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 June 30, 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 001-40608

ESTRELLA IMMUNOPHARMA, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**86-1314502**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5858 Horton Street, Suite 370 Emeryville, California	**94608**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 318-9098

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	ESLA	The Nasdaq Stock Market LLC
Warrants, each warrant exercisable for one share of Common Stock, each at an exercise price of $11.50 per share	ESLAW	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of $1.01 per share of the Registrant's common stock on the Nasdaq Stock Market LLC on July 1, 2024, was $40,271,957.

The number of Registrant's shares of common stock outstanding as of September 20, 2024 was 36,190,896.

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ESTRELLA MARKET AND INDUSTRY DATA

This Annual Report includes estimates regarding market and industry data and forecasts, which are based on our own estimates utilizing our management's knowledge of and experience in, as well as information obtained from our subscribers, trade and business organizations, and other contacts in the market sectors in which we compete, and from statistical information obtained from publicly available information, industry publications and surveys, reports from government agencies, and reports by market research firms. We confirm that, where such information is reproduced herein, such information has been accurately reproduced and that, so far as we are aware and are able to ascertain from information published by publicly available sources and other publications, no facts have been omitted that would render the reproduced information inaccurate or misleading. Industry publications, reports, and other published data generally state that the information contained therein has been obtained from sources believed to be reliable, but we cannot assure you that the information contained in these reports, and therefore the information contained in this Annual Report that is derived therefrom, is accurate or complete. Our estimates of our market position may prove to be inaccurate because of the method by which we obtain some of the data for our estimates or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process, and other limitations and uncertainties. As a result, although we believe our sources are reliable, we have not independently verified the information and cannot guarantee its accuracy and completeness.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. This includes, without limitation, statements regarding our vision and business strategy, including the plans and objectives of management for our future operations; our market opportunities, our future revenue opportunities, performance of our partnerships, and our future performance and financial condition. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. When used in this Annual Report, words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "expected to," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "strive," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements are predictions, projections, and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this Annual Report, including, but not limited to:

- the projected financial information, anticipated growth rate, and market opportunities of Estrella;
- the ability to maintain the listing of the Common Stock on Nasdaq;
- Estrella's public securities' potential liquidity and trading;
- Estrella's ability to raise financing in the future;
- Estrella's success in retaining or recruiting, or changes required in, officers, key employees, or directors;
- potential effects of extensive government regulation;

- Estrella's future financial performance and capital requirements;
- the impact of supply chain disruptions;
- high inflation rates and interest rate increases;
- the impact of the 2022 Russian invasion of Ukraine and 2023 Israel/Hamas conflict;

- the impact of pandemics, including on preclinical studies and potential future clinical trials; and
- factors relating to the business, operations, and financial performance of Estrella, including:
  - Estrella's ability to operate as a standalone company;
  - the initiation, cost, timing, progress, and results of research and development activities, preclinical studies, or clinical trials with respect to Estrella's current and potential future product candidates;
  - Estrella's ability to advance research on EB103 and its use in conjunction with CF33-CD19t;
  - Estrella's ability to identify, develop, and commercialize product candidates;
  - Estrella's ability to advance its current and potential future product candidates into, and successfully complete, preclinical studies and clinical trials;
  - Estrella's or Eureka's ability to obtain and maintain regulatory approval of Estrella's current and potential future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
  - Estrella's ability to obtain funding for its operations;
  - Estrella's and Eureka's ability to obtain, maintain and enforce intellectual property protection for their technologies and product candidates;
  - Estrella's ability to successfully commercialize its current and any potential future product candidates;
  - the rate and degree of market acceptance of Estrella's current and any potential future product candidates;
  - regulatory developments in the United States and international jurisdictions;
  - Estrella's and Eureka's ability to attract and retain key scientific and management personnel;
  - Estrella's ability to effectively manage the growth of its operations;
  - Estrella's ability to maintain its current licenses and contractual arrangements with Eureka;
  - potential liability lawsuits and penalties related to Estrella's licensed or acquired technologies, product candidates, and current and future relationships with third parties;
  - Estrella's ability to continue to contract with third-party suppliers and manufacturers and their ability to perform adequately under those arrangements; and
  - Estrella's ability to compete effectively with existing competitors and new market entrants.

These forward-looking statements are based on information available as of the date of this Annual Report and current expectations, forecasts, and assumptions, and involve a number of judgments, risks, and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws. We intend the forward-looking statements contained in this Annual Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the "Securities Act", and Section 21E of the Securities Exchange Act of 1934, as amended, or the "Exchange Act".

As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. You should not place undue reliance on these forward-looking statements.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled "Risk Factors" in this Annual Report, that represent challenges that we face in connection with the successful implementation of our strategy and the growth of our business. In particular, the following considerations, among others, may offset our competitive strengths, or have a negative effect on our business strategy, which could cause a decline in the price of shares of our Common Stock or Warrants and result in a loss of all or a portion of your investment:

- We are a clinical stage biotechnology company and expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.

- Our current or potential future product candidates may not demonstrate the safety, purity, or efficacy necessary to become approvable or commercially viable.
- Although we intend to explore other therapeutic opportunities in addition to the product candidates we are currently pursuing, we may fail to identify viable new product candidates for clinical development, which could materially harm our business.
- Clinical development includes a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- We rely on third parties to conduct our preclinical studies, and plan to rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily. If third parties on which we intend to rely to conduct certain preclinical and clinical studies do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed or unsuccessful, and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected, or at all.
- We may not be able to maintain our existing strategic partnerships and collaboration arrangements or enter into new strategic partnerships and collaborations for the development, manufacturing, and commercialization of product candidates on terms that are acceptable to us, or at all.
- The manufacturing of our product candidates is complex. If Eureka, or other third parties, encounter difficulties in production, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.
- 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, or 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.

- Our future success depends on our ability and Eureka's ability to retain key employees, directors, and advisors and to attract, retain, and motivate qualified personnel.
- Our business, operations, and clinical development plans and timelines could be adversely affected by the ongoing COVID-19 pandemic, including business interruptions, staffing shortages and supply chain issues arising from the pandemic on the manufacturing, clinical trial, and other business activities performed by us or by third parties with whom we may conduct business, including our anticipated contract manufacturers, contract research organizations ("CROs"), suppliers, shippers, and others.
- The anticipated benefits of the Separation may not be achieved.
- If we are unable to obtain or protect intellectual property rights related to our in-licensed technology, future technologies, and current or future product candidates, or if our intellectual property rights are inadequate, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.
- We may be unable to obtain U.S. or foreign regulatory approval and, as a result, be unable to commercialize our current or potential future product candidates.
- Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.
- We or the third parties we depend on may be adversely affected by natural disasters, including earthquake, flood, fire, explosion, extreme weather conditions, or epidemics.
- If any negative data were to arise with respect to the use of our licensed technology in territories where such technology is licensed to a third party, it could negatively affect our ability to develop our product candidates in territories where we license such technology.

PART I

In this Annual Report, unless the context otherwise requires, references to "we," "us," "our," "Estrella," or the "Company" refer to Estrella Biopharma, Inc. as a private company before September 29, 2023, and, on and after September 29, 2023, refer to Estrella Immunopharma, Inc. and, where appropriate, Estrella Biopharma, Inc. as a wholly-owned subsidiary of Estrella Immunopharma, Inc. prior to Estrella Biopharma, Inc. merging with and into Estrella Immunopharma, Inc. on June 30, 2024.

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company developing T-cell therapies with the capacity to address treatment challenges for patients with cancers and autoimmune diseases. The Company was originally incorporated as Estrella Biopharma, Inc. in the State of Delaware on March 30, 2022, by Eureka Therapeutics, Inc. ("Eureka"), which was established in California in February 2006 and reincorporated in Delaware in March 2018. On June 28, 2022, Estrella entered into a Contribution Agreement with Eureka, under which Eureka contributed certain assets related to T-cell therapies targeting CD19 and CD22 proteins in exchange for 105,000,000 shares of Estrella's Series AA Preferred Stock (the "Separation"). This Separation included Estrella entering into a License Agreement with Eureka and Eureka Therapeutics (Cayman) Ltd., granting Estrella an exclusive license to develop CD19 and CD22 targeted T-cell therapies using Eureka's ARTEMIS® platform. Additionally, Estrella assumed the Collaboration Agreement between Eureka and Imugene Limited, which covers the development of solid tumor treatments using Imugene's CF33-CD19t in conjunction with Estrella's EB103 therapy.

On September 29, 2023, Estrella consummated a business combination (the "Business Combination") with TradeUP Acquisition Corp. ("UPTD"), a blank-check company, pursuant to the Agreement and Plan of Merger dated September 30, 2022 (the "Merger Agreement"). Under the terms of the Merger Agreement, Tradeup Merger Sub Inc., a wholly-owned subsidiary of UPTD, merged with and into Estrella, resulting in Estrella becoming a wholly-owned subsidiary of UPTD. Following the closing of the business combination, UPTD was renamed Estrella Immunopharma, Inc. On June 26, 2024, Estrella Immunopharma, Inc. filed a Certificate of Ownership and Merger with the Delaware Secretary of State to effect a merger with its wholly-owned subsidiary, Estrella Biopharma, Inc. under Section 253 of the Delaware General Corporation Law. This merger, effective at 11:59 PM Eastern Time on June 30, 2024, was approved by the unanimous written consent of the Company's board of directors. As a result of the merger, the separate existence of Estrella ceased, and Estrella Immunopharma, Inc. became the surviving corporation, assuming all assets, liabilities, and obligations of Estrella.

We believe T-cell therapy continues to represent a revolutionary step towards providing a potential solution for many forms of cancer, including cancers poorly addressed by current approaches. Existing chimeric antigen receptor T-cell, or CAR-T, therapies, the initial class of T-cell therapies, have demonstrated remarkable efficacy and significant survival benefit in certain CD19-positive blood cancers like lymphomas and leukemias. CD19 is a protein expressed on the surface of almost all B-cell leukemias and lymphomas. Current CAR-T cell therapies, however, have limitations that may preclude broad adoption, including potentially life-threatening side effects like the hypersecretion of inflammatory cytokines known as Cytokine Release Syndrome ("CRS") and immune effector cell-associated neurotoxicity syndrome ("ICANS"). This side effect, however, is considered addressable with other treatment if the net effect is to target and kill cancer cells in the body. Additionally, CAR-T therapies target and kill all cells expressing CD19 (including healthy B-cells). These side effects have limited currently approved CAR-T therapies to specialized cancer centers and later lines of treatment for patients that have undergone other types of treatment unsuccessfully.

Our mission is to harness the evolutionary power of the human immune system to transform the lives of patients fighting cancer and autoimmune disease with safe, effective therapies. To accomplish this mission, our lead product candidate, EB103, which is a T-cell therapy we also call "CD19-Redirected ARTEMIS® T-Cell Therapy," utilizes Eureka's ARTEMIS ® technology to target CD19. Unlike a traditional CAR-T cell, the unique design of an ARTEMIS® T-Cell, like EB103 T-cells, allows it to be activated and regulated upon engagement with cancer targets that use a cellular mechanism more closely resembling the one from the endogenous T-cell receptor (TCR). EB103 is currently undergoing a Phase I/II clinical trial (STARLIGHT-1) to assess safety and determine the Recommended Phase II Dose (RP2D) in patients with relapsed/refractory B-cell Non-Hodgkin's Lymphomas. As of September 2024, two patients have been treated in the STARLIGHT-1 clinical trial.

We are also developing EB104, a T-cell therapy we also call "CD19/22 Dual-Targeting ARTEMIS ® T-Cell Therapy." Like EB103, EB104 utilizes Eureka's ARTEMIS® technology to target not only CD19, but also CD22, a protein that, like CD19, is expressed on the surface of most B-cell malignancies. EB104's dual-targeting strategy has the potential to more effectively treat patients with lower surface CD19 density or a greater prevalence of CD22, and reduce relapse due to CD19 antigen loss.

Solid tumors represent approximately 90% of all cancers. To date, T-cell therapy such as CAR-T has demonstrated limited success treating solid tumors. One major barrier limiting the potential of T-cell therapy is the lack of tumor-specific targets. We believe that, in collaboration with Imugene and Imugene's product candidate, CF33-CD19t, an oncolytic virus, EB103 T-cells have the potential to overcome this barrier using a "mark and kill" strategy. This "mark and kill" strategy entails using CF33-CD19t, to induce solid tumor cells into expressing the CD19 protein on the cell surface. Our EB103 T-cells can then pursue and kill the now CD19-expressing solid tumor cells, offering a potential treatment to cancers that lack solid tumor-specific targets.

Hematological Cancers

Hematological cancers, or blood cancers, are cancers that begin in blood-forming tissue, such as the bone marrow, or in the cells of the body's immune system. Examples of hematologic cancers are leukemia, lymphoma, and multiple myeloma. Leukemia is a broad term for cancers of the blood cells. The type of leukemia depends on the type of blood cell that becomes cancer and whether it grows quickly or slowly. Leukemia occurs most often in adults older than 55, but it is also the most common cancer in children younger than 15. The National Cancer Institute estimates that there will be over 60,000 new cases of leukemia in the United States in 2022, representing approximately 3.2% of all new cancer cases. B-cell lymphoma is a type of cancer that forms in B-cells (a type of immune system cell). B-cell lymphomas may be either indolent (slow-growing) or aggressive (fast-growing). Non-Hodgkin lymphoma (NHL) has an incidence rate of 19.0 per 100,000 per year and B-cell lymphomas make up most (about 85%) of NHL in the United States. There are many different types of B-cell non-Hodgkin lymphomas. These include Burkitt lymphoma (BL), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), and mantle cell lymphoma (MCL).

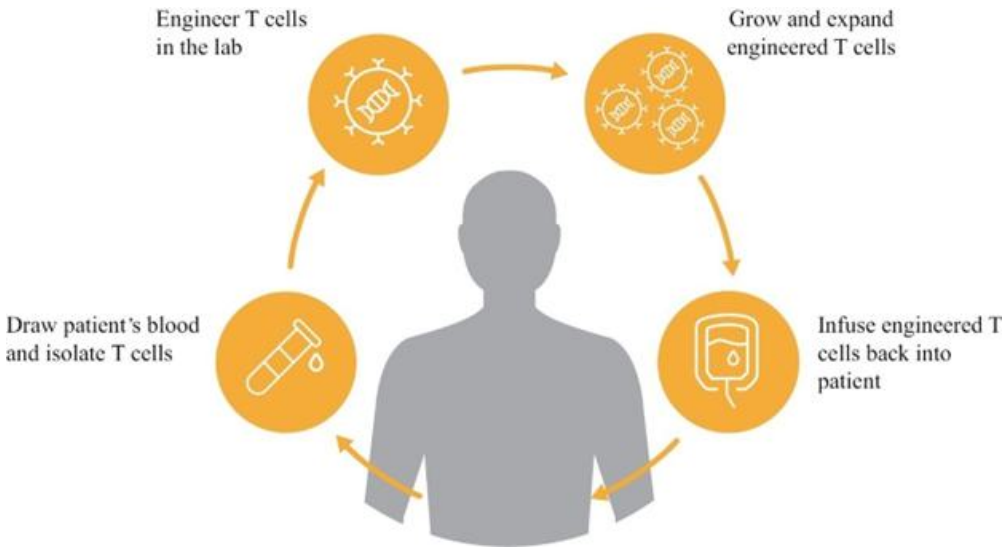
T-cell Therapies

The field of immunotherapy has evolved rapidly over the past few decades, and we believe that we are positioned to build upon previous research to harness the potential of immunotherapy to drive significant advances in cancer treatment. T-cells are white blood cells in the body's immune system that fight infections and tumor cells. T-cells also act to signal other immune cells to respond to threats. T-cells are ideally suited for immuno-oncology applications based on several characteristics. T-cells recognize their targets because they are created in a way that allows them to specifically recognize foreign antigens on the surface of other cells. T-cells are extremely specific, able to recognize a cancer cell and kill it, while ignoring an almost identical healthy cell. However, tumor cells sometimes evolve to escape killing by T-cells by activating a number of pathways that suppress T-cell function. The goal with T-cell immunotherapy is to reprogram a patient's own T-cells so that the T-cells can seek out and destroy cancer cells wherever they are hiding in the body, despite normal tumor suppressive mechanisms. T-cell therapy is also referred to as T-cell transfer therapy, adoptive cell therapy, adoptive immunotherapy and immune cell therapy.

T-cell therapies involve collecting a patient's own T-cells, growing large numbers of these T-cells in a lab, and then giving the cells back to the patient through a needle in the patient's vein. During the process of growing a patient's T-cells in a lab environment, a patient may have treatment with chemotherapy and, maybe, radiation therapy to eliminate other immune cells, as reducing the patient's immune cells can help the transferred T-cells to be more effective.

One type of T-cell therapy for treating cancer, CAR-T cell therapy, uses T-cells reprogrammed to express chimeric antigen receptors (CAR) directed at a certain target ("CAR-T cells"), allowing the CAR-T cells to attach to specific proteins on the surface of cancer cells, improving their ability to attack the cancer cells.

CAR-T THERAPY PROCESS



History and Development of T-cell Therapies

Over the past 20 years, using T-cells to treat cancer has moved from a radical ideal to clinical reality, with the first major successes occurring around 2010, when small clinical trials produced dramatically positive results in fighting aggressive blood cancers. The first T-cell trials were conducted in the mid-1990s targeting HIV CAR-T cells — the initial class of T-cell therapy. The effects of these first trials to fight HIV were mild, but the effort ended with the creation of successful HIV drug cocktails and, importantly, revealed that CAR-T-cells survived for more than 17 years in patients following treatment. In the mid-2000s, clinical trials using CAR-T-cells to treat solid tumors were largely unsuccessful. A few years later, trials for CAR-T-cells that targeted a surface protein called CD19, which is found only on the immune system's B cells and mutate to cause certain types of leukemia and lymphoma, showed positive results in three patients with leukemia. Those trials, however, also had the unexpected result of triggering CRS, in which the reengineered T-cells trigger the release of inflammatory signaling molecules called cytokines, causing severe fever, nausea, fatigue and body aches that can be life-threatening. Over the past decade, clinicians developed strategies to treat the side effects of T-cell therapies. Still, because of risks associated with CRS and ICANS, nearly all T-cell therapies to treat cancer must be administered at dedicated cancer centers.

The data that accumulated in the mid-2010s from trials by pharmaceutical companies Novartis and Kite Pharma was compelling, and in 2017, the FDA approved Novartis' Kymriah™ for adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy and Kite Pharma's Yescarta™ for patients with large-B-cell lymphomas whose cancer had progressed after receiving at least two prior treatment regimens. Since 2017, four additional CAR-T therapies have been approved by the FDA.

Limitations on T-cell Therapies

The approvals of CAR-T therapies over the past five years demonstrate the viability of T-cell therapies as a new class of cancer immunotherapies. Analogous to the advent of monoclonal antibodies, we believe that T-cell therapies have the potential to become some of the most impactful cancer immunotherapy products over the next decade, but will first need to overcome certain limitations that have constrained widespread use over the past five years. In particular, we believe the existing classes of commercially approved T-cell therapies may be unable to realize their full potential due to the following limitations:

- ***Hyperactivation of T-Cells Resulting in Severe Toxicities.*** The uncontrolled activation of T-cells can lead to CRS. Currently marketed CAR-T therapies include a boxed warning citing fatal or life-threatening risks of CRS and ICANS. We believe these severe toxicity risks will likely limit the incorporation of these therapies into earlier lines of therapy and their adoption in community outpatient settings.

- ***High Costs and Consequences of Toxicities.*** CRS and ICANS are very costly side effects to manage. The risk of these occurrences results in standard treatment protocols that can add significant indirect costs on top of direct reimbursement costs and are burdensome to patients and the healthcare system overall. Experimental clinical strategies aimed at mitigating these risks include utilization of restrictive enrollment screening criteria to reduce the potential for CAR-T related toxicities. Such screening tactics would decrease the number of patients eligible for these therapies and could also increase the overall burden and cost of treatment. Currently, the average cost of standard CAR-T cell treatment plans is approximately $400,000.

- ***Challenges in the Treatment of Solid Tumor Cancers.*** Due to its ability to target cancer-specific intracellular antigens, the currently preferred T-cell therapy platform to target solid tumors is engineered T-Cell Receptor T-cells, or TCR-T. However, TCR-T therapies face the following challenges: (i) T-cell receptors, or TCRs, have a suboptimal affinity for their target antigens; (ii) enhancing TCRs' affinity for therapeutic purposes can introduce off-target toxicity; and (iii) engineered TCRs can mis-pair with endogenous TCRs, leading to cross-reactivity with unknown consequences.

We believe that EB103 and EB104 have the potential to overcome these limitations through providing a more selective immune response, limiting tertiary costs associated with side effects of treatment, and attacking solid tumors with a "mark and kill" strategy.

Emerging opportunities in expanding the curative capacity of T-cell therapy to autoimmune diseases

Autoimmune diseases occur when the immune system, which normally defends the body against harmful invaders, mistakenly attacks healthy tissues. These diseases can affect various organs, leading to chronic inflammation, tissue damage, and in some cases, life-threatening complications. Common examples include systemic lupus erythematosus (SLE), rheumatoid arthritis, and multiple sclerosis. The cause is often an overactive immune response, particularly involving autoreactive B cells that produce antibodies targeting the body's own tissues.

Traditional treatments for autoimmune diseases have focused on controlling symptoms and slowing disease progression. B-cell depletion therapies, such as CD20-targeting antibodies (e.g., Rituximab, Ocrelizumab) and BAFF inhibitors (e.g., Belimumab), have provided some relief for conditions like lupus and multiple sclerosis. These therapies aim to reduce the number of autoreactive B cells. However, they have limitations. Most existing treatments only manage symptoms and are rarely curative. Long-term administration is often required, and patients may experience serious side

effects, while the underlying disease continues to progress or return.

We believe CD19-redirected T-cell therapy offers a promising new approach to treating autoimmune diseases. In recent clinical studies, CD19-redirected CAR T-cell therapy has shown the potential to go beyond symptom management by depleting the entire population of autoreactive B cells, leading to rapid and durable disease remission. A notable study in lupus patients demonstrated that a single dose of CD19-targeting CAR T-cells resulted in significant improvements, with most patients entering remission and experiencing long-lasting benefits.

We are expanding our clinical investigation of our CD19-redirected ARTEMIS T-cell therapy into autoimmune diseases. Our EB201 program, in preclinical development, is being explored as a potential therapeutic approach targeting Systemic Lupus Erythematosus (SLE).

ARTEMIS® Cell Receptor Platform

Eureka has granted us an exclusive license relating to targeted T-cell therapies, which we are developing, in the Licensed Territory. We are using Eureka's ARTEMIS® (**A**ntibody **R**edirected **T**-Cells with **E**ndogenous **M**odular **I**mmune **S**ignaling) platform technology to develop such targeted T-cell therapies. The ARTEMIS® platform builds on successes of current CAR-T therapies by using T-cells engineered to use a cellular mechanism more closely resembling one from an endogenous T-cell receptor, producing a more natural and restrained immune response.

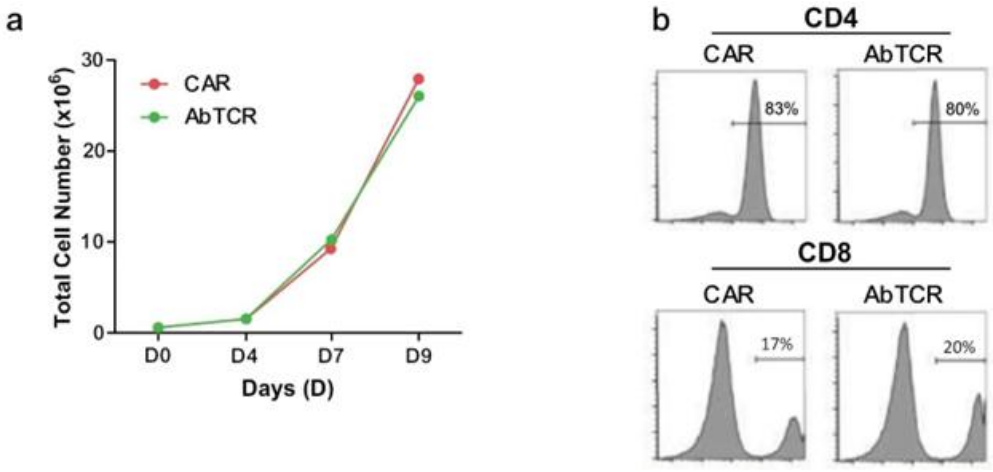
The key units of ARTEMIS® T-cells comprise of an antibody-T-cell-receptor (AbTCR) and a co-stimulatory molecule. The AbTCR serves as the core component featuring a target-binding domain derived from an antibody fragment antigen-binding (Fab) region and an effector domain derived from portions of a human gamma/delta (γδ) TCR. Given that the AbTCR includes portions of a human TCR, the AbTCR by its nature associates with the endogenous CD3 complex. This enables the AbTCR to use the same activation and regulatory pathways employed by natural TCRs. The co-stimulatory molecule is an additional key component featuring a target-binding domain derived from a single-chain variable fragment (scFv) and co-stimulatory domain derived from portions of a human co-stimulatory receptor.

Preclinical Data

In preclinical data from Eureka's 2018 paper published in *Cell Discovery* (the "2018 Paper"), ARTEMIS® T-cells expressing an AbTCR construct targeting CD19 functionally matched the potency of CAR-T cells, but released lower levels of cytokines upon the killing of target-positive cells in both in vitro and tumor xenograft mouse models. The 2018 Paper explored ARTEMIS® T-cells expressing only the AbTCR receptor, as the co-stimulatory molecule was added (and the current form of EB103 was created) in late 2018.

Eureka conducted the study at Children's Hospital of Philadelphia (CHOP) and Lumigenics (Richmond, CA) using female NSG mice aged eight to ten weeks. To compare the phenotypes between AbTCR-T cells and CAR-T cells, Eureka engineered a single-chain variable fragment and fused it with a widely-used CAR T-cell (also called a "second generation" CAR T-cell). This allowed Eureka to evaluate AbTCR-T cells in comparison to an existing CAR-T platform that is widely used clinically.

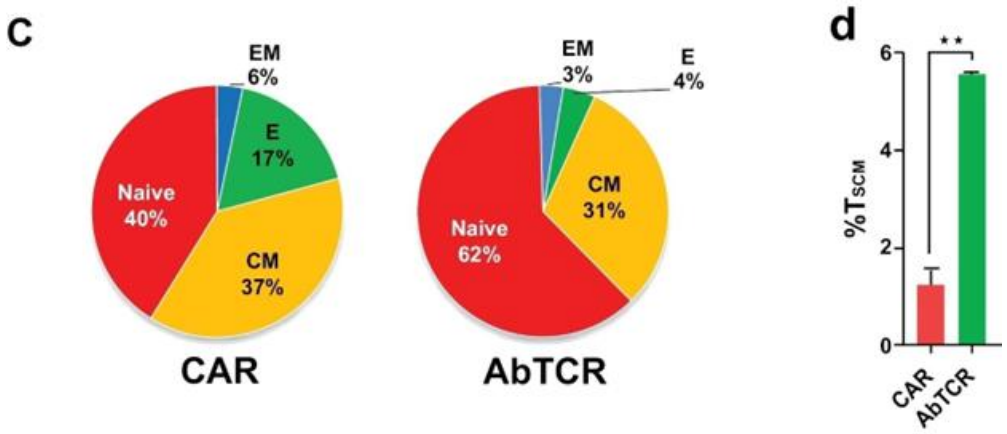
During T-cell manufacturing, AbTCR-T cells expanded with similar growth kinetics as the CAR T-cells and yielded T-cell populations with similar transduction efficiencies and the composition of CD4+ T-cells and CD8+ T-cells, which are subsets of T-cells, which is a well-accepted metric for evaluating the subsets of manufactured T-cells.



