled to receive any dividends paid or distributions made to our holders of Common Stock on an "as if converted" basis.

The December 2024 Common Warrants prohibit us from entering into specified fundamental transactions unless the successor entity assumes all of our obligations under the December 2024 Common Warrants under a written agreement before the transaction is completed. Upon specified corporate events, a holder of December 2024 Common Warrants will thereafter have the right to receive upon an exercise such shares, securities, cash, assets or any other property whatsoever which the holder would have been entitled to receive upon the happening of the applicable corporate event had the December 2024 Common Warrants been exercised immediately prior to the applicable corporate event. Upon the consummation of any Fundamental Transaction, the Company shall exchange the December 2024 Common Warrants for consideration equal to the Black Scholes Value of such portion of the December 2024 Common Warrants subject to exchange (collectively, the "Aggregate Black Scholes Value") in the form of, at the Company's election (such election to pay in cash or by delivery of the Rights (as defined below), a "Consideration Election"), either (I) rights (with a beneficial ownership limitation, *mutatis mutandis*) (the "Rights"), convertible in whole, or in part, at any time, without the requirement to pay any additional consideration, at the option of the Holder, into such Corporate Event Consideration applicable to such Fundamental Transaction equal in value to the Aggregate Black Scholes Value issuable upon conversion of the Rights to be determined in increments of 10% (or such greater percentage as the Holder may notify the Company from time to time) of the portion of the Aggregate Black Scholes Value attributable to such Shares (the "Share Value Increment"), with the aggregate number of Shares issuable upon exercise of the Rights with respect to the first Successor Share Value Increment determined based on 70% of the Closing Bid Price of the Shares on the date the Rights are issued and on each of the nine subsequent Trading Days, in each case, the aggregate number of additional Shares issuable upon exercise of the Rights shall be determined based upon a Share Value Increment at 70% of the Closing Bid Price of the Shares in effect for such corresponding Trading Day (such ten (10) Trading Day period commencing on, and including, the date the Rights are issued, the "Rights Measuring Period")), or (II) in cash; provided, that the Company shall not consummate a Fundamental Transaction if the Corporate Event Consideration includes capital stock or other equity interest (the "Successor Shares") either in an entity that is not listed on an Eligible Market or an entity in which the daily share volume for the applicable Successor Shares for each of the twenty Trading Days prior to the date of consummation of such Fundamental Transaction is less than the aggregate number of Successor Shares issuable to the Holder upon conversion in full of the applicable Rights (without regard to any limitations on conversion therein, assuming the exercise in full of the Rights on the date of issuance of the Rights and assuming the Closing Bid Price of the Successor Shares for each Trading Day in the Rights Measuring Period is the Closing Bid Price on the Trading Day ended immediately prior to the time of consummation of the Fundamental Transaction).

The Company's December 2024 Common Warrants are exercisable into Common Stock, which has no cash redemption features that require liability treatment. The Company has recorded the December 2024 Common Warrants as equity.

On December 23, 2024, in connection with the issuance of the December 2024 Warrants, the Company calculated the fair value of such warrants using the Black-Scholes option-pricing model, and the Company determined that the aggregate total fair value of the December 2024 Warrants amounted to approximately $0.3 million, which were considered offering costs and were netted against the net proceeds received by the warrant exercise under the guidance of ASU 2021-04.

Preferred Warrants

The 2,500 Preferred Warrants were initially exercisable for cash at an exercise price equal to $800. The exercise price was subject to adjustment for stock splits, combinations and similar events, and, in the event of stock dividends and splits, the number of shares of Series A Preferred Stock issuable upon the exercise of the Preferred Warrant will also be adjusted so that the aggregate exercise price shall be the same immediately before and immediately after any such adjustment.