(a) AbTCR and CAR T- were cultured and the number of cells determined at the indicated time points.

(b) Proportions of CD4/CD8 within receptor+ cells.

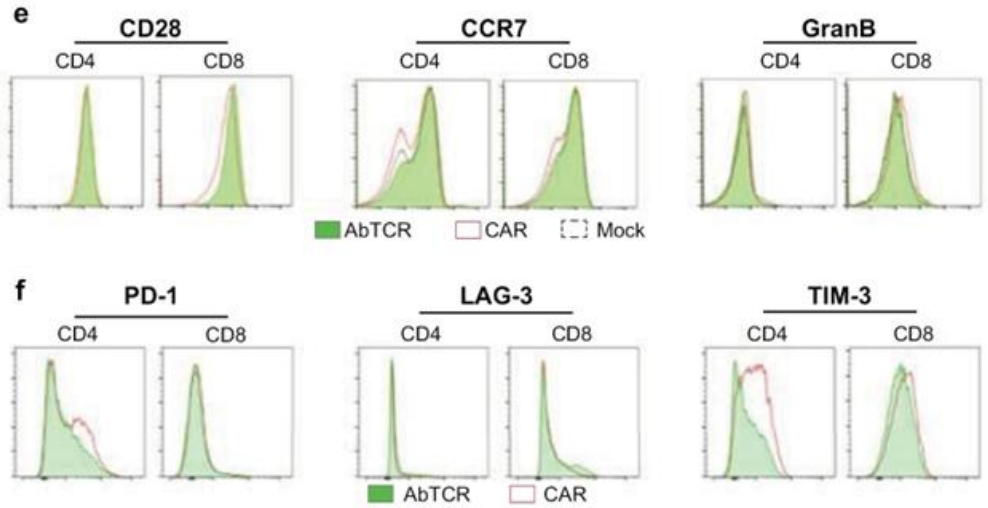
Retrospective analysis from published CAR-T clinical studies have found that T-cells that are more naive, less differentiated, and less exhausted correlate with improved efficacy. After T-cell "expansion", where T-cells proliferate multiple times during an immune reaction to fight disease, but before antigen engagement, AbTCR-T cells in the study displayed a more naive and stem cell memory T-cell phenotype compared to the CAR T-cells.



(c) Frequency of naïve (CCR7+ CD45RA+), central memory (CM; CCR7+ CD45RA−), effector memory (EM; CCR7- CD45RA-) and effector (E; CCR7- CD45RA+) T cells within CD8+ receptor+ cells.

(d) Frequency of stem cell memory (SCM; CCR7+ CD45RO- CD95+ CD122+) T cells within CD8+ receptor+ cells.

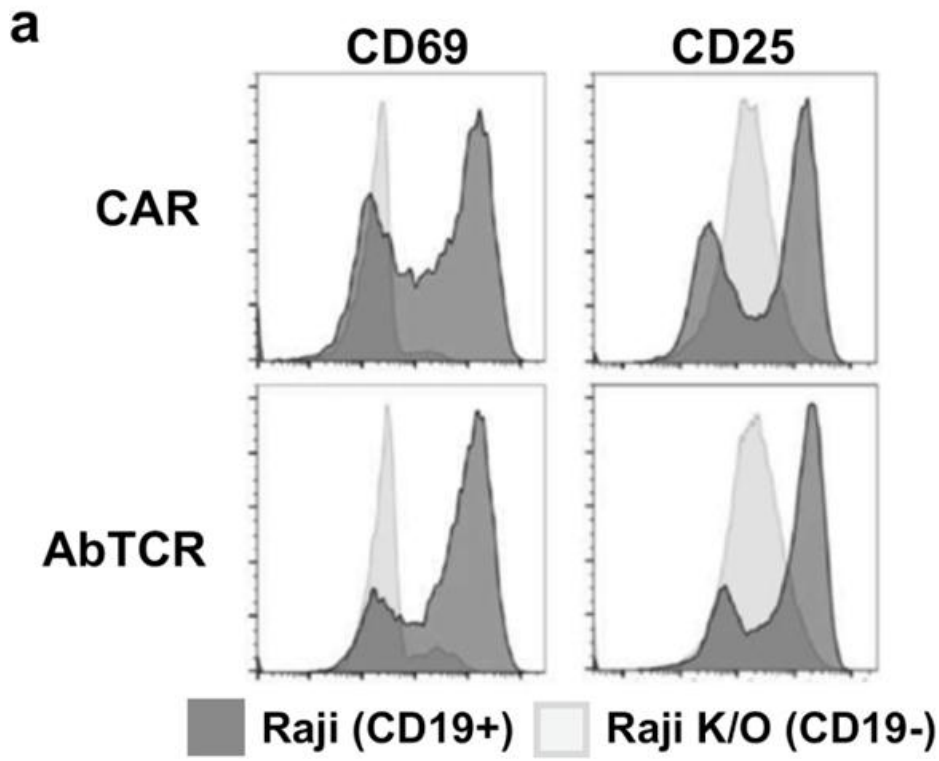
Taken together with the shifts in increased CD28, which is a protein expressed on T-cells that provides co-stimulatory signals required for T-cell activation, and lower granzyme B, which is a biomarker of immune cell activation, on CD8+ AbTCR-T cells, the increased CCR7 (a biomarker for naïve and stem cell memory T-cells) expression indicates that T-cells engineered with AbTCR are less differentiated. Furthermore, expression of programmed cell death-1 (“PD-1”) and T-cell immunoglobulin mucin-3 (“TIM-3”), which are both markers of T-cell exhaustion, and TIM-3 were lower on AbTCR-T cells than in CAR-T cells.



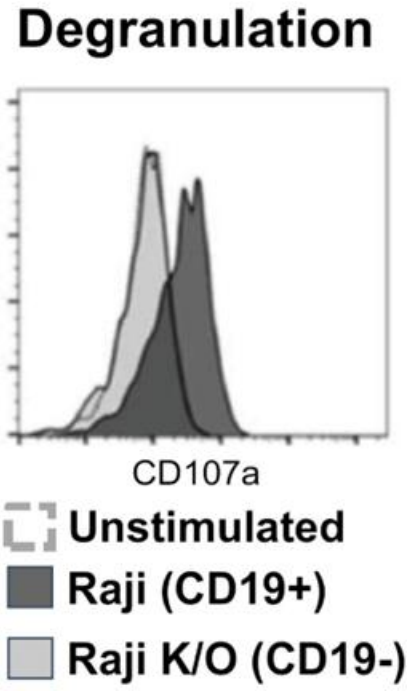
(e) Expression of T cell differentiation markers CD28, CCR7, and granzyme B.

(f) Expression of T cell exhaustion markers PD-1, LAG-3, and TIM-3.

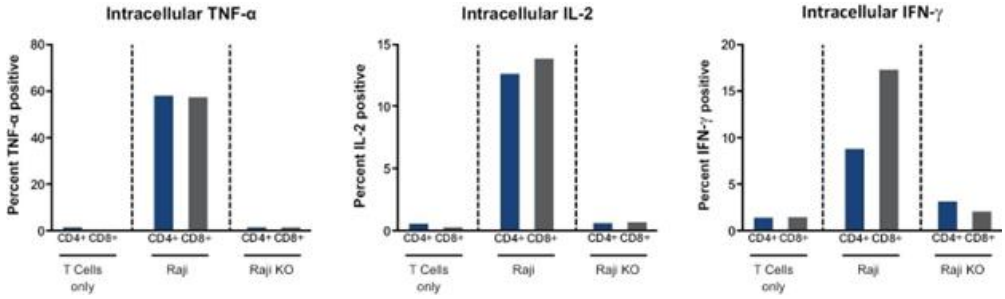
Eureka next characterized the T-cell phenotypes resulting from activation through the AbTCR. Eureka co-incubated the CAR T-cells with Raji cells, which are from a human B lymphoblastoid cell line originally derived from a patient with Burkitt Lymphoma. The Raji cells were either CD19-positive (“CD19+”) cells or cells in which CD19 was not present, or “knocked out” (“CD19ko”) using CRISPR technology, which allows for genetic material to be added, removed, or altered. Upon engagement with CD19+ cells, the AbTCR T-cells expressed activation markers CD69 and CD25, demonstrating the ability of the ET190L1-AbTCR to trigger T-cell activation in an antigen-dependent manner.



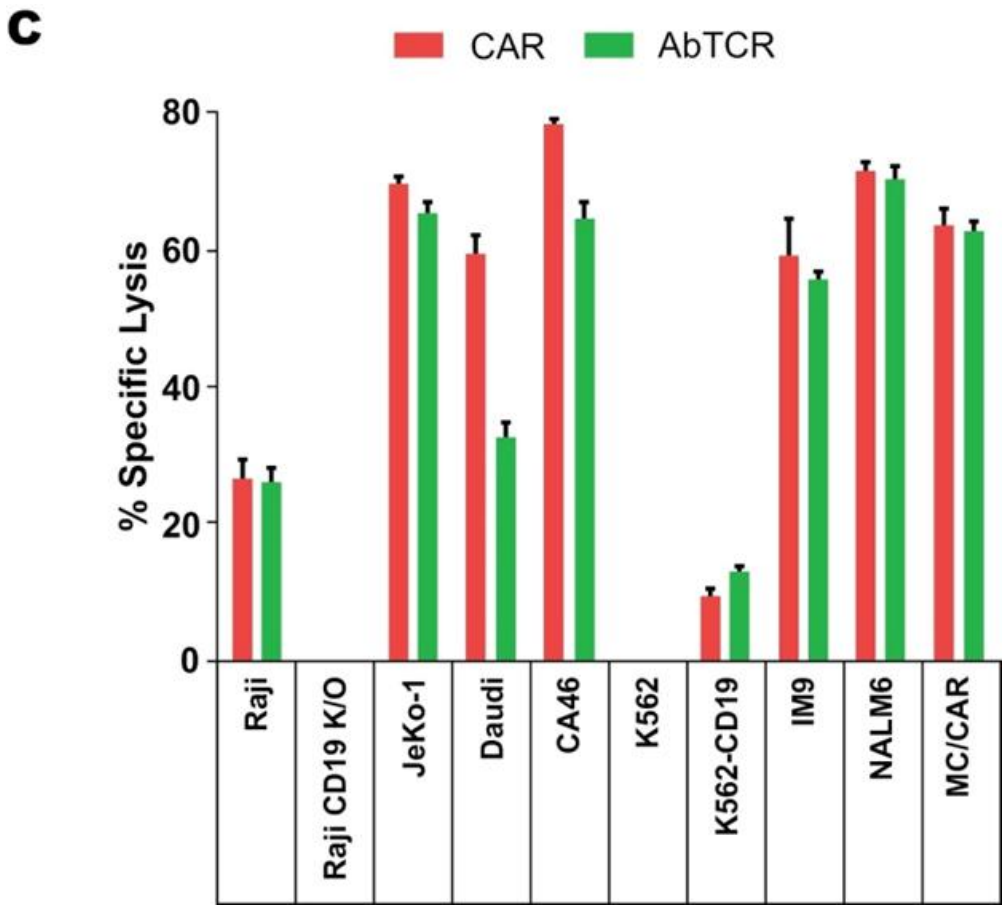
The accumulation of CD107a, a marker for T-cell degranulation following stimulation, was determined as a measure of cellular degranulation, a prerequisite for T-cell-mediated bursting of tumor cells, or cytolysis. T-cells degranulated when the AbTCR was stimulated with CD19+ cells.



In addition, when AbTCR-T cells were co-incubated with CD19+ cells, the analysis with intracellular flow cytometry showed that cytokines, such as TNFα, IL-2, and IFNγ, are induced in response to CD19 antigen. Importantly, no cytokines were produced when the AbTCR-T cells were co-cultured with CD19ko cells. These data demonstrate the ability of the AbTCR to trigger T-cell activation in an antigen-dependent manner.

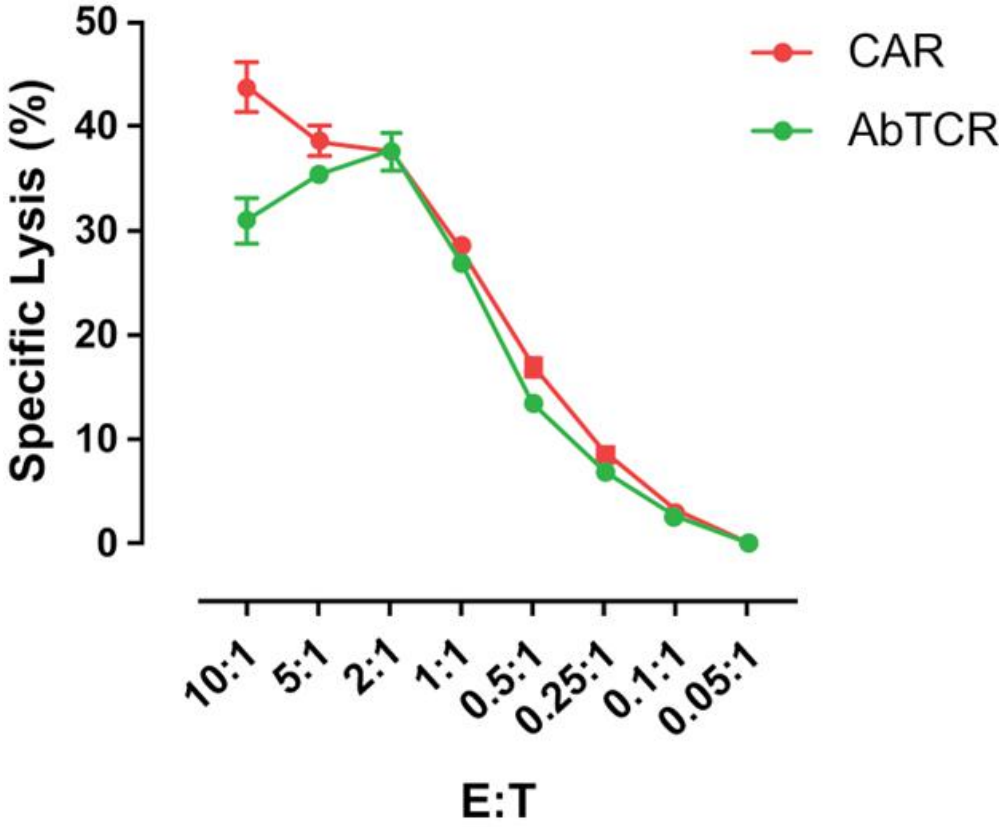


To better characterize the activities of AbTCR-T cells, Eureka set up experiments to directly compare phenotypes of the AbTCR-T cells with the CAR-T cells. The percentage of AbTCR-positive and CAR-positive T cells were matched by dilutions with un-transduced mock T-cells and co-cultured with multiple tumor cell lines.

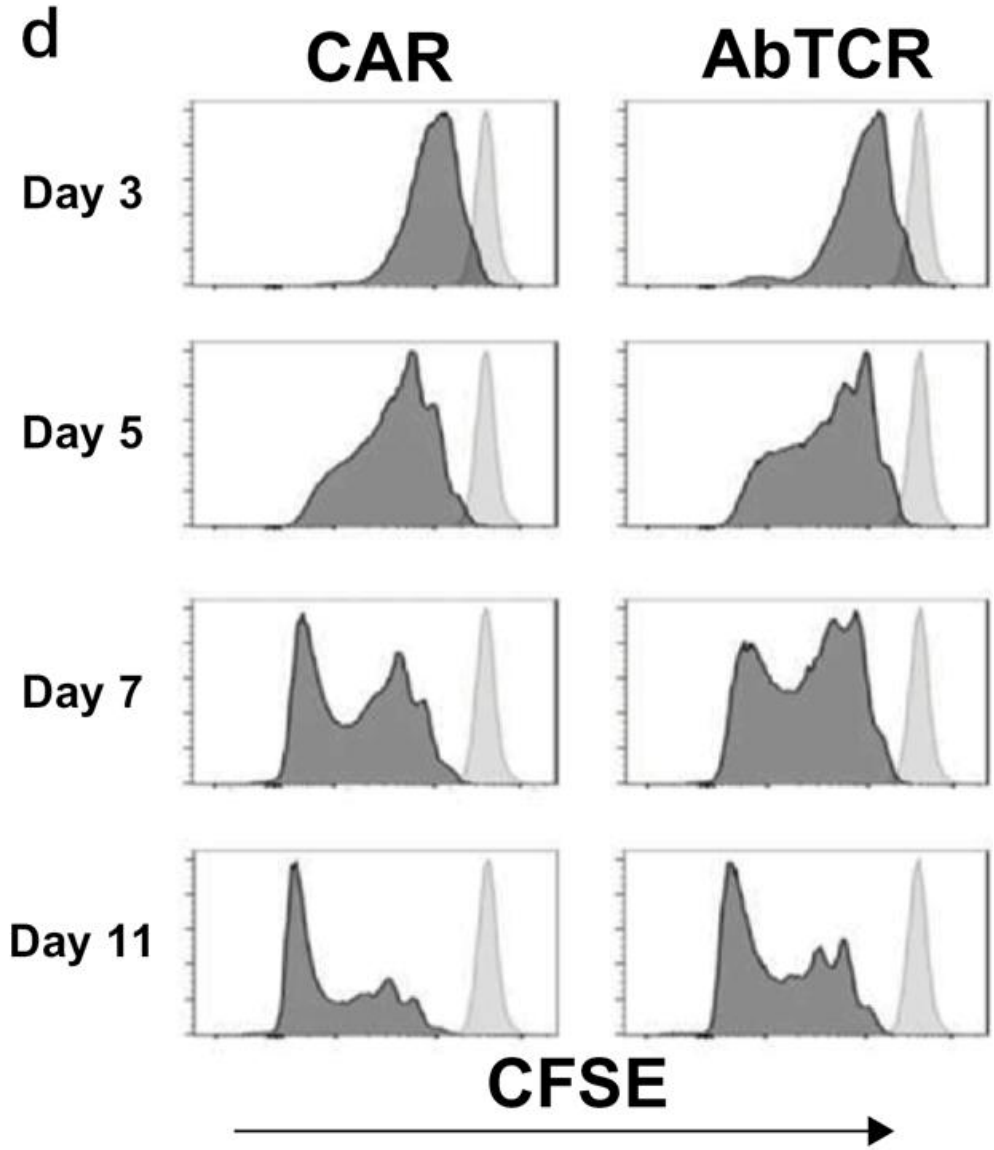


* T-cells were incubated with target cells for 16 hours at an effector to target ratio of 2:1. Cytotoxicity was measured by lactate dehydrogenase release assay (n = 3 technical replicates).

Specific lysis, or disintegration, of only CD19+ tumor lines confirmed the antigen specificity of both the AbTCR-T cells and CAR-T cells while demonstrating comparable cellular cytotoxicity and degranulation. In addition, specific lysis across a range of effector to target ("E:T") ratios, or ratios of AbTCR T-cells versus tumor cells, also showed comparable T-cell killing at low E:T ratios, further demonstrating the cytotoxic potential of using the AbTCR.

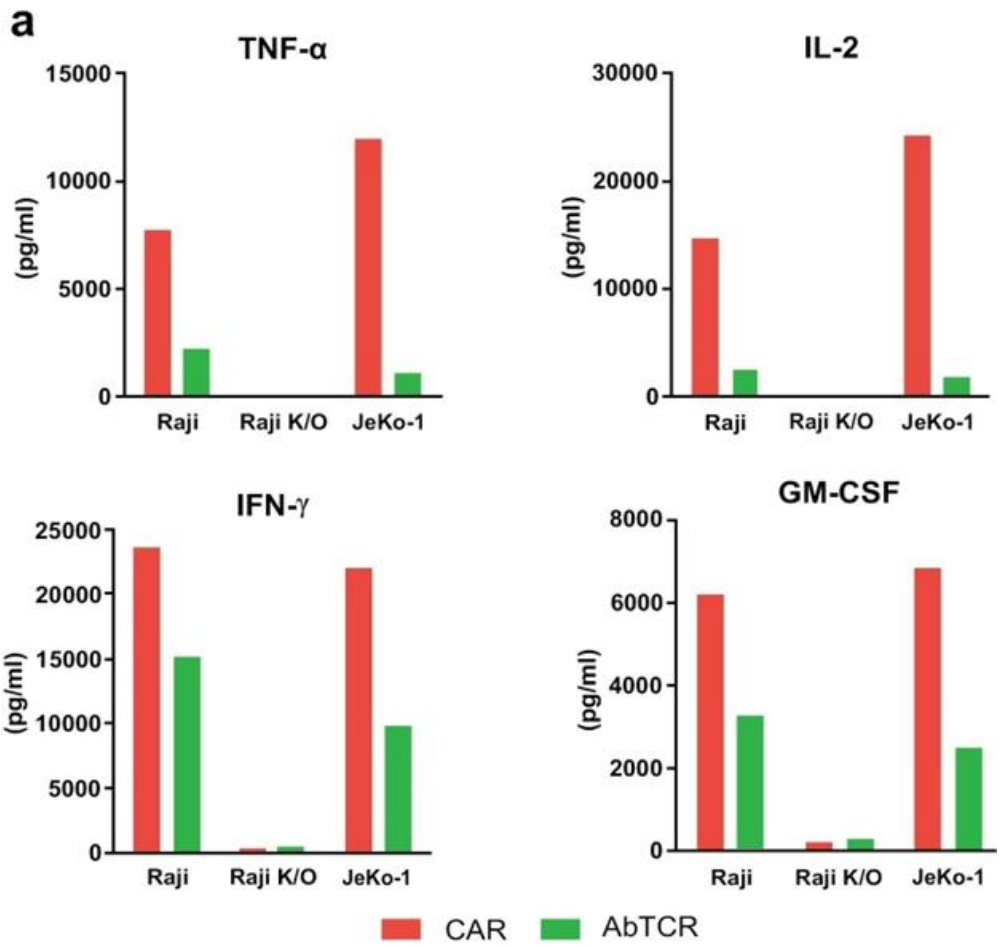


Replicative capacity of therapeutic T-cell in leukemia patients has been reported to be a key predictive biomarker for clinical efficacy. Eureka used a fluorescent dye-based (or CFSE-based) assay to assess in vitro T-cell proliferation upon antigen stimulation. As shown in the graphic below, AbTCR-T cells divided in response to antigen with kinetics comparable to that observed with CAR-T cells.



Despite a slight increase in the expression of CD69 and CD25 activation markers, which show T-cell activation levels, on tumor stimulated AbTCR-T cells compared to CAR-T cells, AbTCR CD4+ T-cells expressed lower levels of the PD-1 exhaustion marker, than CAR-T CD4+ cells, and, in both CD4+ and CD8+ AbTCR-T cells, lymphocyte-activation gene 3, or LAG-3, which is an immune checkpoint receptor protein found on the cell surface of T-cells that has been found to inhibit the activation of T-cells and suppress immune response, was lower.

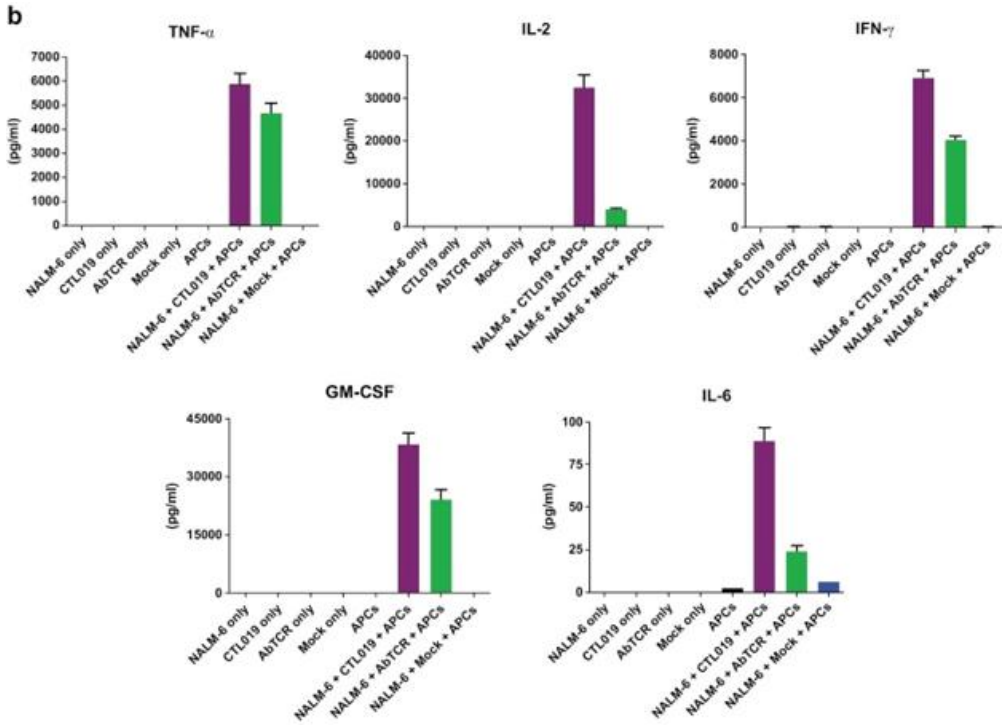
Furthermore, while AbTCR-T cells have comparable cytotoxicity and proliferative potential compared to existing CAR-T cells, the AbTCR-T cells released lower levels of inflammatory cytokines, including TNF-α, IL-2, IFN-γ, and GM-CSF, after a 16 hour in vitro killing test.



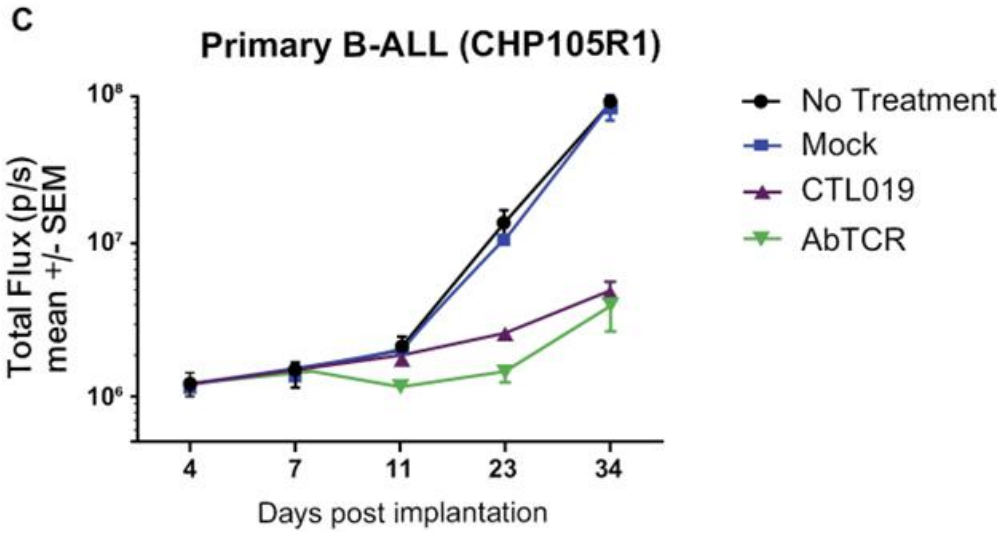
Comparisons between TCR-T and CAR-T cells have previously shown that activation through the TCR can comparatively reduce cytokine release while simultaneously increasing antigen sensitivity. Although the CAR construct incorporates a covalently-linked CD28 costimulatory domain, Raji cells express CD80 and CD86 and thus provide CD28 costimulation to both CAR-T cells and AbTCR-T cells. The study suggests that the cytokine secretion and exhaustion differences between AbTCR and CAR-T cells stem from the utilization of endogenous signaling pathways by the γδTCR effector domain of the AbTCR receptor.

While the potential of AbTCR-T cells to reduce the secretion of several inflammatory cytokines has exciting clinical possibilities, the discovery that tocilizumab, an anti-IL6R antibody, alleviates CRS pathology, singles out interleukin 6 receptors (IL6R) with particular clinical significance. Because the majority of IL-6 is produced by antigen-presenting cells, including monocytes, macrophages, and dendritic cells, Eureka performed a co-culture assay to measure IL-6 concentrations. The experiment separated T-cells and tumor cells from monocyte-lineage cells. Next, the AbTCR-T cells were compared to one of the anti-CD19 CAR-T cells that had been extensively studied and FDA-approved (CTL019, a research grade version of Kymriah™). In addition, CTL019 uses CD137 (4-1BB), a costimulatory receptor, for costimulation, thus offering an opportunity to compare the AbTCR to a CD137-based CAR-T cell.

Similar to the observed differences in cytokine release between the AbTCR-T cells and CAR-T cells, the AbTCR-T cells released lower levels of TNF-α, IL-2, IFN-γ, GM-CSF compared to CTL019-T cells. In the figure below, the purple bar indicates CTL019 targeting NALM-6 (B cell precursor leukemia) plus APCs (monocyte-lineage cells). The green bar indicates AbTCR T cells targeting NALM-6 plus APCs. The blue bar indicates plain T cells (without engineering) targeting NALM-6 plus APCs.

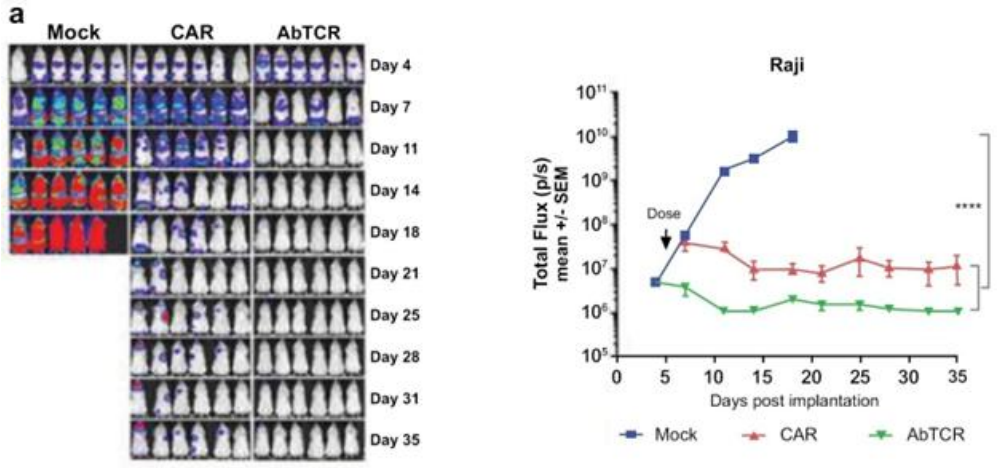


The study found that AbTCR-T cells induced monocyte-lineage cells to release substantially less IL-6 than CTL019-T cells. To test if the reduced cytokine release had an effect on in vivo anti-tumor activity, Eureka used AbTCR-T cells to treat a patient-derived xenograft (PDX) mouse model of primary B-ALL (CHP105R1, which has fewer cytokines due to lack of CD28 ligand for co-stimulation) and observed similar tumor inhibition between mice treated with the AbTCR and CTL019-T cells.

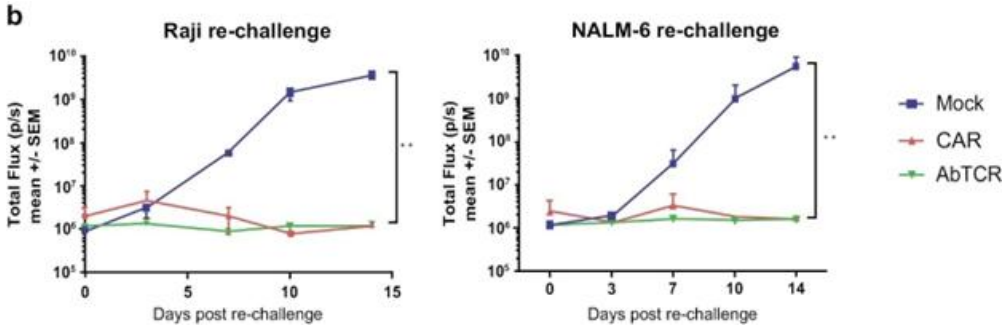


Thus, consistent with the in vitro studies described above, the study concluded that T-cells engineered with AbTCR reduced cytokine release without a loss of anti-tumor activity in a PDX tumor model that lacked CD80 and CD86 costimulation.

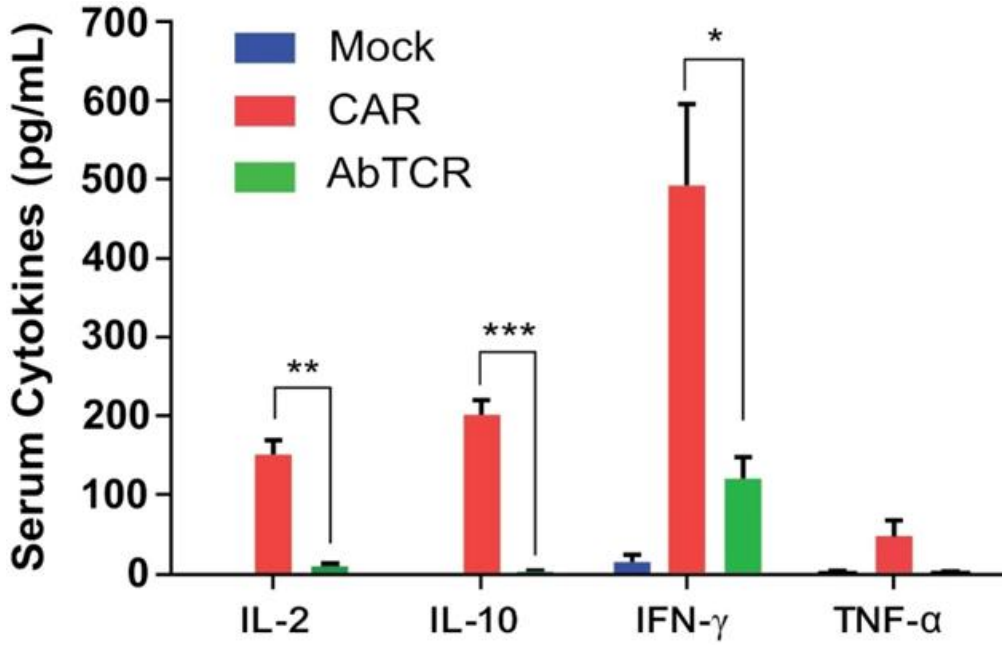
The study next tested the in vivo anti-tumor activity of the AbTCR-T cells in an established human CD19+ Raji B-cell lymphoma xenograft model. As shown in the figures below, the study found that both the AbTCR and ET190L1 T-cell treatments resulted in tumor regression and long-lasting tumor rejection. At the time when mice treated with mock T-cells had to be euthanized, tumor burden was on average approximately 1000-fold less in mice treated with ET190L1 T-cells than in the mock-treated mice and on average approximately 5300-fold less in mice treated with AbTCR-T cells than in the mock arm in the experiment. The figure below shows bioluminescent images (left) and total flux (right) over time of three groups of six to eight Raji-implanted mice intravenously administered with 5×10^6 (1) un-transduced donor-matched T-cells (“Mock”), (2) ET190L1-CAR-T cells (“CAR”), or (3) AbTCR-T cells (“AbTCR”). Doses were based on number of receptor-positive cells.



The ability of persisting AbTCR-T cells to prevent growth of “newly-introduced” tumor cells was tested by re-injecting mice with tumor cells weeks after the T-cells had cleared the initial tumor burden. While tumors grew rapidly in control mice, two to three mice in each of the six groups treated previously with either AbTCR-T cells or CAR-T cells were resistant to Raji lymphoma re-challenge (left). Furthermore, a set of two to three mice in each of the six groups were re-challenged with NALM-6 cancer cells (right), which is CD80 and CD86 negative. The resistance of tumor growth showed that AbTCR T-cells can be used for tumor types which do not express CD28 relevant ligands.

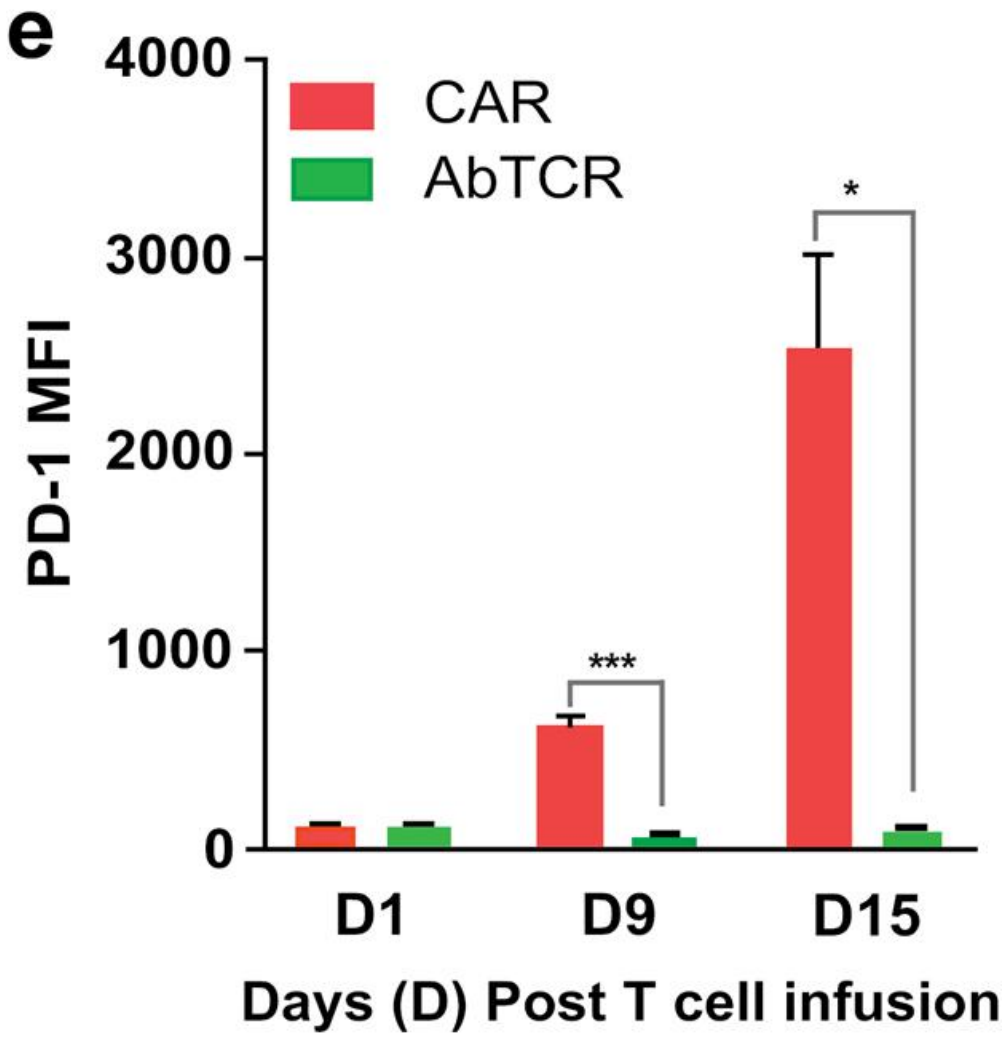


The study found that in vivo cytokine release and exhaustion markers on T-cells recapitulated in vitro findings. Whereas ET190L1 T-cell treatment caused marked elevation of inflammatory cytokines, including IL-2, IL-10, IFN-γ, and TNF-α, lower levels of these cytokines were released following AbTCR treatment. Serum cytokine levels were collected and measured from six to eight Raji-bearing mice 24 hours after T-cell dosing.



T-cell collected from peripheral blood nine days and 15 days post-T-cell dosing also revealed that AbTCR-T cells expressed lower levels of PD-1 than CAR-T cells. PD-1 expression levels (measured by mean fluorescent intensity) are shown below on the CAR-T cells and AbTCR T-cells at select

times from six to eight Raji-bearing mice after T-cell infusion.

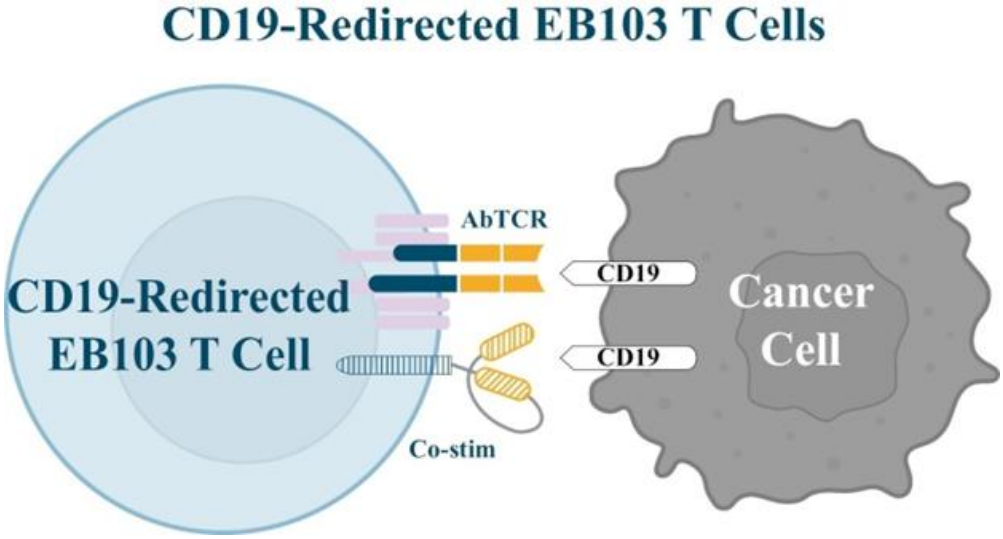


Collectively, the data from the study suggested that AbTCR T-cells exhibited potent in vitro and in vivo anti-tumor activity, yet released lower levels of inflammatory cytokines and expressed lower levels of exhaustion markers than CAR-T cells.

Following the study, to further augment AbTCR signaling, Eureka subsequently optimized the ARTEMIS ® cell receptor platform to include the co-stimulatory molecule. Importantly, the co-stimulatory molecule is provided as a separate molecule and not directly fused to the AbTCR. This is in contrast to conventional CARs, which include the direct fusion of the target-binding domain to the co-stimulatory and CD3ζ domains, which drives sustained T-cell activation and, often, subsequent release of large amounts of inflammatory cytokines. Thus, unlike the linear CAR design of traditional CAR-T cell platforms, the configuration of the ARTEMIS® cell receptor platform resembles the endogenous TCR/co-stimulatory receptor architecture in which co-stimulation is provided through separate receptors and acts as a potent synergistic signal that is naturally regulated by the body.

EB103 T-cells

During the manufacturing process, our EB103 T-cells are engineered to express ARTEMIS ® cell receptors (i.e., the AbTCR and co-stimulatory molecule) on their cell surfaces. Both the AbTCR and co-stimulatory molecule of EB103 are designed to recognize and bind the CD19 antigen. The resulting EB103 T-cells are expanded and then cryopreserved for delivery into the patient. Once infused, EB103 T-cells engage CD19-positive cancer cells. The AbTCR expressed on the EB103 T-cell by its nature associates, via its effector domain (γδ TCR chains), with the endogenous CD3 complex. When the AbTCR binds to its target, CD19, expressed on the cancer cell, AbTCR/CD3 complex-mediated signal transduction within the EB103 T-cell is initiated. This signal transduction process ultimately leads to the activation of the EB103 T-cell. A second “enhancement” signal is generated when the co-stimulatory molecule expressed on the EB103 T-cells binds to its target, CD19, expressed on the cancer cell. The main function of the co-stimulatory molecule is to “boost” AbTCR signaling, resulting in increased expansion and survival of EB103 T-cells inside the body. The co-stimulatory molecule has also been optimized to provide EB103 T-cells with enhanced T-cell activation. In summary, EB103 T-cells seek out CD19-positive cancer cells, bind to these cells, and destroy them.



EB103 Clinical Studies

First Affiliated Investigator-Initiated Study

From November 2018 to April 2021, the First Affiliated Hospital of Xi'an Jiaotong University ("First Affiliated") conducted an exploratory, single-arm, open-label, non-randomized early investigator-initiated study ("IIS") to assess the safety and feasibility of administering EB103 T-cells to patients with CD19-positive relapsed/refractory(r/r) B-cell lymphoma. Unlike studies conducted by pharmaceutical companies, IISs are clinical studies initiated and managed by nonpharmaceutical company researchers who could be an individual investigator, an institution, or a group of institutions, a collaborative study group, or a cooperative group. Often, as in this case, IIS studies are exploratory in nature. Generally, IISs are reviewed and approved by review boards or ethics committees at hospitals. First Affiliated sponsored the IIS study in collaboration with Eureka and conducted the study at First Affiliated. Eureka provided EB103-related information to support the IIS study application and gave comments to the investigator on the IIS study design and clinical protocol. The Ethics Committee of First Affiliated reviewed preclinical data and approved the clinical protocol. The study was registered at *www.clinicaltrials.gov* as #NCT03642496.All participants in the study provided written informed consent. The study results were published in 2022 in the Journal of Cancer Research and Clinical Oncology.

Patients were eligible for the study if they had histologically confirmed CD19-positive r/r B-cell lymphoma. Previous therapy must have included at least one cycle of R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) or a similar R-CHOP, like chemotherapy. Eligibility also required measurable disease as defined by at least one measurable node of which the longest diameter (LDi) is greater than 1.5 cm or at least one measurable extra nodal lesion of which the LDi is greater than 1.0 cm. In addition, an Eastern Cooperative Oncology Group (ECOG) performance status, which is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis, of less than or equal to two was required.

The primary endpoints included the tolerability of EB103 T-cell therapy and the cellular kinetics (i.e., expansion and persistence, which refers to the number of T-cells and continuous presence of T-cells in vivo after infusion) of EB103 T-cells after infusion. Secondary endpoints and other terms used in the study are explained below:

- **Complete Response (CR):**The disappearance of all signs of cancer in response to treatment. It is also called complete remission. For tumor assessments after EB103 treatment, a CR indicated the disappearance of measurable disease via computerized tomography (CT) scan or residual masses that are positron emission tomography (PET)-negative.

- **Partial Response (PR):**A decrease in the size of a tumor, or in the extent of cancer in the body, in response to treatment. It is also called partial remission. For tumor assessments after EB103 treatment, a PR indicates at least 50% decrease in tumor burden with ongoing PET avidity.

- **Objective Response Rate (ORR):**The proportion of patients with a complete response (CR) or partial response (PR) to treatment.

- **Duration of Response (DoR):**the length of time that a tumor continues to respond to treatment without the cancer growing or spreading. For tumor assessment after EB103 treatment, DoR is the time from the first documented disease response (CR or PR) to the date of first documented progression or death.

- **Remission:** A decrease in or disappearance of signs and symptoms of cancer. In partial remission, some, but not all, signs and symptoms of cancer have disappeared. In complete remission, all signs and symptoms of cancer have disappeared, although cancer still may be in the body.

- **Stable Disease:** Cancer that is neither decreasing nor increasing in extent or severity.

- **Progressive Disease:** Cancer that is growing, spreading, or getting worse.

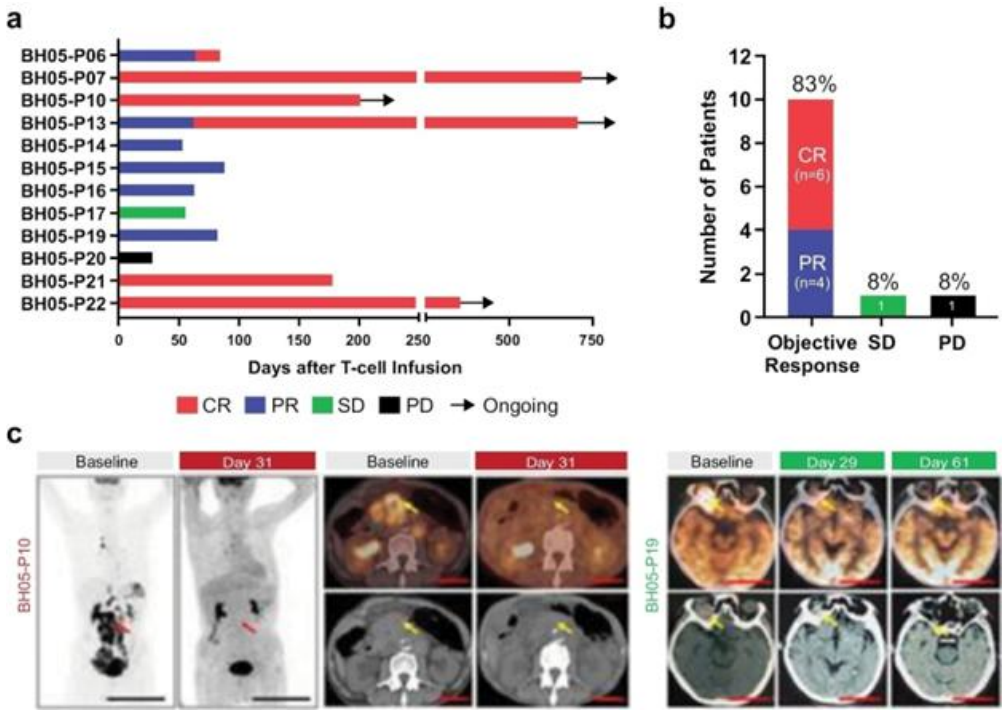
Tumor assessments were conducted at one, two, three, six, nine, 12, 18, and 24 months after initial infusion and response to treatment was assessed by the principal investigator and radiologist according to the Lugano Classification 2014 ("Lugano Criteria"), which is the most recent guideline to assess the presence of lymphoma, measure response to therapeutics intervention, and evaluate imaging and clinical data. By the Lugano Criteria, a CR indicates the disappearance of measurable disease via computerized tomography (CT) scan or residual masses that are positron emission tomography (PET)-negative. PR indicates at least a 50% decrease in tumor burden via PET scan.

Between November 2018, and April 2021, 16 patients were enrolled, and a total of 12 patients received EB103 T-cells. Four patients did not receive an infusion because of an inability to manufacture T-cells as a result of the patient's poor T-cell activation (one patient), high tumor burden (one patient), or active infection (two patients). As of the data cutoff date in April 2021, the median duration of follow-up was 128 days (range: 34 to 728 days). Of the 12 patients treated, six patients (50%) achieved a CR, and four (33%) achieved a PR, with a best ORR of 83%. CRs were durable, including two patients with ongoing CRs for over 22 months.

EB103 was well-tolerated by patients in the IIS study. No patients experienced severe (grade $\geq$ 3, based on the standards set by the American Society for Transplantation and Cellular Therapy) CRS, and only one patient experienced ICANS of any grade. In addition, heightened elevations of cytokine levels were not seen, even in patients with a marked expansion of EB103 T-cells. For the small patient population size, a P-value is not available.

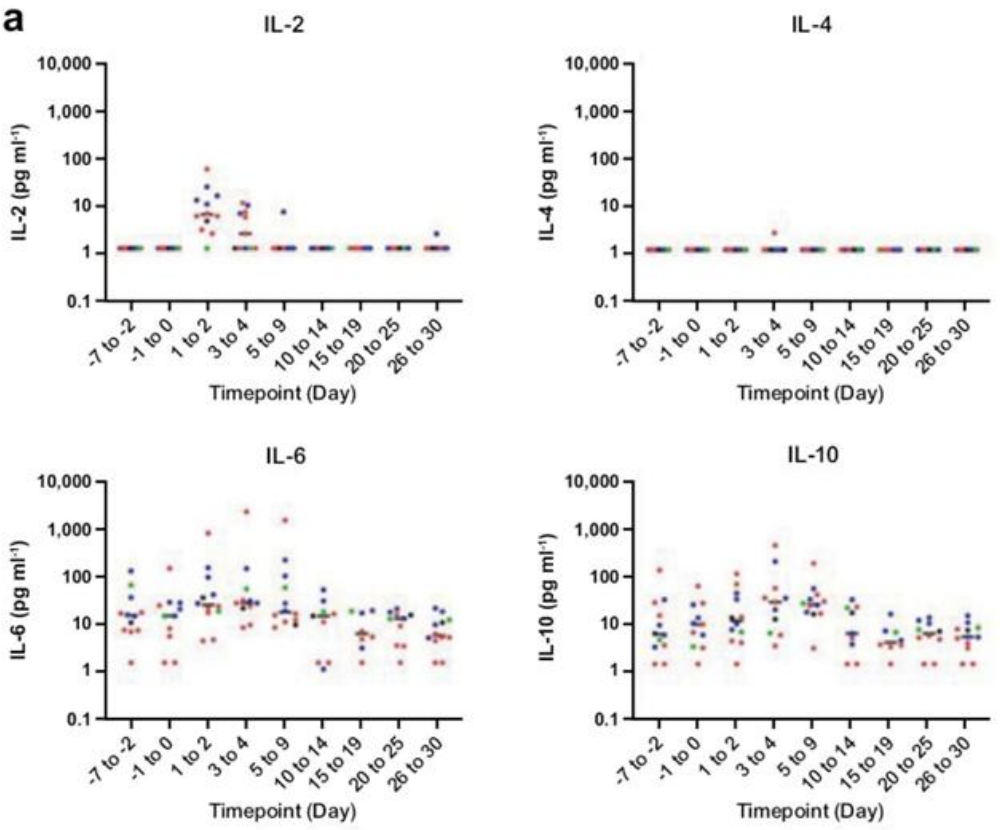
While additional studies are required to confirm the results of this small, exploratory IIS study, the findings are consistent with the design of the ARTEMIS® platform as a potential alternative to other engineered T-cell therapies, such as CAR T-cell therapies. The results from this early IIS study were disclosed to the FDA as supplementary supporting information for the IND application of EB103 in malignant B-cell lymphoma treatment.