We had the right, conditional upon the share price of CERO stock to be trading above $100.00 per share, to require the holders of Preferred Warrants to exercise such Preferred Warrants into up to an aggregate number of shares of Preferred Stock equal to the holder's pro rata amount of 2,500 shares of Preferred Stock. In connection with the Series C PIPE Financing, we agreed with certain holders of the Preferred Warrants not to exercise such right to require such exercise by the holders thereof in consideration for their investment in the Series C PIPE Financing.

The Preferred Warrants prohibited us from entering into specified fundamental transactions unless the Successor assumes all of our obligations under the Preferred Warrants under a written agreement before the transaction is completed. Upon specified corporate events, a holder of the Preferred Warrants thereafter had the right to receive upon an exercise such shares, securities, cash, assets or any other property whatsoever which the holder would have been entitled to receive upon the happening of the applicable corporate event had the Preferred Warrant been exercised immediately prior to the applicable corporate event.

During the period from February 14, 2024 through December 31, 2024, 1,875 Series A Preferred Warrants were exercised into 1,875 shares of Series A Preferred Stock for gross proceeds of $938,800. The remaining 625 Series A Preferred Warrants were exercised in January 2025 for gross proceeds of $500,000 (See Note 14).

The Company's Preferred Warrants were exercisable into Series A Preferred Stock, which had no cash redemption features that required liability treatment. The Company recorded the Preferred Warrants as equity.

A summary of outstanding warrants as of December 31, 2024 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Public Warrants	91,925	$ 1,150.00	4.13
February 2024 Series A Common Warrants	6,127	139.00	2.62
Series A Preferred Warrants	625	800.00	0.12
September 2024 Series C Common Warrants	81,753	9.80	3.23
December 2024 Common Warrants	84,061	5.61	3.48
Outstanding as of December 31, 2024	264,491	$ 409.61	3.60

NOTE 10 – FAIR VALUE MEASUREMENTS

Predecessor estimated the fair value of the Predecessor Series A Preferred Stock Warrants at December 31, 2023, using Black-Scholes with the following assumptions:

	December 31, 2023 (Predecessor)
Risk-free interest rate	5.40%
Expected life (in years)	0.25
Expected dividend yield	-%
Expected volatility	65.90%

The Company initially recorded the earnout liability at estimated fair value using a Monte Carlo analysis and has revalued the Earnout liability at each subsequent period. The Monte Carlo analysis used the following assumptions:

	December 31, 2024 (Successor)	February 14 2024 (Successor)
Starting share price	$ 6.00	$ 490.00
Tranche 1 trigger price	$ 1.25	$ 3.20
Tranche 2 trigger price	$ 1.25	$ 3.85
Contractual term	3.1	4.0
Volatility	100%	90%
Risk-free interest rate	4.23%	4.20%

At December 31, 2024 for the Successor and December 31, 2023 for the Predecessor, the fair value of earnout liability and derivative liabilities were classified as follows:

The classification of the fair value of the earnout liability and derivative liabilities and the change in the fair value measurement using significant inputs (Level 3) for the year ended December 31, 2023 and for the period from January 1, 2024 through February 14, 2024 for Predecessor and February 14, 2024 through December 31, 2024 for the Company is presented below:

	Level 1	Level 2	Level 3	Total
Preferred stock warrant liability (Predecessor):				
Balance at January 1, 2023	$ -	$ -	$ 610,381	$ 610,381
Gain on revaluation of warrant liability	-	-	(290,264)	(290,264)
Balance at December 31, 2023	-	-	320,117	320,117
Reclassification of warrant liability to equity	-	-	(320,117)	(320,117)
Balance at February 13, 2024	$ -	$ -	$ -	$ -
Earnout liability (Successor):				
Balance at February 14, 2024	-	-	4,900,000	4,900,000
Gain on revaluation of earnout liability	-	-	(4,880,000)	(4,880,000)
Balance at December 31, 2024	$ -	$ -	$ 20,000	$ 20,000

NOTE 11 – STOCK-BASED COMPENSATION

In October 2016, Predecessor's Board of Directors approved the adoption of an Equity Incentive Plan ("Predecessor EIP"). As amended, the Predecessor EIP permitted the Predecessor to grant awards allowing for the issuance of up to 4,888,402 shares of Predecessor's common stock. On close of the Merger, outstanding awards issued for the Predecessor EIP were converted to options to purchase a number of shares of the Company's Common Stock equal to the number of Predecessor shares multiplied by the Merger Exchange Ratio of 0.064452 at a price of the Predecessor option strike price divided by the Merger Exchange Ratio. The Predecessor EIP was then cancelled.

During the six months ended June 30, 2024, the Company's Board of Directors granted directors, officers and employees options to purchase up to 50,400 shares of Common Stock for exercise prices ranging from $35.20 per share to $481.00 per share under the 2024 Plan (as defined below). The grants have various vesting conditions, including time-based and performance-based terms. These stock options expire through June 24, 2034. On September 30, 2024 and October 1, 2024, 34,550 of these stock options were cancelled due to termination or other reasons. Additionally, on October 1, 2024, the exercise price of the remaining 15,850 outstanding options granted under the 2024 Plan was adjusted to $10.00 per share, with all other terms of the original grant to remain without adjustment. On October 1, 2024, the Company calculated the total fair value of the consideration for the modification of these stock options, which includes the incremental fair value of the stock options (determined by comparing the fair values immediately prior to and immediately after the modification). The fair values were calculated using the Black-Scholes option-pricing model, and the Company determined that the total fair value of the consideration related to the modification of these stock options amounted to $76,027, of which $28,636 was expensed immediately and $47,391 will be recorded as stock-based compensation expense over the remaining vesting term.

On October 1, 2024, the Company's Board of Directors granted directors, officers and employees options to purchase up to 47,780 shares of common stock for $10.00 per share. The grants have various vesting conditions, including time-based and performance-based terms. These stock options expire on October 1, 2034.

Predecessor's Stock option activity for the period from December 31, 2023 through February 14, 2024 and the Company's stock option activity for the period from February 14, 2024 through December 31, 2024, was as follows:

	Outstanding Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Balance, December 31, 2023 (Predecessor)	504	$ 418.92	6.86
Options cancelled (Predecessor)	(504)	$ 418.92	
Balance, February 14, 2024 (Predecessor)	-	$ -	-
Balance, February 14, 2024 (Predecessor)	-	$ -	-
Options granted (Successor)	98,180	$ 90.91	-
Options cancelled (Successor)	(33,232)	$ 146.12	-
Balance, December 31, 2024 (Successor)	64,948	$ 10.00	9.64
Options exercisable as of December 31, 2024	49,480	$ 10.00	9.68

The intrinsic value of Predecessor options exercised during the year ended December 31, 2023 was $9,458. No options were exercised in the Successor period from February 14, 2024 to December 31, 2024.

On March 25, 2024, the stockholders approved the CERo Therapeutics Holdings, Inc. 2024 Equity Incentive Plan (the "2024 Plan") and 2024 Employee Stock Purchase Plan ("2024 ESPP"), with an initial reserve of 51,726 and 50,993 shares of common stock, respectively. The 2024 Plan and 2024 ESPP became effective on February 14, 2024 in connection with the closing of the Business Combination. At a special meeting of stockholders on April 30, 2024, the stockholders approved an increase in the number of shares available for issuance under the 2024 Plan and the number of shares that may be issued pursuant to incentive stock options, by an additional 20,000 shares each. At a special meeting of stockholders on November 11, 2024, the stockholders approved an increase in the number of shares available for issuance under the 2024 Plan and the number of shares that may be issued pursuant to incentive stock options, by an additional 208,454 shares each. As of December 31, 2024, no awards have been granted under the 2024 ESPP. The 2024 Plan has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2024 Plan to be added on the first day of January, starting with January 1, 2025, in an amount equal to the lesser of (i) 5% of the fully diluted shares of our Common Stock on the immediately preceding December 31 or (ii) such number of shares as determined by our board in each case subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. On January 1, 2025, the number of shares reserved under the 2024 Plan was increased by 5% of the fully diluted shares of our common stock on the immediately preceding December 31, or 189,701 shares. The 2024 ESPP has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2024 ESPP to be added on the first day of each January, starting with January 1, 2025, by the lesser of (i) 10,198 shares of our common stock, (ii) 1% of the fully diluted shares of common stock on the immediately preceding December 31, or (iii) such number of shares of common stock as determined by our board. The number of shares reserved under the 2024 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of December 31, 2024, the board of directors has granted an aggregate of 64,948 option awards under the 2024 Plan, leaving 215,232 shares reserved for future issuance under the 2024 Plan.