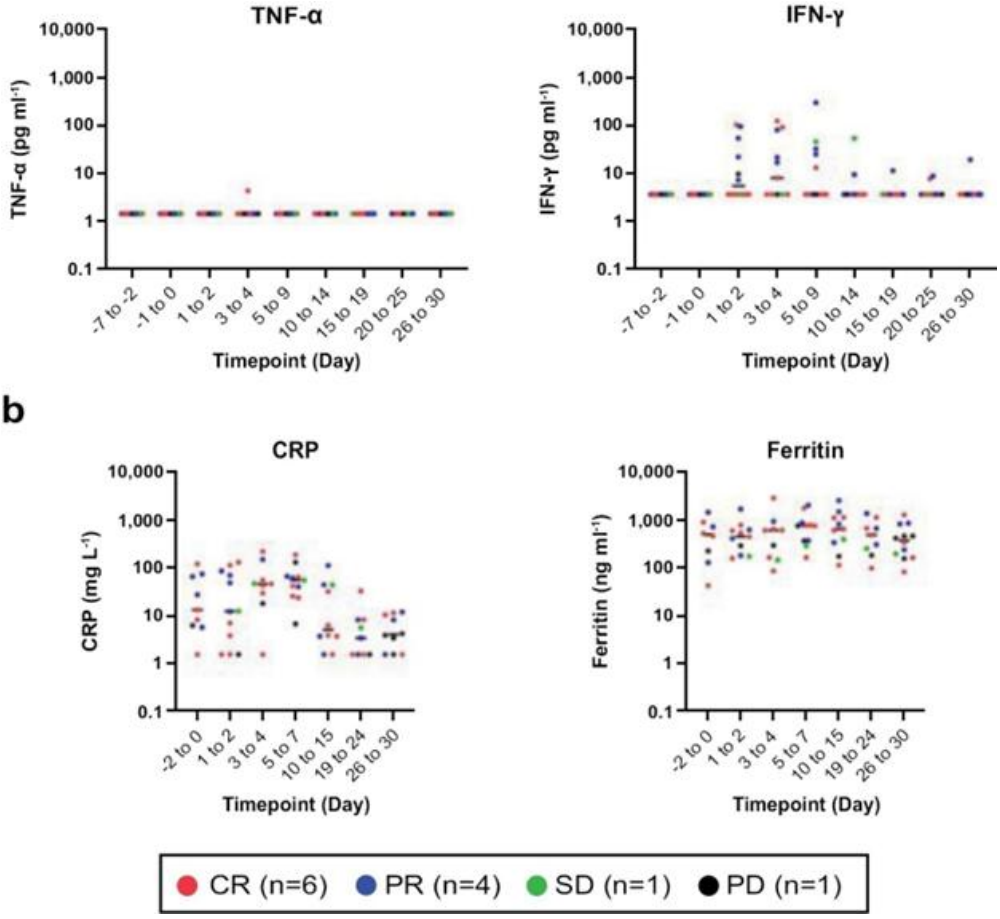
Clinical Responses to EB103



(a) Treatment response and duration of response after initial infusion of EB103 T-cells. Black arrows indicate ongoing remission and follow-up. (b) Best response for the 12 patients. Best response was defined as the best response (i.e., CR > PR > SD > PD) the patient achieved at any time after receiving EB103. CR — complete response, PR — partial response, SD — stable disease, PD — progressive disease. (c) Representative radiographic images of two responders (BH05-P10 and BH05-P19) at baseline and the indicated time points after EB103. Red or yellow arrows mark the tumor lesions. Full body images are PET-CT scans. Cross-sectional images are PET scans (top rows) and CT scans (bottom rows). Scale bars: black, 20 cm; red, 6 cm.

Levels of cytokines and serum inflammatory markers after EB103 T-cell infusion





(a) Cytokine levels. (b) Serum c-reactive protein (CRP) and ferritin levels in patients during the first month of EB103. Horizontal lines denote median values. Patients' best responses are denoted by color of the symbols: CR (red), PR (blue), SD (green), and PD (black).

Union Hospital Clinical Study

From July 2019 to August 2022, Union Hospital affiliated to Huazhong University of Science and Technology in Wuhan, China ("Union Hospital"),

in collaboration with Eureka, conducted the first-in-human, single-center investigator-initiated study designed to evaluate the safety and efficacy of EB103 T-cells in patients with CD19 malignancies. Eight patients with relapsed or refractory diffuse large B-cell lymphoma (RR DLBCL) were reported in the study. The Medical Ethics Committee of Union Hospital approved the study. The study was performed at Union Hospital in Wuhan, China. The study was registered at *www.clinicaltrials.gov* as #NCT04014894. The study results were published on January 21, 2023 in the Journal of Hematology & Oncology.

Eureka collaborated with Union Hospital to support the study. The fully human anti-CD19 antibody was selected from Eureka Therapeutics E-ALPHA® phage display library. Dr. Cheng Liu, Eureka's President, CEO and Chairman, and Qi Chang, an employee of Eureka, supervised EB103 production and conducted the preclinical research. Dr. Cheng Liu and Qi Chang are two of the twenty-one listed authors of the report, and each's employment by Eureka was disclosed as a competing interest. No other competing interests were declared.

Inclusion and Exclusion Criteria

The inclusion criteria for the study were as follows: (i) patient or his or her legal guardian voluntarily participates in and signs an informed consent form; (ii) male or female, aged 18 to 75 years; (iii) pathologically confirmed CD19+ B-cell malignancies, and patients met the following criteria for refractory or relapsed B-cell malignancies: (a) refractory/relapsed B-cell lymphoblastic leukemia (meeting one of the following): (1) recurrence within six months after first remission; (2) primary refractory disease which cannot achieve complete remission after two cycles of standardized chemotherapy regimen; (3) failure to achieve complete remission or relapse after one line or multiple lines of salvage chemotherapy; or (4) not suitable for hematopoietic stem cell transplantation (HSCT), abandonment of HSCT due to various restrictions, or relapse after HSCT; or (b) refractory/relapsed B-cell lymphoma (meeting one of the following three items plus item four): (1) tumor shrinkage less than 50% or disease progression after four cycles of standard chemotherapy or (2) achieved complete remission after standard chemotherapy, but relapsed within six months or (3) two or more relapses after complete remission plus (4) subjects must have received adequate treatment in the past, including anti-CD20 monoclonal antibody and combination chemotherapy with anthracyclines; (iv) having a measurable or evaluable lesion: (a) patients with lymphoma require a single lesion greater than or equal to 15 mm or two or more lesions greater than or equal to 10mm or (b) patients with leukemia require persistent positive or positive relapse of bone marrow MRD; (v) patient's main organs functioning well: (a) liver function: ALT/AST less than or equal to 3 times the upper limit of normal (ULN) and total bilirubin less than two times ULN; (b) renal function: creatinine less than 220μmol/L; (c) pulmonary function: indoor oxygen saturation greater than or equal to 95% and (d) cardiac function: left ventricular ejection fraction (LVEF) greater than or equal to 50%; (vi) greater than or equal to two weeks since prior therapy at the time of enrollment, and the toxicity related to previous treatments returned to less than grade 1 (except for low grade toxicity such as alopecia); (vii) ECOG score less than or equal to two; and (viii) estimated survival time greater than or equal to three months.

The exclusion criteria for the study were as follows: (i) women who are pregnant or breastfeeding; (ii) women of child-bearing potential and all male participants can't use effective methods of contraception for at least 12 months following infusion; (iii) patients fail to collect enough PBMC; (iv) patients with other uncontrolled diseases, such as active infection; (v) active hepatitis B or active hepatitis C; (vi) known HIV positive patients; (vii) patients with active autoimmune diseases requiring systemic immunosuppressive therapy; (viii) participants with other active malignancies (except non-melanoma skin cancer and cervical cancer) within three years; (ix) patients with severe mental disorder or disorders of consciousness; (x) patients who need immediate treatment to control tumor progression or relieve tumor burden; (xi) patients participated in other clinical treatments within six weeks; (xii) patients with drug addiction; and (xiii) patients with poor treatment compliance.

Endpoints

The primary objectives were incidence of adverse events (AEs) and ORR. CRS and ICANS were graded using the American Society for Transplantation and Cellular Therapy consensus grading. All other AEs were graded according to the Common Terminology Criteria for Adverse Events. Dose-limiting toxicities (DLTs) were defined as EB103-related AEs within 30 days after infusion and included ≥ grade 3 cardiac, hepatic, pulmonary, and renal toxicities, and ≥ grade 3 CRS and ICANS that lasted over 72 hours after treatment. Exceptions to this definition were not counted as a DLT. Response was assessed using the Lugano Criteria.

The secondary objectives included Duration of Response (DoR), progression-free survival (PFS), overall survival (OS), and expansion and persistence of EB103 T-cells, and serum cytokines in the peripheral blood (PB) after infusion. PB refers to the blood circulating in the body's blood vessels. DoR, PFS, and OS were defined per the revised response criteria for malignant lymphoma. Under the criteria, DoR is defined as from the time when criteria for response (CR or PR) are met, for which the event is the first documentation of relapse or progression. PFS is defined as the time from entry into a study until lymphoma progression or death as a result of any cause. OS is defined as the time from entry onto the clinical trial until death as a result of any cause. Only the first infusion was included in the main analyses of safety and efficacy. Exploratory endpoints included the safety and efficacy among patients retreated with EB103 T-cells.

Imaging and pathological examination

F-fluorodeoxyglucose positron emission tomography-computed tomography (PET-CT), computed tomography (CT), magnetic resonance imaging (MRI), cerebrospinal fluid (CSF) assessment, and biopsies were performed on the patients following the Lugano Criteria. The assessments of tumor tissue were conducted and reviewed by two independent pathologists.

Statistical analyses

All eight patients who received the infusion were included in the analyses. Descriptive statistics include means with 95% confidence interval (CI) or medians with minimum and maximum (range) for continuous variables and counts and percentages for categorical variables. Missing data were not imputed. Continuous variables were compared using paired t-test when the data were normally distributed. Otherwise, the Wilcoxon test was used. DoR, PFS, OS, and associated 95% CI were determined by the Kaplan — Meier methods and compared with the log-rank test between subgroups. Analysis was performed using Graphpad Prism version 8.0. P values less than 0.05 (two-tailed) were considered significant.

Tolerability

All eight patients experienced adverse events (AEs) of grade 3 or higher. Three patients (37.5%) experienced grade 1 CRS that resolved spontaneously, with a median onset of four days (range: two to nine days) and a median duration of three days (range: one to eight days). Patient Two developed grade 3 ICANS after CRS, which manifested as confusion, barylalia, tremor, and agitation, but Patient Two responded to treatment with corticosteroids. ICANS occurred on the ninth day following infusion and lasted for nine days; thus, it was judged as a DLT. Apart from Patient Two, DLTs were not observed in the patient cohort. Patient Eight had a pulmonary infection on day 15 that lasted for four days after antibiotic treatment. Other infectious complications were not observed within one month due to the administration of antiviral and antifungal preventative medicines in these patients.

Patient Four had lymphoma involvement in the intestinal tract and suffered an acute intestinal perforation, resulting in emergency surgery 16 days after infusion. Ultimately, all acute AEs were reversible with supportive treatment.

Tocilizumab, an anti-IL6R antibody, which can alleviate CRS. Was not administered. The increase in inflammatory cytokines from baseline to peak were modest, except for the elevation of IL6R levels in Patients Two, Four, and Eight, which were greater than tenfold the baseline value. This elevation generally coincided with serum C-reactive protein levels and was concurrent with the onset of CRS and ICANS in Patient Two, intestinal perforation in Patient Four, and pulmonary infection in Patient Eight. Therefore, the study concluded that there might be alternative causes for the elevated inflammatory markers in these three patients other than the EB103 treatment.

Blood-based toxicities were the most common AEs, including low levels of white blood cells (neutropenia) and low levels of platelets of grade 3 or 4 in seven (87.5%), six (75%), and two (25%) patients after EB103 infusion, respectively. Severe anemia was not observed. The preconditioning regimens exhibited significant adverse effects on leucocytes, lymphocytes, monocytes (all types of blood cells), and hemoglobin levels, but not on platelets and neutrophils (a type of white blood cell). The median time from infusion to recovery of ≤ grade 2 neutropenia and leukopenia (low levels of leukocytes) was 13 days (range, four to 26) days and 13 (range, four to 26) days, respectively. Delayed recovery from severe thrombocytopenia (platelet deficiency) was observed in Patient Two for over two months.

B-cell aplasia, defined as CD19+ B-cells representing less than three percent of lymphocytes in peripheral blood (PB), was observed in all patients at baseline. The preconditioning chemotherapy exhibited significant inhibition on T cells and NK cells (another type of immune cell) in the PB, and EB103 cells showed effects on T cells. CD4+ T cells and CD8+ T cells decreased significantly after the preconditioning chemotherapy and expanded on day 14 after EB103 infusion. Three patients (37.5%) had preexisting hypogammaglobulinemia, a disorder caused by low serum immunoglobulin (a type of antibody) levels, defined as serum IgG less than 800 mg/dL, IgM less than 50 mg/dL, and IgA less than 100 mg/dL. Serum IgG, IgM, and IgA are all types of antibodies. The reduction of serum IgG, IgA, and IgM after EB103 infusion was observed in seven (87.5%), eight (100%), and six (75%) patients, respectively. The recovery of serum IgG, IgA, and IgM to their normal levels during follow-up was observed in three (42.8%), two (25%), and four (66.7%) patients respectively.

Patient One experienced two treatable long-term AEs: viral encephalitis at month 18 and MOG + encephalomyelitis at month 30. At the time of these AEs, EB103 cells were undetectable in the patient. As such, the authors of the study believed that these delayed AEs were not directly caused by EB103 cells.

Efficacy

In the clinical study, clinical responses were achieved by 87.5% of patients, with 75% achieving CR and 62.5% having ongoing CR. The Kaplan-Meier estimated OS at 12-36 months was 75.0% (95% CI: 31.5-93.1). The Kaplan-Meier estimated progression-free survival (PFS) at 12-36 months was 62.5% (95% CI: 22.9-86.1), with a DoR at 12-36 months of 71.4% (95% CI:25.8-92.0).

Patient One with primary central nervous system lymphoma had been refractory to eight previous lines of therapies. She experienced a continuing CR for over three years after EB103 infusion. Numerous EB103 cells were detectable in both the PB and CSF after infusion (See Figure 4B below), indicating that EB103 cells could sufficiently traffic from the periphery to the central nervous system. Patient Two had extensive lesions and attained a quick PR at month one, but the diseases progressed at month two. A second tissue biopsy demonstrated DLBCL. The patient received a second infusion with poor expansion, and the diseases progressed on day 14; consequently, the patient withdrew from the study for other salvage therapy. Patient Three had two major lesions in the right eyeball and the pelvic cavity, and she attained a PR on day 14 and an ongoing CR for over two years. Patient Four achieved a CR at month two and kept CR for over two years. Patient Five's EB103 cells exhibited rapid clearance and durable control of a bulky tumor. Patient Six, with lymphoma mainly in the abdominal cavity, did not respond to EB103 treatment and withdrew from the study at month two. Patient Seven had extensive lesions mainly in the lung and the abdominal cavity and attained a CR at month five. However, new lesions appeared at month nine, and a second infusion failed. Patient Eight had two lymph node lesions in the left heart diaphragm angle and retroperitoneal space, and obtained a CR on day 24, and kept durable CR at month 24.

Secondary Infusion

Patients Two, Five and Seven received a second infusion. Patients Two and Seven received a second infusion as salvage therapy after disease progression but did not respond. Patient Five maintained CR according to the Lugano Criteria at month six, but PET-CT scans showed minimal residual lesions in the hepatogastric space-pancreatic head. Despite low levels of EB103 cells in peripheral blood, Patient Five received a repeated infusion without preconditioning chemotherapy and experienced self-limiting severe neutropenia, leukopenia, and thrombocytopenia. Apart from hematologic toxicities observed in Patients Two and Five, no other adverse events were reported.

Expansion and persistence of EB103

After being infused into a patient, EB103 cells showed maximum expansion between nine and 21 days. At their peak, these cells reached a median count of 318 cells per milliliter (mL) of PB, with a range of 32 to 4,308,109 cells/mL. The number of EB103 cells in PB was determined through flow cytometry, which is a technique used to measure the characteristics of cells. Additionally, quantitative polymerase chain reaction (qPCR) measurements showed a median count of 76,897 copies per microgram (μg) of genomic DNA with a range of 21,278 to 273,032 copies/μg. qPCR is a method used to measure the amount of specific DNA sequences in a sample. The median area under the curve from day 0 to day 28 post-infusion was calculated to be 585,493.5 copies/μg × days. This value represents the total amount of EB103 cells present in the patient over time. At the end of the first year following infusion, EB103 cells were still detectable in PB in half of the patients. However, expansion was poor during second infusions.

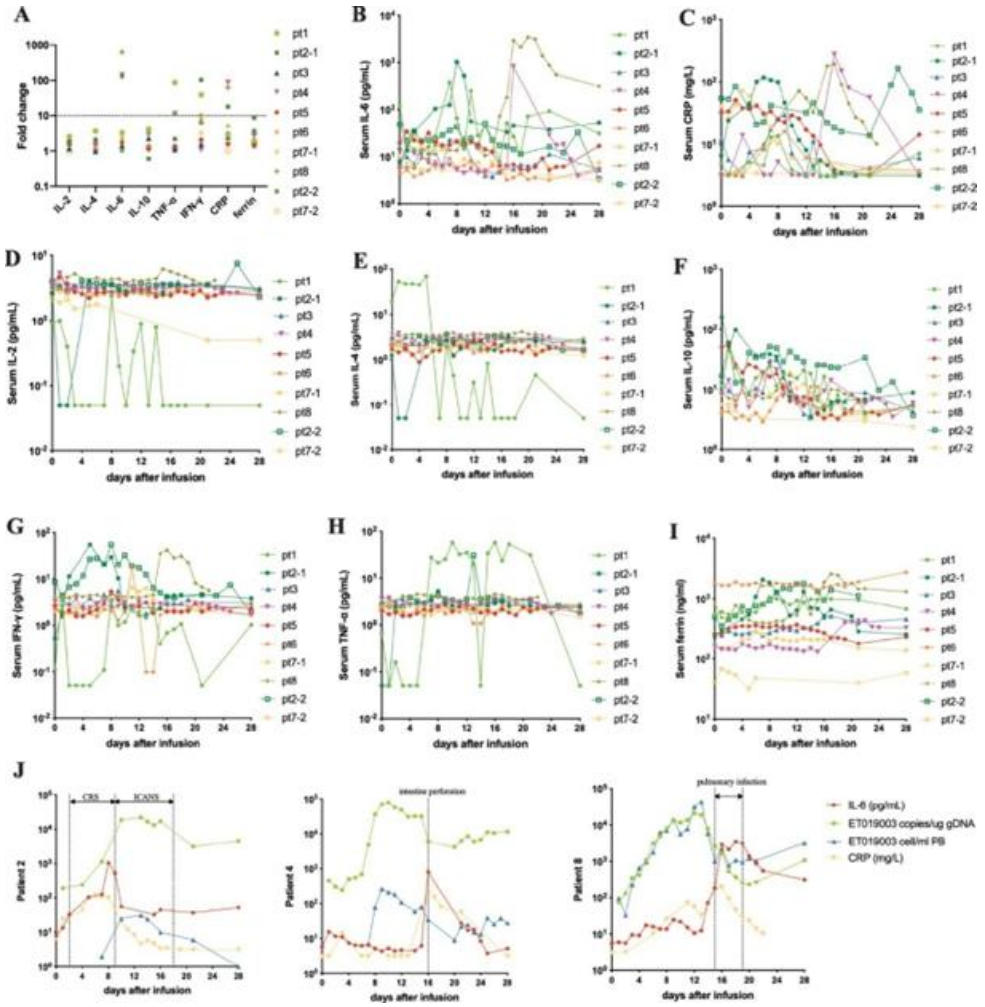
Conclusion

The authors of the study concluded that the data suggest that EB103 T-cells represent a novel and potentially potent therapeutic option for the patient population being studied. However, the authors noted that the findings were limited by the small sample size, and a recommended phase 2 dose was not identified. The authors also stated that larger and multi-center trials are needed to verify the long-term safety and efficacy of CD19-specific T cells in RR DLBCL.

Figures

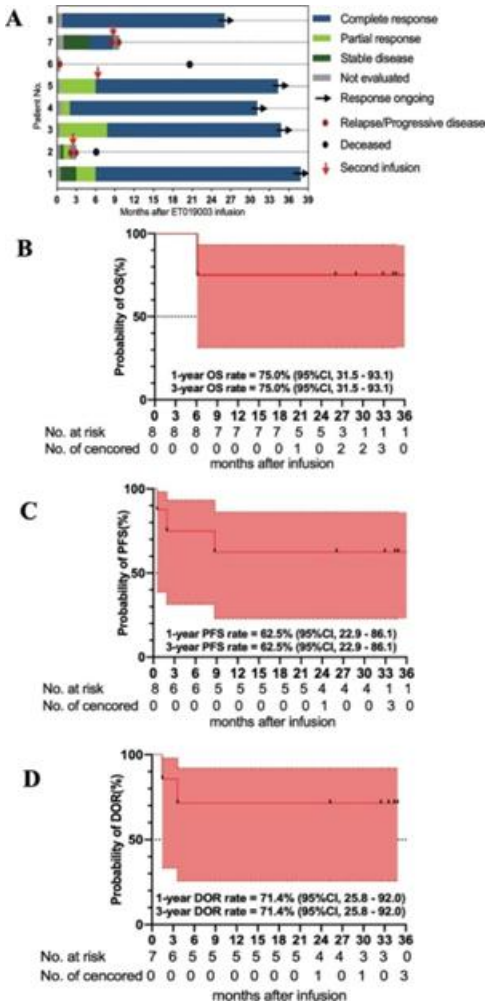
Below are four figures from the clinical study report related to the findings described above.

Changes in serum inflammatory markers within 1 month after EB103 infusion



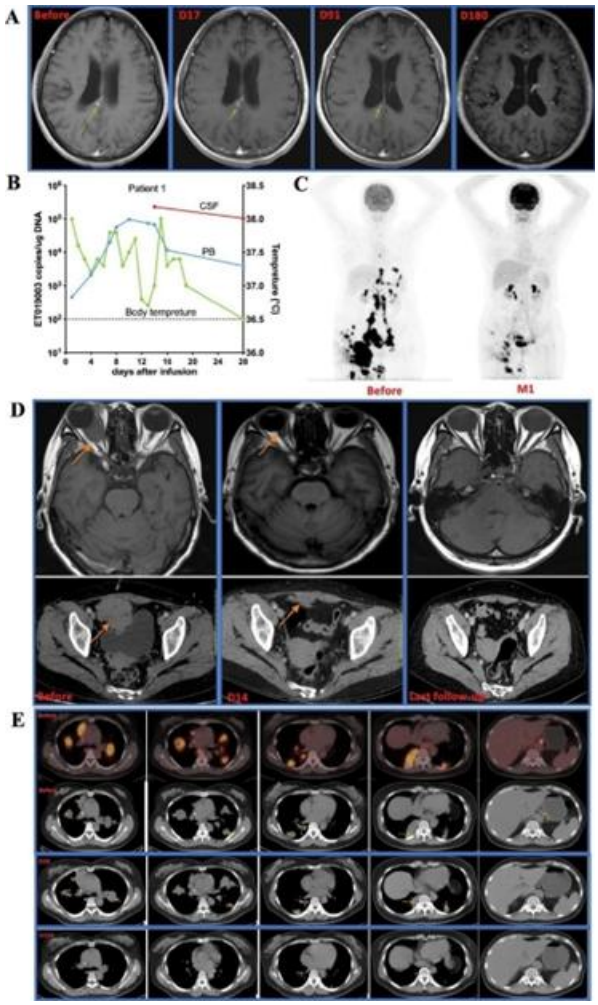
(A) Fold changes of inflammatory cytokines from baseline to peak (n = 10). Patient Five received the repeated infusions in the outpatient department and data were not available. (B-I) Changes in the serum interleukin (IL)-6, C-reactive protein (CRP), IL-2, IL-4, IL-10, interferon-γ (IFN-γ), tumor necrosis factor-α (TNF-α) and ferritin in individuals. (J) Changes in serum IL-6, CRP, and EB103 counts and copies in peripheral blood (PB) of Patients Two, Four, and Eight.

Swimmer's plot and long-term outcomes of the treated patients



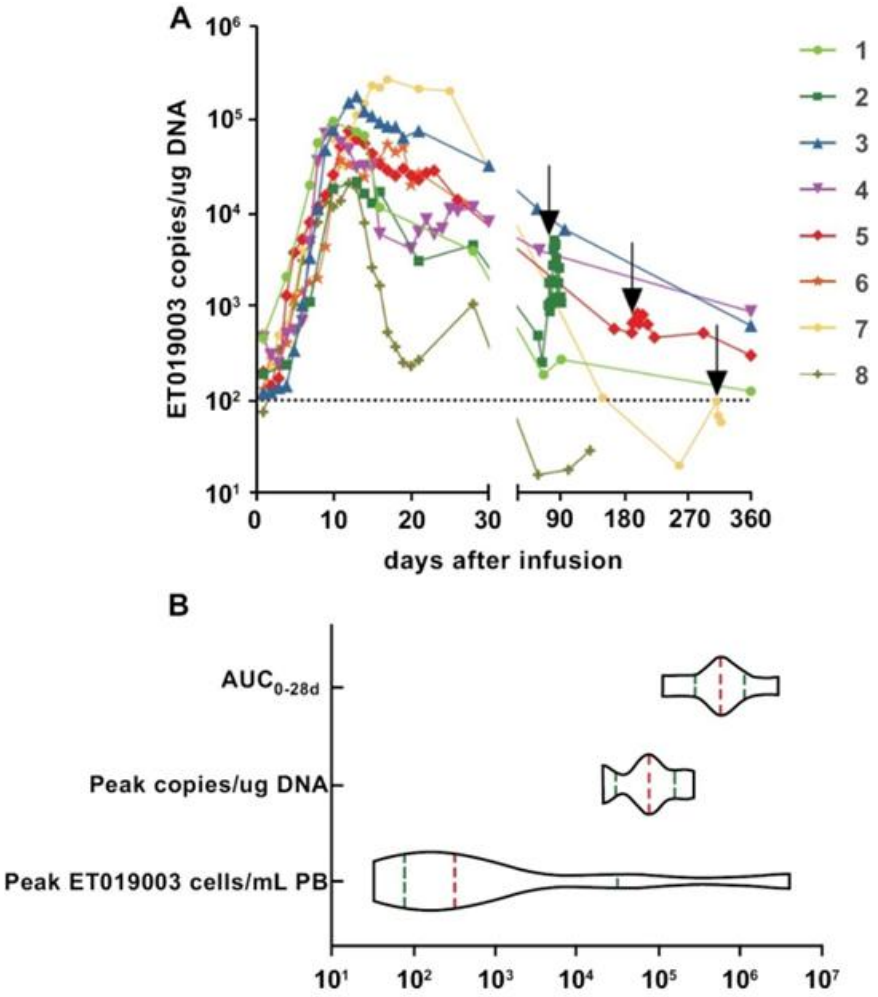
(A) Swimmer's plot of the eight treated patients. (B-D) Kaplan — Meier estimates of the OS, PFS and DoR.

Clinical responses of EB103 cells



(A) Changes in cranial MRI scans of Patient One. (B) EB103 copies per microgram (μg) of genomic DNA in PB and CSF and body temperature changes in Patient One within one month after infusion. (C) Changes in PET-CT scans of Patient Two. (D) Changes in ocular enhanced MRI and abdominal-enhanced CT of Patient Three. (E) Changes in PET-CT scans of Patient Seven.

In vivo kinetics of EB103 cells



(A) EB103 expansion and persistence were measured as copies per microgram (µg) of the genomic DNA by qPCR in the eight treated patients within one year. The detectable threshold was 100 copies per µg of the genomic DNA. The black arrow indicates the second infusion. (B) The violin plot of peak EB103 cells per milliliter of PB (cells/mL PB) as measured by flow cytometry, peak copies per µg of genomic DNA (copies/µg DNA) as measured by qPCR and area under the curve from 0 to 28 days after infusion (AUC_{0-28d}).

Manufacturing

Pursuant to the Services Agreement and Statement of Work #001, among other services, Eureka agreed to provide Estrella with access to Eureka's T-cell manufacturing and lentiviral vector (LVV) processes in connection with the IND application and clinical trials for EB103. See "— *Material Agreements — Services Agreement and Statement of Work #001* " below for additional information regarding the terms of the agreements.

Strengths and Advantages

Eureka developed the ARTEMIS® platform in response to significant tolerability issues, including potentially fatal side effects CRS and ICANS, observed after CAR-T-cell infusions in patients with hematological cancers. We believe that the ARTEMIS® platform and our EB103 T-cell Therapy are superior to current T-cell therapy technologies based on three key features:

Key Features	Advantage
Antibody-based target recognition AbTCR includes portions of a human TCR	The ability to achieve high specificity and binding affinity to intended cancer target when compared to TCRs. The AbTCR associates with the endogenous CD3 complex enabling the AbTCR to use the same activation and regulatory signaling pathways employed by natural TCRs. This feature may lead to a decreased risk of side effects in patients.
Co-stimulation provided as a separate molecule	The AbTCR construct does not include an intracellular signaling domain covalently-linked to a co-stimulatory domain, and thus has the potential to eliminate T-cell hyperactivation and consequently, lower the risk of CRS and ICANS commonly observed with CAR-T therapy.

In addition to the advantages provided above, we believe that the decreased risks of side effects of our EB103 T-cells have the potential to allow for patients to receive treatments in locations other than dedicated cancer centers. This would allow for more patients to be able to receive EB103 T-cells and would ultimately decrease the costs associated with monitoring for side effects following treatment, hospital stays, and other miscellaneous expenses associated with current treatments.

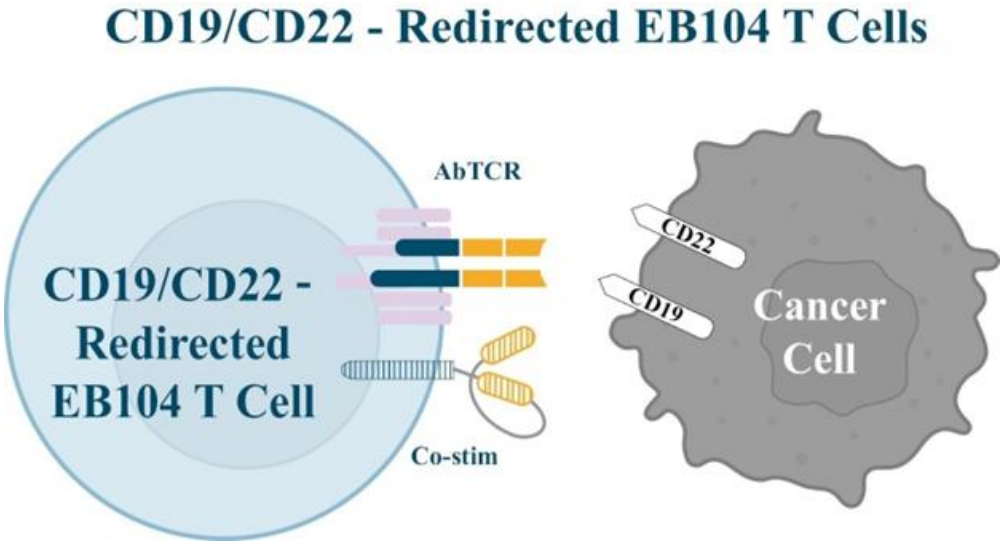
Potential Market

According to Vision Research Reports, the cancer immunotherapy market size is expected to grow at a CAGR of 10.6% during the forecasted

period of 2022 to 2030 and is expected to grow to $130.6 billion in 2030 compared to $60.1 billion in 2020. Generally, T-cell treatments for blood cancers is covered by insurance, and each treatment costs an average of $400,000.

EB104

EB104 T-cells are engineered to express ARTEMIS ® cell receptors (i.e., the AbTCR and co-stimulatory molecule) on their cell surfaces in a manner similar to EB103. Like EB103, both the AbTCR and co-stimulatory molecule of EB104 are designed to recognize and bind the CD19 antigen. In addition, the AbTCR in EB104 T-cells recognizes and binds the CD22 antigen as well. Once infused, EB104 T-cells are able to engage CD19- and CD22-positive cancer cells. The AbTCR expressed on the EB104 T-cell by its nature associates, via its effector domain (γδ TCR chains), with the endogenous CD3 complex. When the AbTCR binds to its target, CD19 or CD22, expressed on the cancer cell, AbTCR/CD3 complex-mediated signal transduction within the EB104 T-cell is initiated. This signal transduction process ultimately leads to the activation of the EB104 T-cell. A second "enhancement" signal is generated when the co-stimulatory molecule expressed on the EB104 T-cells binds to its target, CD19, expressed on the cancer cell. Although the co-stimulatory molecule expressed on EB104 T-cells cannot bind to CD22, EB104 T-cells are able to engage CD19 or CD22 (with the AbTCR) while the co-stimulatory molecule binds to CD19. Like EB103, the main function of the co-stimulatory molecule is to "boost" AbTCR signaling, resulting in increased expansion and survival of EB104 T-cells inside the body, and the co-stimulatory molecule has also been optimized to provide EB104 T-cells with enhanced T-cell activation. In summary, EB104 T-cells seek out CD19 and CD22-positive cancer cells, bind to these cells, and destroy them.

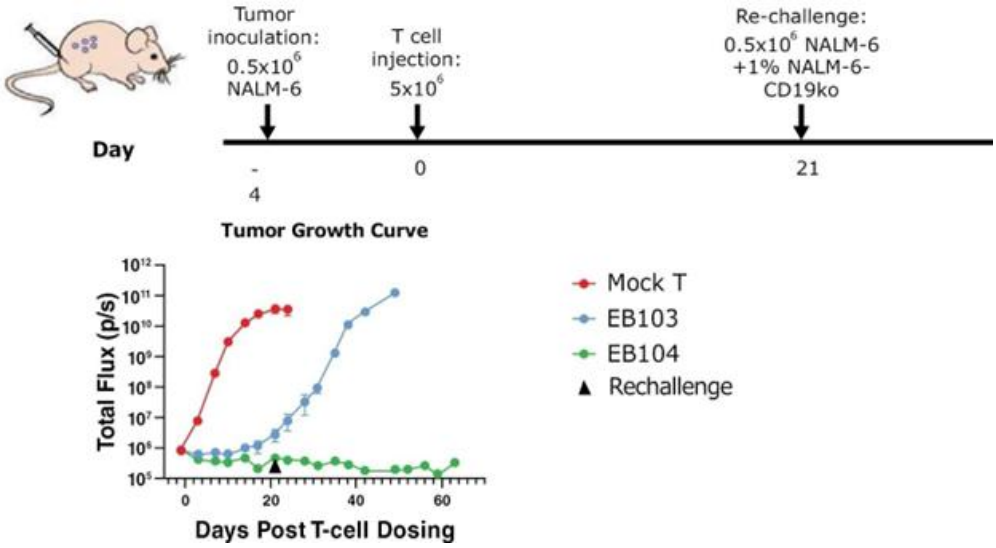


Despite impressive outcomes of CAR-T cell treatments over the past five years, more than 50% of patients treated with CD19-targeted CAR-T cell therapy experience progressive disease. In addition, many patients treated with CD19-target CAR-T cell therapies subsequently show absent or low CD19. Further, disease progression associated with loss of cell surface CD19 has been reported in 30 – 95% of relapses after CD19-targeted CAR-T therapy in B-cell acute lymphoblastic leukemia. We believe that this obstacle can be addressed by dual-targeting both CD19 and CD22 with EB104. For patients that may exhibit lower CD19 surface density, EB104 has the potential to bind to both CD19 and CD22 to increase the odds of effective T-cell therapy.

EB104 Preclinical Data

To test the anti-tumor activity of EB104 towards low or no CD19 surface expression cancer cells, in 2019, Eureka constructed a Nalm-6-CD19ko cell line, which is a B-cell precursor leukemia cell line, with the "knockout" of CD19 gene expression. This cell line mimics patients' diminished CD19 surface expression after CD19-directed immunotherapies. To confirm if EB104 T-cells have the potential to overcome CD19 antigen loss in cancer cells, Eureka tested the activity of EB104 as well as EB103 cells in mice using NSG™ xenograft models (which are highly immunodeficient mice) of leukemia with Nalm-6 and Nalm-6-CD19ko cells with a bioluminescence reporter. The total flux from the bioluminescence reporter measured the tumor growth. In the experiments shown below, Eureka tested EB104, EB103, and mock T-cells head-to-head, against the NSG™ xenograft model, with six mice for each treatment group, respectively. Four days before the T-cells were infused, 0.5x106 leukemia cells Nalm-6 (expressing both CD19 and CD22) with bioluminescence reporter were injected into mice. Four days later, the mice were infused with a total of T-cells containing EB103 or EB104, or mock T cells, using the mock T-cells as the control group. The infusion of EB103 and EB104 showed tumor control until day 21, while the control group showed rapid tumor growth.

Furthermore, EB104 showed potentially better tumor control compared to EB103. At day 21, Nalm-6 cells with 1% Nalm-6-CD19ko (expressing CD22, but not CD19) cells were injected into mice that were previously treated by EB103 or EB104 as re-challenge. This re-challenge experiment mimicked the tumor relapse in patients due to CD19 antigen escape. Mice treated with EB104 showed "durable" tumor control, meaning that the tumor continued to respond to treatment without the cancer growing or spreading, and "clearance" of tumors, which refers to the complete killing of tumor cells, for a total of more than 60 days or 40 days after the re-challenge. However, mice treated with EB103 showed rapid tumor growth after the re-challenge.



These pre-clinical results showed that EB104 T-cells have the potential to eradicate Nalm-6 Primary Tumors and Nalm-6-CD19ko re-challenge tumors in the xenograft model, suggesting that EB104 T-cells have the potential to control the growth of tumor cells that do not express CD19.

Our Collaboration with Imugene and CF33-CD19t

CF33-CD19t and EB103

A major challenge for current T-cell therapies is the identification of antigens that are expressed only on tumors and not in healthy tissue. In the absence of such restricted expression, CAR-T cell therapy poses considerable safety concerns and potentially narrows therapeutic window for their application against solid tumors. CD19 has been an ideal target for CAR-T cells against hematological malignancies for several reasons, including its highly restricted expression on B cells and acceptable off-tumor and on-target properties. In addition to the shared expression of solid tumor antigens on normal tissue, most of these antigens also have heterogeneous and nonuniform expression patterns in tumors, limiting the potential for effective and durable antitumor responses. Many solid tumors, including triple-negative breast cancers and liver cancers, lack amenable tumor antigens for CAR-T cell development. To potentially address the issue of the lack of solid tumor-specific targets, we are collaborating with Imugene and its product candidate, CF33-CD19t, to research the use of EB103 in conjunction with CF33-CD19t to treat solid tumors using a “mark and kill” strategy.

This “mark and kill” strategy entails first using CF33-CD19t to infect solid tumor cells which induces them to express the CD19 protein on the cell surface, thereby labeling the tumor cell as a target for EB103 T-Cells. The EB103 T-cells are then infused into the patient where they would target and kill the now CD19-positive solid tumor cells.

Collaboration Agreement

On October 29, 2021, Eureka entered into a collaboration agreement (the “Collaboration Agreement”) with Imugene, a clinical stage immuno-oncology company, to evaluate the use of CF33-CD19t in conjunction with Eureka’s CD19 ARTEMIS T-cell therapy for the treatment of solid tumors.

On July 28, 2022, as part of the Separation, Eureka contributed and assigned the Collaboration Agreement to Estrella. Pursuant to the Collaboration Agreement, Estrella and Imugene have each granted to the other a royalty free, non-exclusive, worldwide license, with the right to grant and authorize sublicenses, to their respective technologies to conduct the research activities each is responsible for performing under the research plan set forth in the Collaboration Agreement. The research plan is required to be reviewed no less frequently than every six to eight months by a joint steering committee comprised of participants from each of Estrella and Imugene.

Following the completion of the research activities performed under the research plan in accordance with the Collaboration Agreement, Estrella and Imugene will be required to discuss whether they want to jointly develop or commercialize the construct that is the subject of the research plan (and all products that include such construct). Notwithstanding the foregoing, neither Estrella nor Imugene will be required to enter into any joint development agreement concerning such construct or any results, records, or reports that are generated by or on behalf of either Estrella or Imugene while performing such research activities.

Additionally, while Estrella and Imugene each retain their intellectual property rights with respect to their respective technologies and any improvements that relate solely to their respective technologies, in the event that new intellectual property is generated from the collaboration (each a “Joint Collaboration Patent Right”), Estrella and Imugene are required to jointly decide the strategy, and with respect to any Joint Collaboration Patent Rights, the preparation, filing, prosecution, and maintenance of all Joint Collaboration Patent Rights throughout the world. Estrella and Imugene are required to share equally in the costs and expenses incurred in preparing, filing, prosecuting, and maintaining such Joint Collaboration Patent Rights. If only one of Estrella or Imugene wishes to file a patent on any Joint Collaboration Patent Rights, then such party will assume all of the costs related to such patent, and the other party will assign all rights to such patent to the prosecuting party as if they were an improvement of that party’s technology, and the other party may only use such patent rights for internal research purposes.

The Collaboration Agreement will continue to be in full force and effect as long as there are research activities being performed under the research plan set forth therein, unless further extended by written consent of Estrella and Imugene, or unless earlier terminated as follows: (i) by written agreement of each of Estrella and Imugene; (ii) from and after October 29, 2022 (or the termination of all research under the research plan set forth therein, whichever occurs first), by either Estrella or Imugene effective upon 60 days’ prior written notice to the other party; or (iii) by either Estrella or Imugene, if the other party materially breaches the Collaboration Agreement and fails to cure such breach within 60 days after receiving written notice thereof.

Potential Uses and Expansion/Market

Solid tumors represent approximately 1,600,000 new cancer cases, or 90% of total cancer diagnoses in the United States, each year. At this time, there are no FDA-approved CAR or TCR-T cell therapies approved for the treatment of solid tumors. Accordingly, it is currently difficult to estimate specific market projections and the potential for our “mark and kill” strategy.

Our Strategy

Key elements of our strategy include:

- ***Progress our lead product candidate, EB103, through clinical development.*** On March 2, 2023, the FDA cleared our IND for EB103, allowing us to initiate the Phase I/II Starlight-1 Clinical Trial, which dosed its first patient in July 2024.

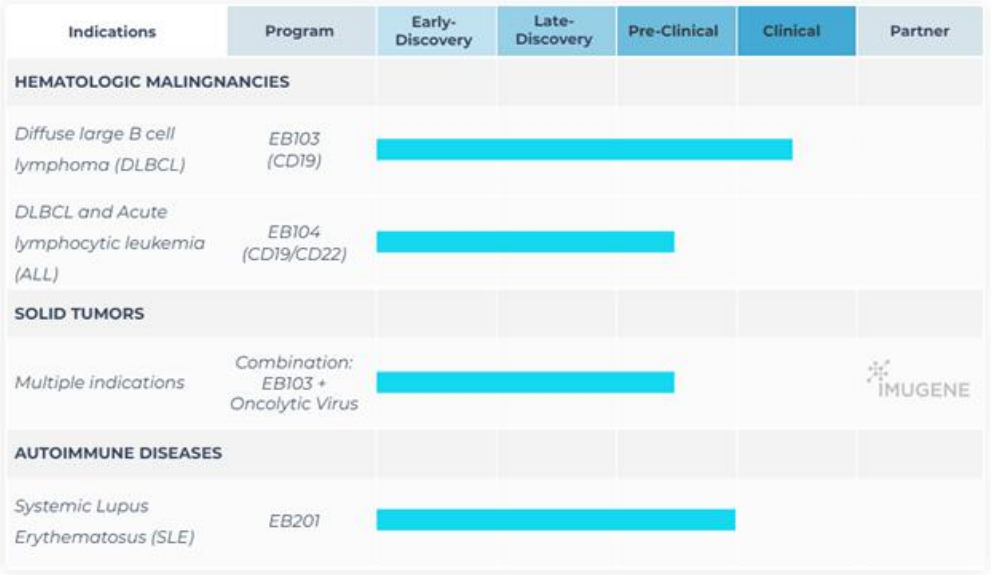
- ***Prepare our second product candidate, EB104, for clinical development.*** We are compiling an IND filing for EB104 for the treatment of relapsed/refractory and high-risk blood cancers. Phase I trials may not commence until the FDA has approved the IND for EB104.

- ***Progress researching the use of EB103 in conjunction with CF33-CD19t for multiple indications of solid tumors through clinical development.*** The FDA cleared our IND for EB103 on March 2, 2023, and the Starlight Phase I/II clinical trial for EB103 dosed its first patient in July 2024. If the Phase I/II Starlight-1 Clinical Trial is successful, we plan to submit an IND filing for the use of EB103 in conjunction with CF33-CD19t in the future. At this time, we have not determined the specific indications of solid tumors to be researched or an exact timeframe for filing our IND application.

- ***Continue to develop a pipeline of T-cell therapies.*** To address certain of the tolerability shortcomings of currently approved CAR-T therapies, we intend to continue pursue development of therapies that may be able to be adopted in earlier lines of treatment and to be delivered in community outpatient settings.

Our Pipeline of Clinical Programs

Our approach is to advance our CD19-Redirected ARTEMIS T Cell programs in relapsed/refractory and high-risk blood cancers first. Meanwhile, we are also developing multiple pipeline candidates against solid tumor and autoimmune disease. The following chart summarizes our clinical programs:



Our Team and Investors

Pursuant to the Services Agreement, we are supported by Eureka's scientific team, which is comprised of leaders in the biopharmaceutical, oncology, and T-cell cancer immunotherapy areas. We have leveraged their expertise to analyze preclinical data and design and implement our clinical trials. Our CEO and President, Dr. Cheng Liu, and members of our scientific advisory board are pioneers in their respective fields, each having spent their careers advancing next-generation technologies and providing treatments in these areas. In addition, our Chief Financial Officer, Peter Xu, brings years of executive experience and investment management abilities.

Our Board includes experienced industry leaders and investors who have been involved with many early-stage companies. Furthermore, we are supported by investors who share our belief that the world needs smarter medical treatments and our long-term vision that T-cell therapies have the potential to transform the way we fight cancer.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid, unpredictable technological advancement and significant competition. These industries dedicate significant resources to developing novel and proprietary therapies for the treatment of cancer, which often incorporate innovative technologies and incorporate valuable intellectual property. We compete with companies in the cell therapy and immunotherapy space, as well as with companies developing other novel targeted therapies for cancer. If approved, our product candidates will compete with commercially available and development-stage innovative products in the fields of cell and immunotherapy, as well as against existing products generally accepted as the standard-of-care for indications in which we plan to seek marketing approval. We anticipate that we will face intense and increasing competition from many different sources, including new and established biotechnology and pharmaceutical companies, academic research institutions, governmental agencies, and public and private research institutions.

Our product candidates cover both hematological malignancies and solid tumors, and we expect to face direct competition in both areas from

companies focused on CAR-T and other cell-based therapies. There are currently eight total FDA-approved drugs or therapies targeting CD19, four of which are CD19-targeting T-cell therapies:

COMPANY	BRAND NAME	YEAR FIRST APPROVED	DISEASE(S)	LOCATIONS APPROVED
Novartis	Kymriah	2017	Acute lymphocytic leukemia; diffuse large B-cell lymphoma; follicular lymphoma	US, EU, UK, Japan, Australia, Canada, South Korea
Kite Pharma (Gilead)	Yescarta	2017	Diffuse large B-cell lymphoma; non-Hodgkin's lymphoma; follicular lymphoma	US, EU, UK, Japan, Canada, China
Kite Pharma (Gilead)	Tecartus	2020	Mantel cell lymphoma; acute lymphocytic leukemia	US, EU, UK
Juno (Bristol Myers Squibb)	Breyanzi	2021	Diffuse large B-cell lymphoma; follicular lymphoma	US, Japan, EU, UK, Canada

Our competitors operating in the T-cell therapy space include, but are not limited to:

- Novartis (Product: Kymriah)
- Kite Pharma, Inc. (Products: Yescarta and Tecartus)
- Juno Therapeutics Inc. (Bristol Myers Squibb) (Product: Breyanzi)
- JW Therapeutics (Product: Carteyva/Relma-cel)
- Adaptimmune Therapeutics PLC (Product Candidate: ADP-A2M4CD8 SPEAR)
- TCR^2 Therapeutics (Product Candidate: TC-520)

- Poseida Therapeutics (Product Candidates: P-BCMA-ALLO1, P-MUC1C-ALLO1, and P-PSMA-ALLO1)
- Autolus Therapeutics PLC (Product Candidates: obe-cel and Auto1/22)

Our competitors pursuing CD19 targeted drugs outside of the T-cell therapy space include, but are not limited to:

- Amgen, Inc. (Product: Blincyto)
- MorphoSys AG (Product: Monjuvi)
- Horizon Therapeutics plc (Product: Uplizna)
- ADC Therapeutics SA (Product: Zynlonta)

Universities and research institutes have been a proven new technology source in the field as well. We also face competition from treatments in the field of immunotherapy which are being developed and/or commercialized by several biotechnology companies as well as by large pharmaceutical companies. Such companies, whose immuno-oncology programs focus on the same indications or antigen targets as our current pipeline. Other known types of immunotherapy, including but not limited to checkpoint inhibition and cancer vaccines, are not currently direct competitors to T-cell-based therapeutics. However, we cannot predict whether these other types of immunotherapy may eventually show efficacy in the indications for which we may seek marketing approval, and it is possible that we may face direct and substantial competition from such sources in the future.

Many of our current or potential competitors, either alone or with a strategic partner, have significantly greater financial, technical, and human resources, as well as more expertise in research and development, manufacturing, preclinical testing, conducting clinical studies and trials and commercializing and marketing approved products. Competitors may compete with us in hiring scientific and management personnel, establishing clinical study sites, registering patients for clinical studies and acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Intellectual Property

Overview

We own certain unregistered intellectual property rights that we use in connection with our business, including a common law trademark for Estrella™. We also own certain plasmids, cell lines, and materials related to CD19 and CD22 in connection with the ARTEMIS® platform, and trade secrets and other intellectual property rights related thereto. A material portion of the intellectual property we use in our business is in-licensed from Eureka, as described below. We are also party to the Collaboration Agreement with Imugene, as described above, to conduct certain preclinical research projects to investigate the use of EB103 in conjunction with CF33-CD19t for efficacy in solid tumors.

License Agreement with Eureka

On June 28, 2022, we entered into the License Agreement with Eureka and Eureka Therapeutics (Cayman), Inc. to license certain functions related to any T-cell products that incorporate (a) the ARTEMIS® platform and (b)(i) the CD19 binder and/or (ii) the CD22 binder identified in the License Agreement (the "Licensed Product"). The License Agreement provides that, during the term, Eureka grants Estrella an exclusive license, with the right to grant sublicenses through multiple tiers to (a) make, import, use, sell or offer to sell the Licensed Products, (b) develop the Licensed Products solely for the purpose of obtaining regulatory approval of such Licensed Products, (c) commercialize such Licensed products and (d) manufacture the Licensed Products solely for the purposes of developing the Licensed Products for purposed of obtaining regulatory approval of such Licensed Products and for commercializing such Licensed Products.

Pursuant to the terms of the License Agreement, in partial consideration of Eureka's grant of the rights and licenses to Estrella, Estrella agreed to pay Eureka a one-time, non-refundable, non-creditable payment of $1,000,000. As of October 2023, $1,000,000 has been paid to Eureka.

Eureka is eligible to receive up to five one-time development milestone payments from Estrella in the aggregate amount of $60,150,000 if all five development milestones are achieved. Effective as of March 1, 2023, the parties further amended the License Agreement to provide that if any development milestone is achieved prior to the Closing of the Business Combination, the corresponding development milestone payment will not be due to Eureka until the Closing of the Business Combination. On January 30, 2023, one development milestone payment in the amount of $50,000 related to the submission of EB103 to the FDA was earned by Eureka under the Agreement, which became due and payable to Eureka upon the Closing of the Business Combination.

Eureka is also eligible to receive up to four one-time sales milestone payments from Estrella based on the aggregate net sales of all Licensed Products by or on behalf of Estrella or any of its affiliates or sublicensees in the Licensed Territory during any consecutive 12-month period in the aggregate amount of $225,000,000 if all four sales milestones are achieved. Each sales milestone payment will only be paid once, regardless of the number of Licensed Products or the number of times a given sales milestone has been achieved. Estrella is also responsible (with input from Eureka) for the preparation, filing, prosecution, and maintenance of the patent rights, including all associated costs.

In addition, during the applicable royalty term, Estrella will be required to pay to Eureka royalties in the amount of a single digit percentage of the aggregate Net Sales of all Licensed Products sold by or on behalf of Estrella or its affiliates or sublicensees in the Licensed Territory during a calendar year. Such amount is subject to certain reductions (not to exceed 50% of the amount otherwise payable) due to the expiration of valid claims of a licensed patent right in a given country in the Licensed Territory or due to 50% or greater declines in sales as a result of generic product competition in a given country in the Licensed Territory. The royalty term begins upon the first commercial sale of a Licensed Product in a country in the Licensed Territory and continues until the later of (a) the date on which such Licensed Product is no longer covered by a valid claim within Eureka's licensed patent rights in such country, (b) the expiration of all exclusive marketing rights or data protection or other exclusivity rights (other than patent rights) conferred by any regulatory authority with respect to a product in a country or jurisdiction that prohibits the commercialization of a generic product, including orphan drug exclusivity or pediatric exclusivity for such licensed product in such country, and (c) 12 years after the first commercial sale of such licensed product in such country.

The License Agreement will remain in effect on a licensed product-by-licensed product and country-by-country basis, until the expiration of the royalty term for a licensed product in a country and will finally expire upon expiration of the royalty term for the final Licensed Product. Estrella may terminate the License Agreement for any reason or no reason upon 120 days' prior written notice to Eureka. Either party has the right to terminate the License Agreement upon material breach of the other party that is not cured within 90 days after the breaching party receives written notice of such breach from the non-breaching party.

As of June 30, 2024, we have fully paid the $1,000,000 license fee to Eureka.

On January 30, 2023, one development milestone payment in the amount of $50,000 related to the submission of EB103 to the FDA was earned by Eureka under the Agreement, which was paid on October 10, 2023. No other development milestone, sales milestone, or royalty payment has been earned as of June 30, 2024, as we do not have any product candidates approved for sale and have not generated any revenue from product sales. With the dosing of the first patient in July 2024 in the STARLIGHT-1 clinical trial, the development milestone pursuant to Section 8.2.1 (First Patient Dosed in the First Clinical Trial of a Licensed Product) in the Licensing Agreement with Eureka was met. As a result, Estrella made a payment of $50,000 to Eureka for reaching this milestone. As of September 2024, two patients have been dosed in the STARLIGHT-1 clinical trial.

Eureka Patent Information

The table below sets forth patents owned by Eureka relating to EB103 and EB104. The expiration date for each patent is October 21, 2036.

TITLE	JURISD.	STATUS	DATE FILED	LOCAL FILING DATE	APPLICATION NO.	PUBLICATION DATE AND NO.	GRANT DATE AND PATENT NO.	TYPE OF PATENT PROT.	PROD. CANDIDATES COVERED
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	AU	Pending	10/21/2016	2/25/22	2022201334	3/31/22 AU2022201334		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	AU	Issued	10/21/2016	3/26/18	2016342041	4/19/18 2016342041	3/17/22 2016342041	Composition of Matter; Use	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	CA	Pending	10/21/2016	4/20/18	3,001,137	4/27/173001137A1		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	EP	Pending	10/21/2016	12/16/20	20214936.5	6/30/21 EP3842450		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	EP	Pending	10/21/2016	5/18/18	16858388.8	8/29/183365364		Composition of Matter; Use; Process	EB103; EB104

Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	IL	Pending	10/21/2016	3/27/18	258405	5/31/18258405		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	IN	Pending	10/21/2016	4/3/18	201817012671	7/20/18 201817012671 A		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	JP	Pending	10/21/2016	12/17/21	2021 – 204862	3/30/22 2022 – 050431		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	JP	Pending	10/21/2016	4/20/18	2018 – 520406	1/17/19 JP2019 – 500848A		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	KR	Pending	10/21/2016	5/17/18	10 – 2018 – 7014004	6/11/18 10 – 2018 – 0063325		Composition of Matter; Use; Process	EB103; EB104

TITLE	JURISD.	STATUS	DATE FILED	LOCAL FILING DATE	APPLICATION NO.	PUBLICATION DATE AND NO.	GRANT DATE AND PATENT NO.	TYPE OF PATENT PROT.	PROD. CANDIDATES COVERED
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	MX	Pending	10/21/2016	4/17/18	MX/a/2018/004721	7/6/18 2018004721		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	NZ	Pending	10/21/2016	10/12/21	781463	10/29/21 NZ781463		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	NZ	Pending	10/21/2016	10/12/21	781465	10/29/21 NZ781465		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	NZ	Pending	10/21/2016	3/26/18	741052	4/27/18741052		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	RU	Pending	10/21/2016	2/14/22	2022103665	3/5/22 RU2022103665		Composition of Matter; Use; Process	EB103; EB104
Antibody/T-cell Receptor Chimeric Constructs and Uses Thereof	US	Issued	10/21/2016	9/4/18	16/121,475	1/24/19 US – 2019 – 0022216 A1	11/5/19 10464988	Use	EB103; EB104

Government Regulation

The U.S. Food and Drug Administration, or FDA, and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, sampling post-approval monitoring and post-approval reporting of biologics such as those we are developing. Any product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences.