The Company estimated the fair value of stock options granted during the period February 14, 2024 through December 31, 2024 using Black-Scholes with the following weighted average assumptions:

- The Common Stock expected dividend yield assumption of 0.0% is based on the expectation of no dividend payouts to Common Stock.
- The risk-free interest rate assumption is based on the U.S. Department of Treasury instruments whose term was most consistent with the expected life of the Company's stock options.
- The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company does not have sufficient public trading history for the Company's Common Stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical price data for the Company's Common Stock becomes available.

- The expected lives of the Company's stock options are estimated based on the type of award issued using approaches that do not rely on the historical data of the Company, as management has concluded there is insufficient data to provide a reasonable forward-looking estimate. The expected life of an incentive stock option is estimated using the simplified method described in Staff Accounting Bulletin Topic 14 – Share-Based Payment. All incentive stock options awarded by the Company have terms consistent with this approach, which is to calculate the weighted average midpoint between the vesting date of each vesting tranche and the termination date of the option. Non-qualified stock options are valued using the contractual life as the expected term.

The Company estimated the fair value of the stock options during the year ended December 31, 2024 using Black-Scholes with the following assumptions. There were no stock options granted by the Predecessor during the year ended December 31, 2023.

	December 31, 2024 (Successor)
Risk-free interest rate	3.75% to 4.89%
Expected life (in years)	5.0 to 7.0
Expected dividend yield	-%
Expected volatility	62.4% to 106.6%

For the period from February 14, 2024 through December 31, 2024, the Company recorded stock-based compensation expense of $924,668, of which $547,910 was related to research and development and $376,758 was related to general and administrative. For the period from January 1, 2024 through February 13, 2024, Predecessor recorded an immaterial amount of stock-based compensation expense.

For the year ended December 31, 2023, the Company recorded stock-based compensation expense of $96,896, of which $91,664 was related to R&D and $5,232 was related to general and administrative.

As of December 31, 2024, the Company had approximately $1,009,000 of unamortized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.02 years. The weighted average grant date calculated fair value per share of the Company's options granted during the period from February 14, 2024, through December 31, 2024, was $61.54.

There were no Predecessor options granted in the year ended December 31, 2023.

NOTE 12 – INCOME TAXES

A reconciliation between the expected income tax provision at the federal statutory rate and the reported income tax provision is approximately as follows:

	2024	2023
Federal income tax at statutory rate	$ (1,745,000)	$ (1,565,000)
State income tax, net of federal benefit	(580,000)	(520,000)
Permanent differences	(1,358,000)	(75,000)
Tax credits generated in current year, net of utilized	(408,000)	(171,000)
Other	51,000	(2,102,000)
Change in valuation allowance	4,040,000	4,433,000
Total	$ -	$ -

The approximate components of the net deferred tax assets as of December 31, 2024 and 2023 were as follows:

	2024	2023
Net operating loss carryforwards	$ 12,227,000	$ 9,067,000
Section 174 research and development capitalization	2,999,000	2,490,000
Research credits	1,943,000	1,535,000
Fixed assets and intangible assets	403,000	401,000
Right of use asset	(410,000)	(613,000)
Lease liability, net	251,000	657,000
Accruals and others	230,000	66,000
	17,643,000	13,603,000
Less: valuation allowance	(17,643,000)	(13,603,000)
Net deferred tax assets	$ -	$ -

The Company has incurred significant tax losses since inception. Based on the available objective evidence, management cannot conclude it is more likely than not that the net deferred tax assets will be fully realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets. For the periods ended December 31, 2024 and 2023, the valuation allowance increased by approximately $4,040,000 and $4,433,000, respectively.