U.S. Regulation

Biologic Development Process

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal, state, local and foreign statutes and their implementing regulations. 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. The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements, or GLP;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice, or GCP, regulations and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity, and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application, or BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity, and potency and, if applicable, to assess compliance with the FDA's current Good Tissue Practice, or cGTP, requirements for the use of human cellular and tissue products, and of selected clinical investigation sites to assess compliance with GCPs;

- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

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

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. Some preclinical testing may continue even after the IND is submitted. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. 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.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial 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 informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, dose tolerance, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product in the intended therapeutic indication, particularly for long-term safety follow-up. Completion of these so-called Phase 4 studies may also be made a condition to approval of the BLA.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the safety, purity, and potency of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA 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 also is subject to review before the FDA accepts it for filing.

Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. For a product candidate that is also a human cellular or tissue product, the FDA also will not approve the application if the manufacturer is not in compliance with cGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. If a CRL is issued, the sponsor must resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks, or otherwise limit the scope of any approval. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient

registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, new biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. 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. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. 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.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product candidate is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the 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 accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by FDA, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to FDA for review during the pre-approval period.

In 2017, the FDA established a new regenerative medicine advanced therapy, or RMAT, designation, which is intended to facilitate an efficient development program for, and expedite review of, any biologic that meets the following criteria: (i) the biologic qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the biologic is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the biologic has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of such therapy.

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

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for a particular drug or biologic for the disease 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, including a full BLA, to market the same biologic for the same indication for seven years, except in limited

circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Competitors 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.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic 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 are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. 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. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Changes to the manufacturing process or facility are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

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

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, 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. Physicians may prescribe, in their independent professional and medical judgment, legally available products for uses that are not

described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed.

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

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 orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

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

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing, and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other health care provider transparency laws and regulations.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. For information regarding risks related to these compliance requirements, see the section titled “Risk Factors — Risks Related to Government Regulations.”

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably.

In the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;

- required manufacturers to participate in a coverage gap discount program, under which they must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic.

Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders issued by the previous administration designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The likelihood of success of these and other measures initiated by the previous administration is uncertain, particularly in light of the new Biden administration. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Individual states in the United States have also become increasingly active in implementing 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.

Data Privacy and Security Laws

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in Europe we are subject to the GDPR in relation to our collection, control, processing and other use of personal data (i.e., data relating to an identifiable living individual). We process personal data in relation to participants in our clinical trials in the EEA, including health and medical information of these participants. The GDPR also provides that individual EEA countries may introduce further conditions of their own, including limitations which could limit our ability to collect, use and share personal data.

The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used; imposes limitations on retention of personal data; defines pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. A breach of the GDPR or other applicable privacy and data protection laws and regulations could also result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, or potential civil claims including class action type litigation. Further, from January 1, 2021, we have to comply with the GDPR and separately the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The GDPR and the UK GDPR each have the ability to fine up to the greater of €20 million/£17 million or 4% of global turnover. Further, the relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, including how data transfers between European Union member states and the United Kingdom will be treated and how United Kingdom data protection laws and regulations will develop in the medium to longer term. Currently there is a four to six-month grace period agreed in the European Union and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from European Union member states to the United Kingdom for a four-year period, subject to subsequent extensions. These changes may lead to additional compliance costs and could increase our overall risk.

In addition, the GDPR places restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the European Union, including a recent decision by the Court of Justice for the European Union that invalidated the EU-U.S. Privacy Shield and, to some extent, called into question the efficacy and legality of using standard contractual clauses. This may increase the complexity of transferring personal data across borders. The GDPR will increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. We are also subject to European Union rules with respect to cross-border transfers of personal data out of the EEA. Recent legal developments in the European Union have created complexity and uncertainty regarding transfers of personal data from the EEA to other countries whose data protection standards have not been deemed "adequate" by the European Commission (including the

United States). On July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy, subject to certain conditions, of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism), future regulatory guidance could result in changes to the use of standard contractual clauses. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, the exit of the United Kingdom, or UK, from the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, the UK exited the European Union on January 1, 2020, subject to a transition period that ended December 31, 2020. Under the post-Brexit Trade and Cooperation Agreement between the European Union and the UK, the UK and European Union have agreed that transfers of personal data to the UK from EEA member states will not be treated as 'restricted transfers' to a non-EEA country for a period of up to four months from January 1, 2021, plus a potential further two months extension, or the Extended Adequacy Assessment Period. Although the current maximum duration of the Extended Adequacy Assessment Period is six months, it may end sooner, for example, in the event that the European Commission adopts an adequacy decision in respect of the UK, or the UK amends the UK GDPR and/or makes certain changes regarding data transfers under the UK GDPR/Data Protection Act 2018 without the consent of the European Union (unless those amendments or decisions are made simply to keep relevant UK laws aligned with the European Union's data protection regime). If the European Commission does not adopt an 'adequacy decision' in respect of the UK prior to the expiry of the Extended Adequacy Assessment Period, from that point onwards the UK will be an 'inadequate third country' under the GDPR and transfers of personal data from the EEA to the UK will require a 'transfer mechanism' such as the Standard Contractual Clauses.

In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state laws govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For example, California enacted the CCPA, which creates individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA became effective on January 1, 2020, and (a) allows the California Attorney General to impose civil penalties for violations and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted. The CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Additionally, a new privacy law, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA significantly modifies the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16 and create a new California data protection agency authorized to issue substantive regulations, and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Ensuring compliance with the CPRA could require us to incur additional costs and expenses.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare and privacy laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. For information regarding risks related to these compliance requirements, see the section titled "Risk Factors — Risks Related to Government Regulation."

Material Agreements

Services Agreement

Pursuant to the Services Agreement, we agreed to (i) pay Eureka $10,000,000 in connection with the services thereunder payable in 12 equal monthly installments and (ii) reimburse Eureka on a monthly basis for reasonable pass-through costs incurred or paid to providers by Eureka in providing the services. In addition, we will be charged for other services performed by Eureka outside the scope of the services set forth in the Services Agreement, at a flat rate, by time or materials or as mutually agreed upon the parties in writing. As of June 30, 2024, we had paid Eureka $10,000,000 for the IND Application Services and $117,920 of pass-through costs for services provided pursuant to the Services Agreement.

Statement of Work #001

Pursuant to the Statement of Work #001, effective March 4, 2024, as amended, we committed to paying Eureka $33,000,000 for services related to the Phase I/II clinical trial of EB103, a T-cell therapy targeting CD19 using ARTEMIS® T-cell technology. As of June 30, 2024, Estrella has paid $3,500,000 to Eureka for the fees associated with milestones achieved. The amended SOW clarifies that, if Estrella exercises its right to terminate or suspend the engagement with Eureka by providing written notice, Estrella will only be obligated to compensate Eureka for (i) services provided in connection with milestones achieved prior to the termination notice, (ii) reasonable and documented pass-through costs incurred prior to the termination notice, and (iii) amounts payable to third parties for commitments reasonably entered into prior to the termination notice, provided that Eureka makes commercially reasonable efforts to cancel or reduce such commitments.

Collaboration Agreement

An overview of the Collaboration Agreement with Imugene is provided above under " *Business — CF33-CD19t and EB103* ."

License Agreement

An overview of the License Agreement with Eureka is provided above under " *Business — Intellectual Property*."

Facilities

Our corporate headquarters are located in Emeryville, California. We believe that our existing facilities are adequate for our near-term needs but expect to need additional space as we grow. We believe that suitable additional or alternative space would be available as required in the future on commercially reasonable terms.

Employees

Most of our day-to-day operations to date have been related to preparing for the Business Combination and technology research and development. Many of the operational tasks that we require are managed by Eureka pursuant to the Services Agreement and SOW. As a result, we have a limited number of employees and do not expect to hire a significant number of new employees in the near future.

Other Information

Estrella Immunopharma, Inc. files reports with the Securities and Exchange Commission (SEC), including annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K. These filings are available on the SEC's website at www.sec.gov. Estrella's own website www.estrellabio.com also provides access to these reports free of charge as soon as reasonably practicable after filing with the SEC.

Item 1A. Risk Factors.

You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this Annual Report. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our securities could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business or results of operations. For a summary of these Risk Factors, see "Summary Risk Factors."

Risks Related to the Equity Subscription Line and Shares Sold by the Selling Stockholders

It is not possible to predict the actual number of shares of Common Stock, if any, we will sell under the Common Stock Purchase Agreement to White Lion or the actual gross proceeds resulting from those sales.

On April 14, 2023, we entered into the Common Stock Purchase Agreement, pursuant to which White Lion has committed to purchase up to the lesser of (i) $50,000,000 in aggregate gross purchase price of newly issued shares of Common Stock and (ii) the Exchange Cap, in each case, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement.

Subject to the satisfaction of certain customary conditions including, Estrella's right to sell shares to White Lion commenced on July 11, 2023 and extend until December 31, 2024. During such term, subject to the terms and conditions of the Common Stock Purchase Agreement, Estrella shall notify White Lion when Estrella exercises its right, in its sole discretion, to sell shares.

We generally have the right to control the timing and amount of any sales of our shares of Common Stock to White Lion under the Common Stock Purchase Agreement. Sales of our shares of Common Stock, if any, to White Lion under the Common Stock Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to White Lion all, some or none of the shares of Common Stock that may be available for us to sell to White Lion pursuant to the Common Stock Purchase Agreement.

Because the purchase price per share of Common Stock to be paid by White Lion for the shares of Common Stock that we may elect to sell to White Lion under the Common Stock Purchase Agreement, if any, will fluctuate based on the market prices of the Common Stock at the time we elect to sell shares of Common Stock to White Lion pursuant to the Common Stock Purchase Agreement, if any, it is not possible for us to predict, prior to any such sales, the number of shares of Common Stock that we will sell to White Lion under the Common Stock Purchase Agreement, the purchase price per share that White Lion will pay for shares of Common Stock purchased from us under the Common Stock Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by White Lion under the Common Stock Purchase Agreement.

The number of shares of Common Stock ultimately offered for sale by White Lion is dependent upon the number of shares of Common Stock, if any, we ultimately elect to sell to White Lion under the Common Stock Purchase Agreement. However, even if we elect to sell shares of Common Stock to White Lion pursuant to the Common Stock Purchase Agreement, White Lion may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices.

Because the market price of our shares of Common Stock may fluctuate from time to time, the actual purchase price to be paid by White Lion for our shares of Common Stock that we elect to sell to White Lion under the Common Stock Purchase Agreement, if any, also may fluctuate because they will be based on such fluctuating market price of our shares of Common Stock, it is possible that we would need to issue and sell more than the number of shares of Common Stock that were registered for resale by White Lion in order to receive aggregate gross proceeds of $50.0 million under the Common Stock Purchase Agreement.

Accordingly, if it becomes necessary for us to issue and sell to White Lion under the Common Stock Purchase Agreement more than the 7,036,726 shares of Common Stock that were registered for resale, in addition to obtaining stockholder approval to exceed the Exchange Cap in accordance with Nasdaq listing rules, we must file with the SEC one or more additional registration statements to register under the Securities Act the resale by White Lion of any such additional shares of Common Stock we wish to sell from time to time under the Common Stock Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of Common Stock to White Lion under the Common Stock Purchase Agreement. Any issuance and sale by us under the Common Stock Purchase Agreement of a substantial amount of shares of Common Stock in addition to the 7,036,726 shares of Common Stock being registered for resale by White Lion could cause additional substantial dilution to our stockholders.

The sale and issuance of shares of Common Stock to White Lion will cause dilution to our existing securityholders, and the resale of the shares of Common Stock by White Lion, or the perception that such resales may occur, could cause the price of our securities to fall.

The purchase price per share of Common Stock to be paid by White Lion for the shares of Common Stock that we may elect to sell to White Lion under the Common Stock Purchase Agreement, if any, will fluctuate based on the market prices of our shares of Common Stock at the time we elect to sell shares of Common Stock to White Lion pursuant to the Common Stock Purchase Agreement. Depending on market liquidity at the time, resales of such shares of Common Stock by White Lion may cause the trading price of our shares of Common Stock to fall.

If and when we elect to sell shares of Common Stock to White Lion, sales of newly issued shares of Common Stock by us to White Lion could result in substantial dilution to the interests of existing holders of our shares of Common Stock. If all of the 7,036,726 shares of Common Stock offered for resale by White Lion (without regard to the $50.0 million aggregate purchase price limit pursuant to the Common Stock Purchase Agreement) were issued and outstanding as of the Closing, such shares of Common Stock would represent approximately 19.99% of the total number of our shares of Common Stock outstanding as of the Closing Date. Additionally, the sale of a substantial number of shares of Common Stock to White Lion, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Investors who buy shares of Common Stock from White Lion at different times will likely pay different prices.

Pursuant to the Common Stock Purchase Agreement, we will have discretion to vary the timing, price and number of shares sold to White Lion, if any. If and when we elect to sell shares of Common Stock to White Lion pursuant to the Common Stock Purchase Agreement, after White Lion has acquired such shares of Common Stock, White Lion may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices. As a result, investors who purchase shares from White Lion at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from White Lion in this offering as a result of future sales made by us to White Lion at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares to White Lion under the Common Stock Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with White Lion may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

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

The shares that were registered for resale represent approximately 37.2% of our total outstanding shares as of the Closing Date. The sale or availability for sale of these shares could adversely affect the prevailing market price of our Common Stock and could impair our ability to raise capital through future sales of our securities. In addition, the PIPE investors who acquired the shares being registered pursuant to the Subscription Agreements purchased their shares at a price of $4.15 per share, the Selling Stockholders who hold an aggregate of 240,000 Founder Shares acquired at a purchase price of $0.001 per share, and the Selling Stockholders who hold an aggregate of 867,500 Founder Shares acquired at a purchase price of $0.022 per share, each of which is significantly lower than the initial public offering price of $10.00 per share of our Common Stock. Therefore, these Selling Stockholders may have an incentive to sell their shares before our public stockholders who purchased shares in the initial public offering, because they could still realize a profit even if the market price of our Common Stock is below the initial public offering price of our Common Stock. For example, on December 14, 2023, our Common Stock closed at $1.25 per share on the Nasdaq Capital Market. If the Selling Stockholders who hold an aggregate of 240,000 Founder Shares acquired for $0.001 per share sold any of their Founder Shares at this price, they would realize a profit of $1.249 per share and an aggregate profit of $299,760 if they each sold all of their Founder Shares. If the Selling Stockholders who hold an aggregate of 867,500 Founder Shares acquired for $0.022 per share sold any of their Founder Shares at this price, they would realize a profit of $1.228 per share and an aggregate profit of $1,065,290 if they each sold all of their Founder Shares. Such sales could create additional downward pressure on the market price of our Common Stock and could cause our stock price to decline.

Risks Related to Estrella's Operating History and Financial Condition

We are a clinical stage biotechnology company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company with a history of losses. Since our inception, we have devoted substantially all of our resources to preparing for the Business Combination, drafting regulatory filings (including the INDs), planning and conducting preclinical and clinical studies, and building our management team, and we have incurred significant operating losses. Our net losses were approximately $7.3 million and $11.1 million for the years ended June 30, 2024 and 2023, respectively. As of June 30, 2024, and June 30, 2023, we had an accumulated deficit of approximately $19.5 million and $12.2 million, respectively. Substantially all of our losses have resulted from expenses incurred in connection with preparing for the Business Combination, regulatory filings, and from general and administrative costs associated with our operations. To date, we have not generated any revenue from product sales, and we have not sought or obtained regulatory approval for any product candidate. Furthermore, we do not expect to generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies, clinical trials, and the regulatory approval process for our current and potential future product candidates.

We expect our net losses to increase substantially as we:

- commence clinical trials of EB103;

- continue preclinical development of EB104;
- acquire and license technologies, if any are discovered, that are aligned with our product candidates;
- seek regulatory approval of current EB103 and EB104;
- incur expenses related to the discovery and development of any potential future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development and commercialization efforts;
- continue to develop, perfect, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

However, the amount of our future losses is uncertain. Our ability to achieve or sustain profitability, if ever, will depend on, among other things, successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, entering into potential future alliances, establishing a sales and marketing organization or suitable third-party alternatives for any approved product, and raising sufficient funds to finance business activities. If we, or our potential future collaborators, are unable to commercialize one or more of our product candidates, or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve or sustain profitability, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We will need substantial additional funds to advance development of product candidates, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize our current or potential future product candidates and technologies.

The development of biotechnology product candidates is capital-intensive. If any of our current or potential future product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing, and sales capabilities. We will require significant funds to continue to develop our product candidates and conduct further research and development, including preclinical studies and clinical trials. In addition, we expect to incur significant additional costs associated with operating as a public company.

As of June 30, 2024 and June 30, 2023, we had approximately $4.2 million and $2.5 million, respectively, in cash and cash equivalents. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. Because the length of time and activities associated with successful research and development of platform technologies and product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development of our current and potential future product candidates;
- the timing and progress of our research of the use of EB103 in conjunction with CF33-CD19t;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the terms of any third-party manufacturing contract or biomanufacturing partnership we may enter into;
- our ability to maintain our current licenses and collaborations, conduct our research and development programs and establish new strategic partnerships and collaborations;
- the progress of the development efforts of our existing strategic partners and third parties with whom we may in the future enter into collaboration and research and development agreements;
- the costs involved in obtaining, maintaining, enforcing, and defending patents and other intellectual property rights;
- the impact of the COVID-19 pandemic on our business;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company.

To date, we have primarily financed our operations through the sale of equity securities. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, grants, and other marketing and distribution arrangements. We cannot assure you that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. Because of the numerous risks and uncertainties associated with the development and commercialization of our current and potential future product candidates and the extent to which we may enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials, including related manufacturing costs. To the extent that we raise additional capital through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our current and potential future product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

We do not expect to realize revenue from product sales or royalties from licensed products for the foreseeable future, if at all, and unless and until our current and potential future product candidates are clinically tested, approved for commercialization, and successfully marketed.

Members of our management team have limited experience in managing the day-to-day operations of a public company and, as a result, we may incur additional expenses associated with the management of our company.

Members of our management team have limited experience in managing the day-to-day operations of a public company. As a result, we may need to obtain outside assistance from legal, accounting, investor relations, or other professionals that could be more costly than planned. We may also hire additional personnel to comply with additional SEC reporting requirements. These compliance costs will make some activities significantly more time-consuming and costly. If we lack cash resources to cover these costs in the future, our failure to comply with reporting requirements and other provisions of securities laws could negatively affect our stock price and adversely affect our potential results of operations, cash flow and financial condition.

Our financial statements expressing substantial doubt about our ability to continue as a going concern due to our history of recurring losses and our expectation that negative cash flows from operations will continue until we can generate sufficient revenue. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.

We have incurred significant operating losses to date, and it is possible we may never generate a profit. Our consolidated financial statements included elsewhere in this Annual Report have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. These consolidated 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 these uncertainties related to our ability to operate on a going concern basis.

We have concluded that our recurring losses from operations and need for additional financing to fund future operations raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements expressing substantial doubt about our ability to continue as a going concern. We believe that the financing proceeds raised at Closing will eliminate this doubt and enable us to continue as a going concern; however, we may need to obtain alternative financing or significantly modify our operational plans for us to continue as a going concern. Based upon our current operating plan and assumptions, we believe that our existing cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results, and costs of preclinical studies, laboratory testing, and clinical trials for our product candidates;

- the number and development requirements of product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope and costs of manufacturing arrangements;
- the cost associated with commercializing any approved product candidates;
- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining, enforcing, and protecting our intellectual property rights, defending intellectual property-related claims, and obtaining licenses to third-party intellectual property;
- the timing and amount of any milestone and royalty payments we are required to make under our present or future license agreements;
- our ability to establish and maintain strategic partnerships and collaborations, including any biomanufacturing partnerships or collaborations involving the use of our products, on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies and associated intellectual property.

We will require additional capital to complete our planned clinical development programs for our current product candidates to obtain regulatory approvals. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

In addition, we cannot guarantee that future financing will be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of Common Stock to decline. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be harmed, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. We were required to make significant payments to Eureka in connection with the Closing of the Business Combination, which could adversely affect our liquidity and financial condition.

Under the terms of our agreements with Eureka, following closing of the Business Combination, significant payments to Eureka became due and payable under our agreements with Eureka. Accordingly, on October 9, 2023, we used a portion of the $19.6 million net proceeds from the Business Combination to pay approximately $8.3 million due to Eureka under the Services Agreement and approximately $0.9 million aggregate amount due to Eureka under the License Agreement, comprised of the remainder of the upfront fee as well as a milestone payment in connection with the submission of the IND application for EB103, which reduced our available capital resources. Furthermore, as the majority shareholder of Estrella, Eureka may have significant control over our management and operations, which could affect our ability to negotiate or modify future payment terms in our favor.

Risks Related to the Development and Clinical Testing of Our Product Candidates

Our current product candidates are in either preclinical or clinical development. One or all of our current product candidates may fail in clinical development or suffer delays that materially and adversely affect their commercial viability.

We have no products on the market or that have gained regulatory approval or that have entered clinical trials. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing product candidates, either with Eureka pursuant to the Services Agreement or with other collaborators.

Before obtaining regulatory approval for the commercial distribution of our product candidates, we or a collaborator must conduct extensive preclinical studies, followed by clinical trials to demonstrate the safety, purity and potency, or efficacy of our product candidates in humans. There is no guarantee that the U.S. Food and Drug Administration (the "FDA") will permit us to conduct clinical trials. Further, we cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs, our clinical protocols or if the outcome of our preclinical studies will ultimately support the further development of our preclinical programs or testing in humans. As a result, we cannot be sure that we will be able to submit investigational new drug applications ("INDs") or similar applications for our proposed clinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials for any of our product candidates to begin.

Our current product candidates are in either preclinical or clinical 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 have initiated a clinical trial for EB103 and anticipate initiating clinical trials for our other product candidates, there is no guarantee that we will be able to proceed with clinical development of any of these 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 clinical stage biotechnology companies such as ours.

We may not be able to access the financial resources to continue development of, or to enter into any collaborations for, any of our current or potential future product candidates. This may be exacerbated if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, a product candidate, such as:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon any or all of our programs;
- product-related side effects experienced by participants in our clinical trials or by individuals using therapeutics similar to our product candidates;
- delays in submitting INDs (other than the IND for EB103, which was cleared by the FDA on March 2, 2023) or comparable foreign applications, or delays or failures to obtain the necessary approvals from regulatory authorities to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;

- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- chemistry, manufacturing, and control ("CMC") challenges associated with the manufacturing and scaling up product candidates to ensure consistent quality, stability, purity, and potency among different batches used in clinical trials;
- greater-than-anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory authority inspection and review of a clinical trial or manufacturing site;
- delays as a result of the COVID-19 pandemic or events associated with the pandemic;
- failure of Eureka or our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines; or
- the FDA or other regulatory authorities interpreting our data differently than we do.

Further, we, Eureka, and any existing or potential future collaborator may never receive approval to market and commercialize any product candidate. Even if we, Eureka, or any existing or potential future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We, Eureka, or an existing or potential future collaborator may also be subject to post-marketing testing requirements to maintain regulatory approval.

We may not be successful in our efforts to use and expand our use of the ARTEMIS® platform to expand our pipeline of product candidates.

A key element of our strategy is to use and advance our use of the ARTEMIS® platform to design, test, and build our portfolio of product candidates focused on the treatment of cancer. Our and Eureka's research and development efforts to date have resulted in our discovery and preclinical development of EB103 and other potential product candidates. We received IND clearance from the FDA for EB103 on March 2, 2023, and dosed our first patient in the STARLIGHT-1 clinical trial (NCT06343311) for EB103 in July 2024. However, we cannot assure you that EB103 or any of our other existing or future product candidates will successfully complete clinical trials or demonstrate these product candidates to be safe or effective therapeutics, and we may not be able to successfully develop any product candidates. Even if we are successful in expanding our pipeline of product candidates, any additional product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of

being shown to have unacceptable effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future. Moreover, our ability to complete the clinical trial for EB103 or commence and complete a clinical trial for any other product candidate may depend on our ability to obtain sufficient funding from various sources. If we fail to obtain adequate funding we may have to delay, reduce, or terminate our clinical development programs.

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Although a substantial amount of our efforts will focus on the planned clinical trials and potential approval of the current and potential future product candidates we are evaluating, we also intend to discover, develop, and globally commercialize additional targeted therapies beyond our current product candidates to treat various forms of cancer and in a variety of therapeutic areas. Even if we identify investigational therapies that initially show promise, we may fail to successfully develop and commercialize such products for many reasons, including the following:

- the research methodology used may not be successful in identifying potential investigational therapies;
- competitors may develop alternatives that render our investigational therapies obsolete;
- investigational therapies we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- an investigational therapy may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio;
- an investigational therapy may not be capable of being produced in clinical or commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

Identifying new investigational therapies requires substantial technical, financial, and human resources, whether or not any investigational therapies are ultimately identified. Because we have limited financial and human resources, we may initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, if we do not accurately evaluate the commercial potential or target market for a particular product candidate or technology, we may relinquish valuable rights to that product candidate or technology through collaborations, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or technology.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

The occurrence of serious complications or side effects in connection with use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates or, post-approval, revocation of marketing authorizations or refusal to approve applications for new indications, which could severely harm our business, prospects, operating results and financial condition.

Undesirable side effects caused by any of our current or potential future product candidates could cause 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 regulatory authorities. While we have not yet initiated clinical trials for our product candidates, it is likely that there will be side effects associated with their use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. It is possible that safety events or concerns such as these or others could negatively affect the development of our product candidates, including adversely affecting patient enrollment among the patient populations that we intend to treat. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. There can be no guarantee that our current or future product candidates will not cause such effects in clinical trials. Any of these occurrences may materially and adversely affect our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

In the event that any of our current or potential future product candidates receives regulatory approval and we or others identify undesirable side effects caused by one of these products, any of the following events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;

- we may be subject to fines, injunctions, or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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

While our IND for EB103 was cleared by the FDA on March 2, 2023 and we believe our pipeline will yield additional INDs, we may not be able to file additional INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

While we expect our pipeline to yield multiple INDs in addition to the IND for EB103, which was cleared by the FDA on March 2, 2023, we cannot be sure that submission of future INDs will result in the FDA allowing testing and clinical trials to begin, or that, once clinical trials for EB103 or other product candidates begin, issues will not arise that suspend or terminate such clinical trials. The manufacturing of our product candidates, including EB104, remain an emerging and evolving field. Accordingly, we expect CMC-related topics, including product specifications, will be a focus of IND reviews, which may delay the clearance of INDs.

Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees (“IBCs”), as set forth in the National Institutes of Health (“NIH”) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (“NIH Guidelines”). Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. 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.

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

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

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

We and our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the time frames that we or they announce, which could have an adverse impact on our business and could cause our stock price to decline.

From time to time, we expect that we will make public statements regarding the expected timing of certain milestones and key events, such as the commencement and completion of preclinical and IND-enabling studies in our product candidate discovery programs with collaborators as well as the commencement and completion of planned clinical trials in those programs. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or any current or future collaborators’ product candidate discovery and development programs, the amount of time, effort and resources committed by us and any current or future collaborators, and the numerous uncertainties inherent in the development of therapies. As a result, there can be no assurance that our or any current or future collaborators’ programs will advance or be completed in the time

frames we or they announce or expect. If we or any collaborators fail to achieve one or more of these milestones or other key events as planned, our business could be materially adversely affected, and the price of our Common Stock could decline.

Clinical trials are expensive, time-consuming, and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our current and potential future product candidates are based on new technologies and discovery approaches, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, the FDA or other regulatory authorities may require us to perform additional testing before commencing clinical trials and be hesitant to allow us to enroll patients impacted with our targeted disease indications in our future clinical trials. If we are unable to enroll patients impacted by our targeted disease indications in our future clinical trials, we would be delayed in obtaining potential proof-of-concept data in humans, which could extend our development timelines. In addition, costs to treat patients and to treat potential side effects that may result from our product candidates may be significant. Accordingly, our clinical trial costs are likely to be high and could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue any clinical trials for our current or potential future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. We cannot predict how difficult it will be to enroll patients for trials in the indications we are studying. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity and availability of clinical trial sites for prospective patients;
- willingness of physicians to refer their patients to our clinical trials;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- 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;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, such as current or potential pandemics, including the COVID-19 pandemic, that may limit the availability of patients, principal investigators or staff or clinical sites to participate in our clinical trials.

In addition, our future clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. 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 will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Additionally, because some of our clinical trials will be in patients with advanced disease who may experience disease progression or adverse events independent from our product candidates, such patients may be unevaluable for purposes of the trial and, as a result, we may require additional enrollment. 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 trials and adversely affect our ability to advance the development of our product candidates.

If clinical trials for our product candidates are prolonged, delayed, or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time, or be completed on schedule, if at all. The commencement or completion of these clinical trials could be substantially delayed or prevented by many factors, including:

- further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, including the endpoint measures required for regulatory approval and our statistical plan;
- the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indications as our product candidates;
- any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient quantities or inability to produce quantities of consistent quality, purity and potency of the product candidate for our clinical trials;

- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board ("IRB") or ethics committee approval to conduct a clinical trial at a prospective site;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy or failure to measure a statistically significant clinical benefit within the dose range with an acceptable safety margin during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- the impact of, and delays related to, health epidemics such as the COVID-19 pandemic;
- the need to suspend, repeat or terminate clinical trials as a result of non-compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and
- the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason by, any future strategic collaborator that has responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies, and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for our current or future product candidates that we may develop.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. We may seek orphan drug designation for certain indications for our product candidates in the future. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Orphan drug designation can entitle a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

In addition, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. The FDA may reduce the seven-year exclusivity if the same drug from a competitor demonstrates clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, and while we may seek orphan drug designation for our product candidates, we may never receive such designations. In addition, the FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

Risks Related to Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trial for EB103, and plan to rely on third parties to conduct any clinical trials for our other product candidates, and those third parties may not perform satisfactorily.

We expect to rely on third-party clinical investigators, CROs, clinical data management organizations, and consultants to design, conduct, supervise, and monitor certain preclinical studies and any clinical trials. Because we intend to rely on these third parties and will not have the ability to conduct certain preclinical studies or clinical trials independently, we will have less control over the timing, quality, and other aspects of such preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs, clinical data management organizations, and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and contract manufacturing organizations and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful, or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

Our reliance on these third parties for such drug development activities will reduce our control over these activities. As a result, we will have less direct control over the conduct, timing, and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we will be responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal, and regulatory requirements and scientific standards, including good laboratory practice ("GLP"), good clinical practice ("GCP"), Current Good Manufacturing Practice ("cGMP"), and Current Good Tissue Practice ("cGTP"), and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with GCP standards, regulations for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs, clinical sites and investigators fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency ("EMA"), or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMP 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 FDA regulatory requirements as well as federal or state healthcare laws and regulations or healthcare privacy and security laws.

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

We depend on strategic partnerships and collaboration arrangements, such as the Collaboration Agreement with Imugene and the Licensing Agreement with Eureka, for the development and commercialization of EB103, EB104, and future product candidates in certain indications, and if these arrangements are unsuccessful, this could impair our ability to generate revenues and materially harm our results of operations.

Our business strategy for the research of EB103's use in conjunction with CF33-CD19t is dependent upon maintaining our current arrangements and potentially establishing new arrangements with strategic partners, research collaborators, and other third parties. The Collaboration Agreement with Imugene allows us to investigate the use of EB103 in conjunction with CF33-CD19t in the treatment of solid tumors and to discuss the development and commercialization of collaboration results. The Licensing Agreement with Eureka grants us an exclusive license to use ARTEMIS® technology in connection with CD19 and CD22 in the Licensed Territory. These agreements provide for, among other things, intellectual property rights and significant future payments should certain development, regulatory, and commercial milestones be achieved.

As a result, we may not be able to conduct these collaborations in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations.

Additionally, the development and commercialization of potential product candidates under our collaboration agreements could be substantially delayed, and our ability to receive future funding could be substantially impaired if one or more of our collaborators:

- shifts its priorities and resources away from our collaborations due to a change in business strategies, or a merger, acquisition, sale, or downsizing of its company or business unit;
- ceases development in therapeutic areas which are the subject of our collaboration;
- fails to select a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product;

- changes the success criteria for a particular product candidate, thereby delaying or ceasing development of such product candidate;
- significantly delays the initiation or conduct of certain activities which could delay our receipt of milestone payments tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product candidate that competes, either directly or indirectly, with our product candidates;
- does not obtain the requisite regulatory approval of a product candidate;
- does not successfully commercialize a product candidate;
- encounters regulatory, resource or quality issues and is unable to meet demand requirements;
- exercises its rights under the agreement to terminate the collaboration, or otherwise withdraws support for, or otherwise impairs development under the collaboration;
- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments, or termination of research and development activities for such product candidate; and
- uses our proprietary information or intellectual property in such a way as to jeopardize our rights in such property.

In addition, the termination of our existing collaborations or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payment, sharing of profits, and other benefits under such agreement. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. Any of these events could have a material adverse effect on our ability to develop and commercialize any of our product candidates and may adversely impact our business, prospects, financial condition, and results of operations.

We may not realize the anticipated benefits of our collaboration agreement with Imugene.

Our collaboration with Imugene will explore therapeutic potential of a combination of Imugene's CF33-CD19t in conjunction with EB103 for the treatment of solid tumors. However, Imugene could develop therapies outside of our collaboration that do not utilize EB103. For example, Imugene could develop an oncolytic virus that forces tumors to express a protein other than CD19 for a "mark and kill" approach to treating solid tumors, which would require a combination with a T-cell therapy other than EB103.

We may not be able to enter into additional strategic transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize current and potential future product candidates and technologies, impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we consider strategic transactions, such as collaborations, geographic partnerships for the co-development and/or co-commercialization of our product candidates in selected territories, acquisitions of companies, asset purchases, joint ventures, out- or in-licensing of product candidates or technologies and biomanufacturing partnerships. For example, we will evaluate and, if strategically attractive, seek to enter into collaborations, including with biotechnology or biopharmaceutical companies, contract development manufacturing organizations, or hospitals. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. If we are not able to enter into strategic transactions, we may not have access to required liquidity or expertise to further develop our current or potential future product candidates. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business.

We also may acquire additional technologies and assets, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of acquiring such assets. Conversely, any new collaboration that we do enter into may be on terms that are not optimal for us, our product candidates, or our technologies. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to negotiate and manage a collaboration or develop acquired products, product candidates, or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, or increased amortization expenses;
- difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business;
- impairment of relationships with key suppliers, manufacturers, or customers of any acquired business due to changes in management and ownership; and
- the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and technologies and have a negative impact on the competitiveness of any product candidate or technology that reaches market.

In addition, to the extent that any future collaborators terminate a collaboration agreement, we may be forced to independently develop our current and future product candidates and technologies, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining, enforcing and defending intellectual property rights, or, in certain instances, abandon product candidates and technologies altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

The manufacturing of our product candidates is complex. We may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. The process of manufacturing our product candidates is also extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or the manufacturing facilities in which they are made, the facilities may need to be closed for an extended period of time to investigate and remedy the contamination. As a result of the complexities, the cost to manufacture biologics in general, and our cell-based product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts.

Changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing, planned, or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Risks Related to Our Business and Operations

If the market opportunities for our current and potential future product candidates, are smaller than we believe they are, our future product revenues may be adversely affected, and our business may suffer.

Our understanding of the number of people who suffer from diseases that our current product candidates may be able to treat are based on estimates. These estimates may prove to be incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our current or potential future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for our candidates may further be reduced if our estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from our product candidates.

Further, there are several factors that could contribute to making the actual number of patients who receive our current or potential future product candidates less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

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 therapies or platform technologies more rapidly than we do, or if their therapies or platform technologies are more effective or have fewer side effects, our ability to develop and successfully commercialize therapies may be adversely affected.

The development and commercialization of T-cell 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 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 EB103, EB104, and research relating to the use of EB103 in conjunction with CF33-CD19t, their associated intellectual property, 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.

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Our success largely depends on the continued service of our and Eureka's key executive management, advisors, and other specialized personnel. Our and Eureka's senior management may terminate their employment with us and Eureka, as applicable, at any time. We do not maintain "key person" insurance for any of our employees. The loss of one or more members of our or Eureka's executive team, management team, or other key employees or advisors could delay our research and development programs and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing, and sales and marketing personnel, will be critical to our success. The loss of the services of members of our or Eureka's senior management or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our or Eureka's senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize our product candidates. Our success also depends on our and Eureka's ability to continue to attract, retain, and motivate highly skilled junior, mid-level, and senior managers, as well as and Eureka's junior, mid-level, and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we and Eureka may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We and Eureka also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, through the Services Agreement with Eureka, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Such consultants and advisors are also consultants and advisors to Eureka, and may have additional commitments under consulting or advisory contracts with other entities, that may limit their availability to us and adversely impact the benefits we realize from the Services Agreement and our research and development and commercialization strategy

We may experience difficulties in managing our growth and expanding our operations.

As our current and potential future product candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development, regulatory, and manufacturing capabilities or contract with other organizations to provide these capabilities for us.

To manage our anticipated future growth, we will continue to implement and improve our managerial, operational, and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes 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.

We may also experience difficulties in the discovery and development of potential future product candidates if we are unable to meet demand as we grow our operations. In the future, we also expect to have to manage additional relationships with collaborators, suppliers, and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial, and management controls, reporting systems, and procedures, and to secure adequate facilities for our operational needs. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

If any of our product candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing, and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.

We will need to develop internal sales, marketing, and distribution capabilities to commercialize each current and potential future product candidate that gains, if ever, FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into collaborations with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration, and compliance capabilities. If we rely on third parties with such capabilities to market any approved products or decide to co-promote products with third parties, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business and results of operations could be materially and adversely affected.

Public opinion and scrutiny of immunotherapy approaches may impact public perception of Estrella and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that immunotherapies are unsafe, unethical, or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to immunotherapy in general could result in greater government regulation and stricter labeling requirements of 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 clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. 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. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

Our potential future international operations may expose us to business, political, operational, and financial risks associated with doing

business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our future clinical trials may be conducted outside of the United States and we may enter into key supply arrangements or do other business with persons outside of the United States. Furthermore, if we or any future collaborator succeeds in developing any products, we anticipate marketing them in the European Union and other jurisdictions in addition to the United States. If approved, we or any future collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting, and changing laws and regulations such as those relating to privacy, data protection and cybersecurity, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the commercialization of our product candidates in various countries;

- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand, and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease (including the COVID-19 pandemic), boycotts, curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

Our business entails a significant risk of product liability, and our inability to obtain sufficient insurance coverage could have a material adverse effect on our business, financial condition, results of operations and prospects.

As we conduct preclinical studies and future clinical trials of our current and potential future product candidates, we will be exposed to significant product liability risks inherent in the development, testing, manufacturing, and marketing of these product candidates. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we or any future collaborators may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our employees, principal investigators, consultants, and commercial collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial collaborators. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and financial condition, including the imposition of significant criminal, civil and administrative fines or other sanctions, such as monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity obligations, reputational harm and the curtailment or restructuring of our operations.

We depend on sophisticated information technology systems and data processing to operate our business. If we experience security or data

privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, we may face costs, significant liabilities, harm to our brand, and business disruption.

We rely on information technology systems and data processing that we or our service providers, collaborators, consultants, contractors, or partners operate to collect, process, transmit and store electronic information in our day-to-day operations, including a variety of personal data, such as name, mailing address, email addresses, phone number and potentially clinical trial information. Additionally, we, and our service providers, collaborators, consultants, contractors or partners, do or will collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, and share personal information, health information, and other information to host or otherwise process some of our anticipated future clinical data and that of users, to develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes. Our internal computer systems and data processing and those of our third-party vendors, consultants, collaborators, contractors, or partners, including future CROs may be vulnerable to a cyber-attack (including supply chain cyber-attacks), malicious intrusion, breakdown, destruction, loss of data privacy, actions or inactions by our employees or contractors that expose security vulnerabilities, theft, or destruction of intellectual property or other confidential or proprietary information, business interruption or other significant security incidents. As the cyber-threat landscape evolves, these attacks are growing in frequency, level of persistence, sophistication, and intensity, and are becoming increasingly difficult to detect. In addition to traditional computer "hackers," threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing), phishing and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). These risks may be increased as a result of COVID-19, owing to an increase in personnel working remotely and higher reliance on internet technology. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

To date, we have only implemented limited privacy, data protection or cybersecurity policies, have not implemented any physical, technical, organizational, and administrative security measures and policies, and have not been, to our knowledge, in compliance in all material respects with all Privacy and Security Requirements (as that term is defined in the Merger Agreement) relating to data loss, theft, and breach of security notification obligations.

There can be no assurance that we, our service providers, collaborators, consultants, contractors, or partners will be successful in efforts to detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data. Any failure by us or our service providers, collaborators, consultants, contractors or partners to detect, prevent, respond to or mitigate security breaches or improper access to, use of, or inappropriate disclosure of any of this information or other confidential or sensitive information, including patients' personal data, or the perception that any such failure has occurred, could result in claims, litigation, regulatory investigations and other proceedings, significant liability under state, federal and international law, and other financial, legal or reputational harm to us. Further, such failures or perceived failures could result in liability and a material disruption of our development programs and our business operations, which could lead to significant delays or setbacks in our research, delays to commercialization of our product candidates, lost revenues, or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cashflow. For example, the loss or alteration of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Additionally, applicable laws and regulations relating to privacy, data protection or cybersecurity, external contractual commitments, and internal privacy and security policies may require us to notify relevant stakeholders if there has been a security breach, including affected individuals, business partners and regulators. Such disclosures are costly, and the disclosures or any actual or alleged failure to comply with such requirements could lead to a materially adverse impact on the business, including negative publicity, a loss of confidence in our services or security measures by our business partners or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or other data protection obligations related to information security or security breaches.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

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 materials, including chemicals and biological 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 for failure to comply with such laws and regulations.

Although we maintain 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 or hazardous materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial, and other business activities performed by us or by third parties with whom we may conduct business, including our anticipated contract manufacturers, CROs, shippers, and others.

Health epidemics could cause significant disruption in our operations and the operations of third-party manufacturers, CROs and other third parties upon whom we rely. For example, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Since then, COVID-19 has spread to most countries and all 50 states within the United States, and the U.S. government has, at various times, ordered the closure of all non-essential businesses, and imposed social distancing measures, "shelter-in-place" orders and restrictions on travel between the United States, Europe, and certain other countries. The global pandemic and government measures taken in response have also had a significant impact on businesses and commerce worldwide, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended across a variety of industries, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The effects of government orders may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a

natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and future clinical trials may be affected by the COVID-19 pandemic or other health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources towards the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state, our preclinical studies and future clinical trial operations could be adversely impacted.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic has resulted in significant volatility for global financial markets, resulting in economic uncertainty that could continue to significantly impact our business and operations and may reduce our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our Common Stock. In addition, any recurrence or new increases in the rates and severity of COVID-19 infection could cause other widespread or more severe impacts depending on where infection rates are highest.

Our business, operations, financial position and clinical development plans and timelines, could be materially adversely affected by the continuing military action in Ukraine and the war between Israel and Hamas.

As a result of the military action commenced in February 2022 by the Russian Federation and Belarus in Ukraine and the war between Israel and Hamas commenced in October 2023, and related economic sanctions imposed or that may in the future be imposed by certain governments, our financial position and operations may be materially and adversely affected. As our ability to continue to operate will be dependent on raising debt and equity finance, any adverse impact to those markets as a result of these conflicts, including due to increased market volatility, decreased availability in third-party financing and/or a deterioration in the terms on which it is available (if at all), could negatively impact our business, results of operations, cash flows, financial condition, and/or prospects. The extent of any potential impact is not yet determinable, however.

Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our Common Stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new solutions, retain or expand our current levels of personnel, improve our existing solutions, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;

- develop or enhance our technological infrastructure and our existing solutions;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of Estrella common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

Rising inflation rates could negatively impact our revenues and profitability if increases in the prices of our products or a decrease in consumer spending results in lower sales. In addition, if our costs increase and we are not able to pass along these price increases to our customers, our net income would be adversely affected, and the adverse impact may be material.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. Increased inflation may result in decreased demand for our products and services, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

Risks Related to the Separation and Our Relationship with Eureka

We incurred significant costs in connection with the Business Combination and will incur incremental costs as a standalone public company.

We incurred approximately $1.6 million in transaction costs in connection with the Business Combination, including accounting, legal, underwriting, financial and capital markets advisory, and other fees and expenses. For operational matters outside of the scope of the Services Agreement, we may hire additional employees, or out-source certain functions, systems, and infrastructure through contracts with third parties. These initiatives may be costly to implement. To the extent we implement any of these initiatives, we may incur additional operating costs, and the amount and timing of such costs is uncertain.

Eureka currently performs or supports many important corporate functions for us pursuant to the Services Agreement. The Services Agreement may be terminated by mutual agreement at any time. Following the termination of, or the expiration of the term of, the Services Agreement, we may not be able to replace the services or enter into appropriate third-party arrangements on terms and conditions, including cost, comparable to those that we will receive from Eureka under our Services Agreement. Additionally, after the Services Agreement terminates, we may be unable to sustain the services at the same levels or obtain the same benefits as when we were receiving such services and benefits from Eureka. If we are required to operate these functions separately in the future, and we do not have our own adequate systems and business functions in place at that time, or are unable to obtain

them from other providers, we may not be able to operate our business effectively or at comparable costs, and our profitability may decline.

We also share office space with Eureka pursuant to an office sharing agreement that commenced in August 2022. If Eureka were to leave or lose its office space, we may not have adequate facilities to operate our business effectively and as required by the Collaboration Agreement or the costs of our office space could increase.

Certain of our officers or directors may have actual or potential conflicts of interest because of their equity interests in or positions with Eureka.

Our CEO, President, and director, Dr. Liu, currently serves as the CEO and President of Eureka. As a result, Dr. Liu devotes less than full time to the operation of our business. Pursuant to his employment agreement, Dr. Liu is expected to fulfill his duties as our CEO, but is not required to provide a specific number of hours to our business per week or per month.

Dr. Liu's position at Eureka and the ownership by our officers and directors of any Eureka equity or equity awards, or Estrella equity awards the vesting for which is based in part on the total stockholder return of Eureka, creates, or may create the appearance of, conflicts of interest when these officers or directors are faced with decisions that could have different implications for Eureka than for us. These potential conflicts could arise, for example, over matters such as the desirability of changes in our business and operations, funding and capital matters, regulatory matters, intellectual property-related conflicts, including those relating to potential improvements to the ARTEMIS® platform, possible acquisitions or other corporate opportunities, and agreements with Eureka relating to the Separation or otherwise, allocation of resources and personnel pursuant to the Services Agreement, employee retention or recruiting, or our dividend policy.

In addition, our officers or directors may own Eureka common stock or equity awards. Certain of our officers, including Dr. Liu, and our director nominees have holdings of Eureka common stock or equity awards that have a material monetary value.

We rely on Eureka for our research and development efforts.

Pursuant to the Services Agreement, Eureka currently performs or supports our important research and development activities. The Services Agreement may be terminated by mutual agreement at any time. Following the termination of, or the expiration of the term of, the Services Agreement, we may not be able to replace the research and development-related services that Eureka provides or enter into appropriate third-party arrangements on terms and conditions, including cost, comparable to those that we will receive from Eureka. Additionally, after the Services Agreement terminates, we may be unable to sustain the research and development-related services at the same levels or obtain the same benefits as when we were receiving such services and benefits from Eureka. If we are required to operate these research and development functions separately in the future, and we do not have our own adequate systems and business functions in place at that time, or are unable to obtain them from other providers, we may not be able to operate our business effectively.

Additionally, our CEO and President, Dr. Liu, currently serves as the CEO and President of Eureka. Dr. Liu may have a conflict of interest in allocating resources and personnel between Estrella and Eureka, including pursuant to the Services Agreement, which may adversely impact the benefits we realize from the Services Agreement and our research and development and commercialization strategy.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our in-licensed technology, future technologies and current or future product candidates, or if our intellectual property rights are inadequate, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.

Our success depends in part on our ability to obtain and maintain protection for our in-licensed intellectual property rights and proprietary technology. We rely on a combination of patents, trademarks, trade secret protection and confidentiality agreements, including in-licenses of intellectual property rights and biologic materials of others, to protect our current or future product candidates, methods used to manufacture our current or future product candidates and methods for treating patients using our current or future product candidates.

We in-license patents and patent applications relating to our product candidates. There is no guarantee that any patents covering our product candidates will issue from the patent applications we in-license, or from any patent applications that we may file in the future, or, if they do, that the issued claims will provide adequate protection for our product candidates, or any meaningful competitive advantage. Further, there is no assurance that any such patents issued will not be infringed, designed around, invalidated by third parties or effectively prevent others from commercializing competitive technologies, products or product candidates.

The patent prosecution process is expensive, complex and time-consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we in-license may fail to result in issued patents, and, even if they do issue as patents, such patents may not cover our current or future technologies or product candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We do not have exclusive control over the preparation, filing and prosecution of patent applications under certain of our in-license agreements, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents, that we may file and then out-license to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Even if our in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our in-licensed patents by developing similar or alternative product candidates in a non-infringing manner.

Further, although we make reasonable efforts to ensure patentability of our in-licensed inventions and our future inventions, we cannot guarantee that all of the potentially relevant prior art relating to our in-licensed patents and any patent applications that we may file in the future has been or will be found. For example, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our licensed platform technologies, our product

candidates, or the use of our technologies. We thus cannot know with certainty whether our licensors were the first to file for patent protection of our licensors' inventions. In addition, the United States Patent and Trademark Office ("USPTO") might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or that names a common inventor. There is no assurance that all potentially relevant prior art relating to our in-licensed patents has been found. For this reason, and because there is no guarantee that any prior art search is absolutely correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent that we license or to prevent any patent applications that we may file in the future from issuing as patents. Invalidation of any patent rights with respect to our in-licensed patents could materially harm our business.

Moreover, the patent positions of biotechnology companies like ours are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. The relevant patent laws and their interpretation, both inside and outside of the United States, is also uncertain. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our platform technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe, misappropriate or otherwise violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our in-licensed platform technology and inventions, our product candidates, future inventions and improvements. We cannot guarantee that patents will be granted with respect to any patent applications we may file or in license in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, or the methods of use or manufacture of those products. Additionally, third parties, including our former employees and collaborators, may challenge the ownership or inventorship of our licensed or future patent rights to claim that they are entitled to ownership and inventorship interest, and we may not be successful in defending against such claims. However, we are not currently facing any such challenges. Moreover, issued patents do not guarantee the right to practice our in-licensed or owned technology or inventions in relation to the commercialization of our products. Issued patents only allow us to block — in some cases — potential competitors from practicing the claimed inventions of the issued patents.

The standards applied by the USPTO and foreign patent offices in granting patents are not always certain and moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. The in-licensed patents and patent applications, and our potential future patent applications, if any, may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of any patent applications we may file in the future or narrow the scope of any patent protection we may obtain from any such patent applications. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and any future product candidates and practicing the in-licensed proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidate and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors or other parties with similar technology. Additionally, our competitors may initiate legal proceedings, such as declaratory judgment actions in federal court or reexaminations or an *inter partes* review at the USPTO in an attempt to invalidate or narrow the scope of our in-licensed patents. However, neither we nor our licensors are currently facing any such proceedings. Furthermore, our competitors or other parties may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product candidate may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Even if patents do successfully issue from any patent applications we may file in the future, and even if such patents cover our in-licensed current technologies or any future technologies or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or to any other patents licensed to us could deprive us of rights necessary for the successful commercialization of any current or future technologies or product candidates that we may develop. Likewise, if such patent applications with respect to our development programs and current or future technologies or product candidates fail to issue, if their breadth or strength is threatened, or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us to develop current or future technologies or product candidates. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain or any loss of patent protection could have a material adverse impact on our business and ability to achieve profitability. We may be unable to prevent competitors from entering the market with a product that is similar or identical to any of our current or potential future product candidates or from utilizing technologies similar to those in our in-licensed T-cell immunotherapy technologies.

The filing of a patent application or the issuance of a patent is not conclusive as to its ownership, inventorship, scope, patentability, validity or enforceability. Issued patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, any potential future patent applications filed by us or our licensors, or any patents that issue therefrom, may be challenged through third-party submissions, opposition or derivation proceedings. By further example, any such issued patents may be challenged through reexamination, *inter partes* review or post-grant review proceedings before the USPTO, or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our in-licensed patent rights or any patent rights arising from issuance of a patent based on an application that we may file in the future, result in the loss of exclusivity, limit our ability to stop others from using or commercializing similar or identical platforms and product candidates, or allow third parties to compete directly with us without payment to us. In addition, if the breadth or strength of protection provided by any patents that might result from our in-licensed patent applications or any patent applications that we may file in the future is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future platforms or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, the Collaboration Agreement allows us to co-own with Imugene patent applications relating to inventions jointly developed under the Collaboration Agreement, and we may in the future co-own additional patents and patent applications with third parties pursuant to agreements that we may enter into. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent application, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided

to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions.

Our in-licensed patent rights may be subject to a reservation of rights by one or more third parties, such as the U.S. government. In addition, our rights in such inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Our in-licensed patent rights may not cover our products or processes, including ARTEMIS ®, or any otherwise viable commercial products or processes and/or may be invalid or unenforceable

We have not specifically evaluated the scope of coverage, validity, or enforceability of our in-licensed patent rights. These patents may not cover any of our current or future products or processes, including ARTEMIS® platform technology, or any otherwise viable commercial products or processes. Even if the patents do cover any of our current or future products, we have not evaluated whether and how easily a competitor may be able to design and market a competing product that does not infringe on any of our in-licensed patent rights. The in-licensed patent rights may have no commercial value. The in-licensed patent rights may be invalid or unenforceable for a variety of reasons including, non-patentable subject matter, anticipation, on-sale bar, public use bar, public disclosure, obviousness, inadequate written description, inadequate disclosure, lack of enablement, estoppel, laches, implied license, failure to mark, misuse, and/or inequitable conduct.