At December 31, 2024, the Company has federal net operating loss carryforwards of approximately $727,000 that begin to expire in 2036. The Company also has federal net operating losses of $39,687,000 that arose after the 2017 tax year that will carry forward indefinitely and the utilization of which is limited to 80% of taxable income for tax years beginning after 2021. The Company has state net operating loss carryforwards of approximately $53,559,000 that will begin to expire in 2036.

Under the Tax Reform Act of 1986, the amount of and benefits from net operating loss carry forwards may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three-year period. The impact of any limitations that may be imposed due to such ownership changes has not been determined.

As of December 31, 2024, the Company has research credit carry forwards of approximately $1,241,000 and $1,509,000 for federal and state tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2040. The California credits can be carried forward indefinitely. The Company has not undertaken a detailed analysis of all amounts claimed as research credits for federal or state tax purposes. As a result, amounts ultimately realized for research credits were included in management's consideration of uncertain tax benefits.

As of December 31, 2024 and 2023, the Company had an unrecognized tax benefit balance of approximately $538,000 and $459,000, respectively, related to R&D credits.

No amount of unrecognized tax benefits as of December 31, 2024 and 2023, if recognized, would reduce the Company's effective tax rate because the benefits would be in the form of tax credit carryforwards, which would attract a full valuation allowance. There are no provisions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date. Because the statute of limitations does not expire until after the net operating loss and credit carryforwards are actually used, the statutes are still open on calendar years ended 2016 and 2017 forward for federal and state purposes.

The Company did not recognize any expense for interest and penalties related to uncertain tax positions during 2024 and 2023, and the Company does not have any amounts related to interest and penalties accrued as of December 31, 2024 and 2023.

The Company files U.S. federal and state tax returns. The Company's tax years will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss credit.

A reconciliation of the beginning and ending amount of the liability for uncertain tax positions, excluding potential interest and penalties, is as follows:

Balance as of December 31, 2023	$	459,000
Increase/(decrease) based on current year tax positions		79,000
Increase/(decrease) for prior year tax positions		-
Lapses of applicable statutes		-
Balance as of December 31, 2024	$	538,000

NOTE 13 – 401(K) RETIREMENT SAVINGS PLAN

The Company sponsors a 401(k) defined contribution plan covering eligible employees who elect to participate. The Company is allowed to make discretionary profit sharing and 401(k) matching contributions as defined in the plan and as approved by the Board of Directors. The Company's contributions for the period from February 14, 2024 through December 31, 2024 was $44,077 and Predecessor contributions during the period from January 1, 2024 through February 13, 2024 was $8,657. The Predecessor made contributions of $63,344 during the year ended December 31, 2023.

NOTE 14 – RELATED-PARTY TRANSACTIONS

In February 2024, we issued and sold an aggregate of 10,039 shares of Series A Preferred Stock, 6,127 Series A Common Warrants and 2,500 Preferred Warrants, at a price of $800 per share of Series A Preferred Stock, for aggregate cash proceeds of approximately $8.0 million, plus additional cash proceeds of up to $2.0 million if the Preferred Warrants are exercised.

The following table summarizes the shares of our Series A Preferred Stock issued to our related parties:

Purchasers	Shares of Series A Preferred Stock		Total Purchase Price
Daniel Corey[(1)]	150	$	150,000
Atwood-Edminster Trust dtd 4-2-2000 [(2)]	1,002	$	1,002,000
Chris Ehrlich[(3)]	275	$	275,000

(1) Daniel Corey served as the Chief Technology Officer and a member of the board of directors of the Company from February 2024 to September 2024, and previously served as Chief Executive Officer, Chief Scientific Officer, and a member of the board of directors of Legacy CERo until the closing of the Business Combination in February 2024.

(2) Brian G. Atwood served as Chairman and Chief Executive Officer of the Company from February 2024 to September 2024, and previously served as Chairman of PBAX until the closing of the Business Combination in February 2024. Mr. Atwood is currently a member of the board of directors of the Company and serves as a trustee of Atwood-Edminster Trust dtd 4-2-2000.

(3) Chris Ehrlich has served as the Chairman and Chief Executive Officer of the Company since December 2024, and previously served as (i) interim Chairman and Chief Executive Officer of the Company from October 2024 to November 2024, (ii) Vice Chairman of the board of directors of the Company from February 2024 to September 2024, and (iii) the Chief Executive Officer of PBAX until the closing of the Business Combination in February 2024.

NOTE 15 – SUBSEQUENT EVENTS

On January 6, 2025, 625 Series A Preferred Warrants were exercised into 625 shares of Series A Preferred Stock for gross cash proceeds of $500,000.

On January 6, 2025, the Company issued warrants to purchase an aggregate of 163,853 shares of Common Stock to a certain investor affiliated with each other to induce investors to exercise their Series A Preferred Warrants for cash (the "January 2025 Common Warrants"). The January 2025 Common Warrants are initially exercisable for cash at an initial exercise price equal to $5.82 (as adjusted for stock splits, stock dividends, stock combinations, recapitalizations and similar events). The January 2025 Common Warrants are exercisable beginning six months after the issuance date (the "Initial Exercisability Date") and expiring on the third anniversary of the Initial Exercisability Date. The January 2025 Common Warrants require "buy-in" payments to be made by us for failure to deliver any shares of Common Stock issuable upon exercise. If at the time of exercise of the January 2025 Common Warrants, there is no effective registration statement registering the shares of the Common Stock underlying the January 2025 Common Warrants, such warrants may be exercised on a cashless basis pursuant to their terms

During the period from January 1, 2025 to April 10, 2025, 1,098 shares of Series A Preferred Stock were converted into 288,832 shares of Common Stock. The conversion ratio was based on the Series A Certificate of Designations and reflected the applicable Alternate Conversion Price.

During the period from January 1, 2025 to April 10, 2025, 75 shares of Series B Preferred Stock were converted into 50,001 shares of Common Stock. The conversion ratio was based on the Series B Certificate of Designations and reflected the applicable Alternate Conversion Price.

During the period from January 1, 2025 to April 10, 2025, the Company sold 290,618 shares of Common Stock of the Company pursuant to the New Keystone Purchase Agreement for net proceeds of $1,227,242.

On February 5, 2025, the Company announced the pricing of a reasonable best efforts public offering (the "Offering"), with participation from a member of the Company's board of directors and a single institutional investor, for the purchase and sale of (i) 2,551,020 shares of its common stock, par value $0.0001 per share (the "Common Stock") or common stock equivalents in lieu thereof; and (ii) common warrants to purchase up to 2,551,020 shares of common stock (the "Warrants"), at a combined public offering price of $1.96 per share and Warrant. In connection with the Offering, on February 5, 2025, the Company entered into a securities purchase agreement (the "SPA") with the investors. The SPA contains customary representations, warranties and agreements of the Company and each investor and customary indemnification rights and obligations of the parties. In connection with this offering, the Company received net proceeds of approximately $4.5 million. From January 1, 2025 to April 11, 2025, the Company issued 2,335,280 shares of its common stock of the aggregate amount of shares of 2,551,020 shares sold. The remaining 215,740 common shares are issuable.

The Warrants have an exercise price of $1.96 per share, will be immediately exercisable upon stockholder approval and will have a term of exercise equal to five years following date of the initial exercise date. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Common Stock and the exercise price.

In connection with the Offering, on February 5, 2025, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with A.G.P./Alliance Global Partners ("A.G.P."), as the exclusive placement agent in connection with the Offering (the "Placement Agent"). Pursuant to a side letter between the Placement Agent and JonesTrading Institutional Services LLC ("Jones"), dated February 3, 2025, Jones agreed to be a financial advisor for the Offering. In connection with the services provided by Jones, the Placement Agent and Jones agreed that the Placement Agent will receive an aggregate fee equal to 6% of the gross proceeds received in the Offering and Jones will receive an aggregate fee equal to 3% of the gross proceeds received in the Offering. In addition, the Company agreed to reimburse the Placement Agent for its legal fees and expenses and other out-of-pocket expenses in an amount up to $85,000, non-accountable expenses of up to $25,000 and has agreed to reimburse Jones for all reasonable and documented out-of-pocket fees and expenses, including but not limited to travel and other out-of-pocket expenses in an amount not to exceed $15,000.

The Company's directors and executive officers agreed not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of common stock or other securities convertible into or exercisable or exchangeable for common stock for a period of 90 days following the closing date of the Offering, which terms may be waived in the sole discretion of and without notice by the Placement Agent, subject to certain exceptions. In addition, the Company has agreed to not enter into variable rate financings for a period of 180 days following the closing date, subject to certain exceptions, or enter into any equity financings for a period of 60 days following the closing date, subject to certain exceptions.

In connection with the Offering, the Conversion Price of the Series A Preferred Stock and Series C Preferred Stock reset to $1.96 per share of Common Stock.

On March 4, 2025, the Company's Board of Directors granted directors, officers and employees options to purchase up to 406,251 shares of common stock for $1.43 per share. The grants have various vesting conditions, including time-based and performance-based terms. These stock options expire on March 4, 2035.

On March 10, 2025, the Company redeemed 316 shares of Series C Preferred Stock from certain investors for a cash payment of $395,000, or $1,250 per share of Series C Preferred Stock.

EXECUTIVE OFFICERS

Chris Ehrlich
Chief Executive Officer

Andrew "Al" Kucharchuk
Chief Financial Officer

Kristen Pierce, Ph.D.
Chief Development Officer

CORPORATE HEADQUARTERS

CERo Therapeutics Holdings, Inc.
201 Haskins Way, Suite 230
South San Francisco, CA 94080

STOCK EXCHANGE INFORMATION

CERo Therapeutics Holdings, Inc., or CERo, stock is publicly traded on the Nasdaq Capital Market under the trading symbol: **CERO**

CERo warrants to purchase shares of CERo's common stock are publicly traded on the Nasdaq Capital Market under the trading symbol: **CEROW**

ANNUAL MEETING

CERo's annual meeting of stockholders will be held virtually via the internet, at:

9:00 a.m., Pacific Time
May 29, 2025
https://www.cstproxy.com/cero/2025

INVESTOR RELATIONS CONTACT

Website: https://www.cero.bio/investors
Contact: investors@cero.bio

COMPANY INFORMATION

Please visit CERo's website at https://www.cero.bio/ for the most recent company news, earnings, and public filings with the U.S. Securities and Exchange Commission.

BOARD OF DIRECTORS

Chris Ehrlich
Chief Executive Officer and Chair
CERo Therapeutics Holdings, Inc.

Brian G. Atwood
Managing Director
Versant Ventures

Michael Byrnes
Chief Financial Officer
Fore Biotherapeutics, Inc.

Kathleen LaPorte
Independent Director

Lindsey Rolfe, M.D.
Chief Medical Officer
3B Pharmaceuticals GmbH

Shami Patel
Managing Director
Launchpad Capital

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Wolf & Company, P.C.
255 State St.
Boston, MA 02109

STOCK TRANSFER AGENT

For shareholder services, please write or call:

Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004-1561
800-509-5586