Our licenses and other material contracts may be invalid, unenforceable, or limited as to intellectual property and/or may impede, limit, or eliminate our ability to secure or protect our intellectual property, including in-licensed patent rights and any future developments.

We have not specifically evaluated the scope, validity, or enforceability of Eureka's license of patent rights to Estrella. The license may not be valid, may be unenforceable, may have a limited scope, and may not confer adequate rights or standing. These risks may undermine our ability to enforce, control, and protect our in-licensed patent rights. We have not specifically evaluated the scope, validity, enforceability, or commercial usefulness of materials contracts as they relate to intellectual property. These contracts may not enable development of commercially valuable intellectual property and may materially limit or eliminate our ability to secure or protect our intellectual property, including in-licensed patent rights.

The patent protection and patent prosecution for some of our product candidates and technologies may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates and technologies, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates and technologies are controlled by our licensors or collaborators. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would.

If any of our licensors or collaborators fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates and technologies, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates and technologies may be adversely affected and we may not be able to prevent competitors from making, using and selling competing product candidates. In addition, even where we have the right to control the prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our current and future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Further, we may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding(s) or defense activities may be less vigorous than had we conducted them ourselves.

We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these third-party proprietary rights. 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 for our product candidates. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Further, our licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Additionally, some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act") and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government may have the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions made through government funded programs if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government

requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We currently, and in the future may continue to, enter into agreements involving licenses or collaborations that provide for access or sharing of intellectual property. These intellectual property-related agreements may impose certain obligations and restrictions on our ability to develop and commercialize our product candidates and technologies that are the subject of such licenses.

We license rights from third parties to use certain intellectual property relevant to one or more of our current and future product candidates. In the future, we may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our current and future product candidates we may identify and pursue. These existing license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. For example, we are a party to the License Agreement with Eureka and Eureka Therapeutics (Cayman), Inc. For a more detailed description of the License Agreement, see the section titled "*Business — Intellectual Property*."

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Further, we or our licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our in-licensed patents may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our in-licensed patents, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial conditions, results of operations and prospects.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our licensed rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that is the subject of such licensed rights could be materially adversely affected. Even where we have the right to control prosecution of patents and patent applications under license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed currently or in the future from various third parties is or may be subject to retained rights. Our predecessors or licensors do and may retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our product candidates, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies and licensed technology into commercial product candidates. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

If we fail to comply with our obligations under any existing or future license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or product candidates or we could lose certain rights to grant sublicenses.

We have certain obligations to third-party licensors from whom we license certain patent rights that are relevant to one or more current and future product candidates. In the future, we may need to obtain additional licenses from other third parties to advance our research and development activities or allow the commercialization of our current and future product candidates. Our existing license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. For a more detailed description of our existing license agreements, see the section titled "*Business — License Agreement*." If we breach any of these obligations, including diligence obligations with respect to development and commercialization of product candidates covered by the intellectual property licensed to us, or use the intellectual property licensed to us in an unauthorized manner or we are subject to bankruptcy-related proceedings, we may be required to pay damages and the licensor may have the right to terminate the respective agreement or materially modify the terms of the license, such as by rendering currently exclusive licenses non-exclusive. License termination or modification could result in our inability to develop, manufacture and sell products that are covered by the licensed intellectual property or could enable a competitor to gain access to the licensed intellectual property.

In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our licensed rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that are the subject of such licensed rights could be materially adversely affected.

Our current or future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to

claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Disputes may arise between us and our present and future licensors regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues, including but not limited to our right to transfer or assign the license;

- whether and the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties, including the terms and conditions thereof;
- our diligence obligations with respect to the development and commercialization of our product candidates that are covered by the license agreement, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition, while we currently do not have any liens, security interests, or other encumbrances on the intellectual property that we own, we may, in the future, need to obtain a loan or a line of credit that will require that we put up our intellectual property as collateral to our lenders or creditors. If we do so, and we violate the terms of any such loan or credit agreement, our lenders or creditors may take possession of such intellectual property, including the rights to receive proceeds derived from such intellectual property.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies or product candidates.

Patents have a limited lifespan. The term of individual patents and applications in-licensed to us and in our portfolio in the future depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we would file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. Extensions of a patent term may be available, but there is no guarantee that such patents may be eligible for extension, or that we would succeed in obtaining any particular extension, and no guarantee any such extension would confer a patent term for a sufficient period of time to exclude others from commercializing product candidates similar or identical to ours. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the USPTO during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") permits a patent term extension of up to five years beyond the expiration of the patent. While 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, and only one patent per approved drug — and only those claims covering the approved drug, a method for using it or a method for manufacturing it — may be extended under the Hatch-Waxman Act. 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 products receive FDA approval or applicable approval in other jurisdictions, we expect to apply for patent term extensions on any issued patents covering those products in the United States and other jurisdictions where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. An extension may not be granted because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If a patent term extension is not granted or the term of any such extension is less than requested, the period during which we can enforce such patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and clinical trials along with our clinical and preclinical data. This could have a material adverse effect on our business and ability to achieve profitability.

The life of a patent and the protection it affords are limited. As a result, our in-licensed patent portfolio provides us with limited rights that may not last for a sufficient period of time to exclude others from commercializing product candidates similar or identical to ours. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. For example, given the large amount of time required for the research, 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 in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current or any future technologies or product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States or elsewhere could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law, which could increase the uncertainties and costs surrounding the prosecution of any potential future owned patents and our in-licensed patents and the enforcement or defense of any potential future owned patents or our in-licensed patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after March 16, 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. The Leahy-Smith Act also allows third-party submission of prior art to the USPTO during patent prosecution and sets forth additional procedures to challenge the validity of a patent by USPTO-administered post-grant proceedings, including derivation, reexamination, *inter partes* review, post-grant review and interference proceedings. The USPTO developed additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our in-licensed patents and any patent applications we may file in the future and the enforcement or defense of our in-licensed patents and any patents we may own in the future, all of which could have a material adverse impact on our business prospects and financial condition.

As referenced above, for example, courts in the U.S. continue to refine the heavily fact-and-circumstance-dependent jurisprudence defining the scope of patent protection available for therapeutics, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This creates uncertainty about our ability to obtain patents in the future and the value of such patents. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. We cannot provide assurance that future developments in U.S. Congress, the federal courts and the USPTO will not adversely impact any patents we may own in the future or our in-licensed patents or any patent applications we may file in the future. The laws and regulations governing patents could change in unpredictable ways that could weaken our and our licensors' ability to obtain new patents or to enforce our existing in-licensed patents and patents that we might obtain or in-license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may have a material adverse effect on our and our licensors' ability to obtain new patents or to protect and enforce our in-licensed patents or patents that we may obtain or in-license in the future.

We or our licensors may be subject to lawsuits or litigation to protect or enforce our in-licensed patents or other intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Third parties may attempt to invalidate our or our licensors' intellectual property rights via procedures including but not limited to patent infringement lawsuits, declaratory judgment actions, interferences, oppositions and *inter partes* reexamination proceedings before the USPTO, U.S. courts and foreign patent offices or foreign courts. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our licensor's patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in United States federal courts, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our licensors' patent claims that would not have been invalidated if first challenged by the third party in a district court action. Even if such rights are not directly challenged, disputes could lead to the weakening of our or our licensors' intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management, and could have a material and adverse impact on our profitability, financial condition and prospects or ability to successfully compete.

We or our licensors may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our in-licensed patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceedings relating to our in-licensed patent or other intellectual property rights, even if resolved in our favor, could be substantial, particularly in a foreign jurisdiction, and any litigation or other proceeding would divert our management's attention. Such litigation or proceedings could materially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Some of our competitors may be able to more effectively sustain the costs of complex patent litigation because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations.

If we or our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability of the asserted patent are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, claiming patent-ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non-enablement, anticipation or obviousness. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our product candidates or certain aspects of our platform technologies. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of

operations and prospects. Patents and other intellectual property rights also will not protect our product candidates and technologies if competitors or third parties design around such product candidates and technologies without legally infringing, misappropriating or violating our in-licensed patents or other intellectual property rights.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents on current or future technologies or 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 countries do not protect intellectual property rights to the same extent as 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 and into the United States or other countries. Competitors or other third parties may use our licensed technologies to develop their own products in jurisdictions where our licensors or we have not obtained patent protection and, further, may export infringing product candidates to territories where our licensors or we may in the future have patent protections, but enforcement is not as strong as that in the United States. These product candidates may compete with our products, and our in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of any in-licensed patents or patents that we may obtain in the future in other countries, or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our in-licensed intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. Such proceedings could also put any in-licensed patents or patents that we may hold in the future at risk of being invalidated or interpreted narrowly, could put our in-licensed patent applications or patent applications that we may file in the future at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits or other adversarial proceedings that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our and our licensors' efforts to enforce such intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of its patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business prospects may be materially adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or violating their intellectual property rights, or seeking to invalidate or avoid our in-licensed patent rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of our potential future collaborators to develop, manufacture, market and sell our current or any future product candidates and to use our proprietary technologies without infringing, misappropriating or violating the proprietary and intellectual property rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the USPTO, U.S. courts, foreign patent offices or foreign courts. As the field of cell therapies advances, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, there is uncertainty as to when, to whom, and with what claims. Any claims of patent infringement, or claims asserting invalidity, unenforceability, or invalidity of our in-licensed patent rights, asserted by third parties would be time consuming and could:

- result in invalidation, unenforceability, scope limitation, or other adverse judgments against our in-licensed patents;
- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

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 pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. Because patent applications can take many years to issue, there may also be currently pending patent applications that may later result in issued patents that our technology or product candidates may infringe. Further, we cannot guarantee that we are aware of all patents and patent applications potentially relevant to our technology or products. We may not be aware of potentially relevant third-party patents or applications for several reasons. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until a patent issues. Patent applications filed in the United States (after November 29, 2000) and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or platform technologies could

have been filed by others without our knowledge. Any such patent application may have priority over our in-licensed patent applications or patents or any patent applications that we may file in the future and any patents issued therefrom, which could require us to obtain rights to issued patents covering such technologies. Additionally, claims pending in patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform, our product candidates or the use of our technologies.

Although no third party has asserted a claim of patent infringement against us as of the date of this Annual Report, others may hold proprietary rights that could prevent our product candidates from being marketed. We or our licensors, or any future strategic collaborator, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current or any potential future product candidates and technologies, including derivation, reexamination, *inter partes* review or post-grant review before the USPTO and similar proceedings in jurisdictions outside of the United States such as opposition proceedings. In some instances, we may be required to indemnify our licensors for the costs associated with any such adversarial proceedings or litigation. Third parties may assert infringement claims against us, our licensors or our strategic collaborators based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic collaborators to enforce or otherwise assert their patent rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are not invalid, and that they are enforceable and have been infringed, which could have a material adverse impact on our ability to utilize our platform technologies or to commercialize our current or any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity by presenting clear and convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence we believe to be clear and convincing, would invalidate the claims of any such U.S. patent.

Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we, or our licensors, or any future strategic collaborators are found to infringe, misappropriate or violate a third-party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney's fees, if we are found to have willfully infringed. In addition, we, or our licensors, or any future strategic collaborators may choose to seek, or be required to seek, a license from a third party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. We could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing our platform technologies or product candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. 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. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Thus, it is possible that one or more third parties will hold patent rights to which we will need a license, which may not be available on reasonable terms or at all. If such third parties refuse to grant us a license to such patent rights on reasonable terms or at all, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing our product candidates, or to develop or license replacement technology, all of which may not be commercially or technically feasible. In such case, we may not be able to market such technology or product candidates and may not be able to perform research and development or other activities covered by these patents. This could have a material adverse effect on our ability to commercialize our product candidates and our business and financial condition.

Lastly, if our in-licensed technology or products are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Common Stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our Common Stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current in-licensed technologies or future technologies or product candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current in-licensed technologies or future technologies or product candidates, which may not be available on commercially reasonable terms or at all.

Because the immunotherapy landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing, misappropriating, or violating third-party rights. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Also, our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect.

There are numerous companies that have pending patent applications and issued patents broadly covering cell therapy generally or covering related inventions that may be relevant for product candidates that we wish to develop. There may be third-party patents and patent applications that claim aspects of our current or potential future product candidates and modifications that we may need to apply to our current or potential future product candidates. There are also many issued patents that claim inventions that may be relevant to products we wish to develop. The holders of such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our current in-licensed technologies or future technologies, product candidates or elements thereof or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current in-licensed technologies or future technologies or product candidates unless we successfully pursue litigation to narrow or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current in-licensed technologies or future technologies or product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current in-licensed technologies or future technologies or product candidates. If such an infringement claim should successfully be brought, we may be required to pay substantial damages or be forced to abandon our current in-licensed technologies or future technologies or product candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders may also actively bring infringement, misappropriation, or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable, and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current in-licensed technologies or future technologies or product candidates that are held to be infringing, misappropriating, or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or product candidates so that we no longer infringe, misappropriate, or violate the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

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 certain aspects of our current in-licensed technologies or future technologies and product candidates, we rely on trade secrets, including confidential and unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property.

Trade secrets and know-how can be difficult to protect. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they are obligated to maintain confidentiality and to assign their inventions to us. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access (such as through a cybersecurity breach) to our trade secrets or independently develop substantially equivalent information and techniques. Moreover, individuals with whom we have such agreements may not comply with their terms. Any of these parties may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breaches. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

We may also become involved in inventorship disputes relating to inventions and patents developed by our employees or consultants under such agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret, or securing title to an employee- or consultant-developed invention if a dispute arises, is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions disfavor or are unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using the technology or information to compete with us. If, in the future, any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be materially and adversely harmed.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of third parties, including our employees' or consultants' former employers or their clients.

We are party to various contracts under which we are obligated to maintain the confidentiality of trade secrets or other confidential and proprietary information of third parties, including our licensors and strategic partners. In addition, many of our employees or consultants and our licensors' employees or consultants were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that one or more of these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of third parties, including former employers of our employees and consultants. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or may be enjoined from using such intellectual property. Any such proceedings and possible aftermath would likely divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current in-licensed technologies or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against any such claims, litigation or arbitration could result in substantial costs and could be a distraction to management.

Our licensors or we may be subject to claims challenging the inventorship of our in-licensed patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our in-licensed patents as an inventor or co-inventor, or in our trade secrets or other intellectual property as a contributor to its development. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions

regarding co-ownership of potential joint inventions. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our licensors' ownership of our in-licensed patents, our trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we or our licensors 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, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Also, our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents or patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our in-licensed patents and any patent rights we may own or in-license in the future. The USPTO and various non-U.S. patent offices require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these requirements, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. In many cases, an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us, our patent counsel or other applicable patent maintenance vendors, can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical product candidates or platforms, which could have a material adverse effect on our business prospects and financial condition.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we use for name recognition by potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be materially adversely affected.

We may also license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to create T-cell therapies that are similar to our product candidates, but that are not covered by the claims of any patents that we own, license or control;
- we, our licensors, or any strategic collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, license or control or may own, license or control in the future;
- we or our licensors might not have been the first to file patent applications covering certain of our in-licensed inventions;
- others may independently develop the same, similar, or alternative technologies without infringing, misappropriating, or violating our in-licensed intellectual property rights;
- it is possible that any patent applications we may file in the future will not lead to issued patents;
- issued patents that we in-license, control or may own in the future may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, including as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such trade secrets or know-how; and

- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse impact on our business, financial condition, results of operations and prospects.

If any negative data were to arise with respect to the use of our licensed technology in territories where such technology is licensed to a third party, it could negatively affect our ability to develop our product candidates in territories where we license such technology.

Pursuant to the Syracuse License Agreement, Eureka licensed to JW Therapeutics (Cayman) Co. Ltd ("JW") the rights to use ARTEMIS ® technology in connection with CD19 and CD22 in Greater China and the ASEAN countries (the "JW Territory"). The JW License allows JW to conduct research and development (but not commercialize) in the U.S., and for Eureka and Estrella to conduct research and development (but not commercialize) in the JW Territory. Accordingly, we may experience conflicts or have potential intellectual property-related disputes with JW in connection with the development of our product candidates. Additionally, if any negative data were to arise from the JW Territory with respect to the use of ARTEMIS ® technology in the JW Territory, it could negatively affect our ability to develop our product candidates and adversely impact our success in the Licensed Territory.

Risks Related to Government Regulation

Clinical development includes a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

All of our current product candidates are in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if our candidates or any potential future product candidates will prove effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies for our current product candidates and then conduct extensive clinical trials to demonstrate the safety, purity and potency, or efficacy of that product candidate in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the development process. The results of preclinical studies and clinical trials of any of our current or potential future product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

We may experience delays in completing our preclinical studies and initiating or completing our clinical studies. We do not know whether planned preclinical studies and clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Our development programs may be delayed for a variety of reasons, including delays related to:

- the FDA or other regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to initiate a clinical trial;

- obtaining regulatory approval to commence a clinical trial;

- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

- obtaining IRB or ethics committee approval at each clinical trial site;

- recruiting suitable patients to participate in a clinical trial;

- having patients complete a clinical trial or return for post-treatment follow-up;

- clinical trial sites deviating from trial protocol or dropping out of a trial;

- the FDA placing the clinical trial on hold;

- subjects failing to enroll or remain in our trial at the rate we expect;

- subjects choosing an alternative treatment for the indication for which we are developing or other product candidates, or participating in competing clinical trials;

- lack of adequate funding to continue the clinical trial;

- subjects experiencing severe or unexpected drug-related adverse events;

- any changes to our manufacturing process that may be necessary or desired;

- adding new clinical trial sites; and

- manufacturing sufficient quantities of our product candidates for use in clinical trials.

Furthermore, we expect to rely on our CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our current or potential future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs of the institutions in which such trials are being conducted, the Data Safety

Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of any of our current or potential future product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may have a material adverse effect on our business, financial condition, results of operations and prospects. 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 current or potential future product candidates.

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

Our current and any potential future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing, and distribution of therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed in the U.S. or foreign jurisdictions. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our potential future collaborators to begin selling them.

The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity, and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in regulatory policy during the period of product development, clinical trials and regulatory review in the United States and other jurisdictions. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenue from the particular product candidate for which we are seeking approval. Further, we and our potential future collaborators may never receive approval to market and commercialize any product candidate. Even if we or a potential future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

Once a product obtains regulatory approval, numerous post approval requirements apply, including periodic monitoring and reporting obligations, review of promotional material, reports on ongoing clinical trials and adverse events and inspections of manufacturing facilities. In addition, material changes to approved products, including any changes to the manufacturing process or labeling, require further review by the appropriate authorities before marketing. Approvals may also be withdrawn or revoked due to safety, effectiveness, or potency concerns, including as a result of adverse events reported in patients or ongoing clinical trials, or failure to comply with cGMP. In addition to revocation or withdrawal of approvals, we and our partners may be subject to warnings, fines, recalls, criminal prosecution or other sanctions if we fail to comply with regulatory requirements. If we or our partners are unable to obtain or maintain regulatory approvals for our products and product candidates, our business, financial position, results of operations and future growth prospects will be negatively impacted and we or our partners may be subject to sanctions. If any of our product candidates prove to be ineffective, unsafe, or commercially unviable, we may have to re-engineer our current or potential future product candidates, and our entire pipeline could have little, if any, value, which could require us to change our focus and approach to product candidate discovery and therapeutic development, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

If we succeed in developing any products, we intend to market them in the United States, as well as the European Union and other foreign jurisdictions. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other

jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

In the past, Eureka has conducted proof-of-concept studies outside of the United States and collaborated with third parties on investigator-initiated studies ("IIS"). We may in the future conduct certain of our clinical trials for our product candidates outside of the United States or use data from proof of concept or IIS studies from outside the United States to support our IND applications and design clinical development programs. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

In the past, Eureka has conducted proof-of-concept studies outside of the United States and collaborated with third parties on investigator-initiated studies ("IIS"). We may in the future conduct certain of our clinical trials for our product candidates outside of the United States or use data from proof of concept or IIS studies from outside the United States to support our IND applications and design clinical development programs. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless (i) those data are applicable to the U.S. population and U.S. medical practice; (ii) the studies were performed by clinical investigators of recognized competence; and (iii) the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. For studies that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Even if we receive regulatory approval for any of our current or potential future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or potential future 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.

Any regulatory approvals that we or potential future collaborators obtain for any of our current or potential future product candidates will be subject to limitations on the approved indicated uses for which a product may be marketed or may be subject to the conditions of approval, or contain requirements for potentially costly post-marketing testing, and surveillance to monitor the safety and efficacy of such product candidate. In addition, if the FDA or any other regulatory authority approves any of our current or potential future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for such product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practices for any clinical trials that we conduct post-approval. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP and cGTP regulations and applicable product tracking and tracing requirements.

Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our 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 candidate, withdrawal of the product candidate from the market or voluntary or mandatory product recalls;
- fines, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic collaborators;
- suspension or revocation of product approvals;
- suspension of any ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties or monetary fines.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy ("REMS") as part of a biologics license application ("BLA") or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

Furthermore, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians may prescribe, in their independent professional medical judgment, products for off-label uses as the FDA does not regulate the behavior of physicians in their choice of drug treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory authorities have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Occurrence of any of the foregoing could have a material adverse effect on our business and results of operations. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("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 twelve years from the date on which the reference product was first licensed. During this twelve-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 its product. The law is complex. The BPCIA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the twelve-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, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act (the "ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. Among the provisions of the ACA, of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and a cap on the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health program;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and

- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act."

Since its enactment, there have been judicial, congressional, and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted.

- On August 2, 2011, the Budget Control Act of 2011 among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and will remain in effect through 2030.

- On January 2, 2013, the American Taxpayer Relief Act of 2012 among other things, reduced Medicare payments to several providers, including hospitals and increased the statute of limitations period for

- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

- On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. For example, in July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles.

These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which, among other things, will allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct purchasers. The law will also, beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. Although these discounts represent a lower percentage of enrollees' costs than the current discounts required below the out-of-pocket maximum (that is, in the "donut hole" phase of Part D coverage), the new manufacturer contribution required above the out-of-pocket maximum could be considerable for very high-cost patients and the total contributions by manufacturers to a Part D enrollee's drug expenses may exceed those currently provided. Further, the law incentivizes the manufacture of biosimilars and vaccine uptake, and limits the Part B or Part D insulin copayment to $35 per month. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing, which could negatively affect our business, financial conditions, results of operation and prospects.

We expect that additional state and federal 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 reduced demand for our current or future product candidates or additional pricing pressures. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our products. It is not clear how other future potential changes to the ACA will change the reimbursement model and market outlook for our current and future product candidates.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other sensitive information to develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes.

To date, we have only implemented limited privacy, data protection, or cybersecurity policies, have not implemented any commercially reasonable physical, technical, organizational, and administrative security measures and policies, and have not been, to the Estrella's knowledge, in compliance in all material respects with all Privacy and Security Requirements relating to data loss, theft, and breach of security notification obligations.

We and any potential future collaborators, partners, or service providers may be subject to federal, state, and foreign data protection laws, regulations, and regulatory guidance, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws, or contractual obligations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, such as the Health Insurance Portability and Accountability Act ("HIPAA"), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of any future potential collaborators or service providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, or if we otherwise violate applicable privacy and data security laws.

International data protection laws, including the EU's General Data Protection Regulation ("GDPR"), may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018, and imposes stringent data protection requirements for processing of personal data of individuals within the European Economic Area ("EEA") as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The GDPR imposes numerous requirements for the collection, use and disclosure of personal data, including stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information.

In addition, the GDPR places restrictions on cross-border data transfers. A decision by the Court of Justice of the European Union ("CJEU") in 2020 invalidated the EU-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe in compliance with the GDPR's cross-border data transfer restrictions, and raised questions about whether the European Commission's Standard Contractual Clauses, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner has opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. Furthermore, on June 4, 2021, the European Commission issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EEA (and not subject to the GDPR). The new forms of standard contractual clauses have replaced the standard contractual clauses that were adopted previously under the Data Protection Directive. We will be required to transition to the new forms of standard contractual clauses and doing so will require significant effort and cost. The new standard contractual clauses may also impact our business as companies based in Europe may be reluctant to utilize the new clauses to legitimize transfers of personal information to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new standard contractual clauses impose upon exporters. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

The GDPR has increased our responsibilities and potential liability in relation to personal data processed subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Companies now have to comply with the GDPR and also the United Kingdom GDPR ("UK GDPR"), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of £17.5 million or 4% of global turnover. In addition, on June 28, 2021, the European Commission adopted an adequacy decision in respect of transfers of personal data to the UK for a four-year period (until June 27, 2025). Similarly, the UK has determined that it considers all of the EEA to be adequate for the purposes of data protection. This ensures that data flows between the UK and the EEA remain unaffected. Compliance with the GDPR and applicable laws and regulations relating to privacy and data protection of EEA Member States and the UK is 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 our European activities. In addition, any failure by us (or our business partners who handle personal data) to comply with GDPR and applicable laws and regulations relating to privacy and data protection of EEA member states and the UK may result in regulators prohibiting our processing of the personal data of EEA data subjects, which could impact our operations and ability to develop our products and provide our services, including interrupting or ending EEA clinical trials.

In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act (the "CCPA") on June 28, 2018, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as

that term is broadly defined and can include any of our current or future employees who may be California residents) and provide such residents new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches and statutory damages, which is expected to increase data breach class action litigation and result in significant exposure to costly legal judgments and settlements. Although the law includes limited exceptions for health-related information, including clinical trial data, such exceptions may not apply to all of our operations and processing activities. As we expand our operations and trials (both preclinical and clinical), the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend towards more stringent privacy legislation in the United States. In November 2020, California passed the California Privacy Rights Act (the "CPRA") which amends and expands the CCPA. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CPRA has created additional uncertainty and may increase our cost of compliance. Other states are beginning to pass similar laws. In the event that we are subject to or affected by HIPAA, the GDPR, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Laws and regulations worldwide relating to privacy, data protection and cybersecurity are, and are likely to remain, uncertain for the foreseeable future. While we strive to comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity to the extent possible, 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 personnel, collaborators, partners or vendors do not comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity. Actual or perceived failure to comply with any laws and regulations relating to privacy, data protection or cybersecurity in the U.S. or foreign jurisdictions could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators or service providers obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with applicable laws or regulations, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, result in regulatory actions and proceedings, in addition to private claims and litigation, and could result in adverse publicity that could harm our business.

We also are, or may be asserted to be, subject to the terms of our external and internal privacy and security policies, representations, certifications, publications, and frameworks and contractual obligations to third parties related to privacy, data protection, information security, and processing. Failure to comply or the perceived failure to comply with any of these, or if any of these policies or any of our representations, certifications, publications, or frameworks are, in whole or part, found or perceived to be inaccurate, incomplete, deceptive, unfair, or misrepresentative of our actual practices, could result in reputational harm, result in litigation, cause a material adverse impact to business operations or financial results, and otherwise result in other material harm to our business.

If we or our existing or potential future collaborators, manufacturers or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates and may harm our reputation.

Healthcare providers, physicians, and third-party payors, among others, will play a primary role in the prescription and recommendation of any product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers, and customers, among others, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations in the United States and other countries, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, a person or entity from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order, arranging for or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws, including the federal False Claims Act, which provides for civil whistleblower or qui tam actions, and civil monetary penalties laws, that impose penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a referral made in violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses as well as their business associates and their subcontractors that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state, and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Affordable Care Act, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the CMS information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests of such physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include payments and transfers of value, made during the previous year to certain non-physician providers, including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives; and

- analogous local, state and foreign laws and regulations, such as state anti-kickback and false claims laws that may apply to healthcare items or services reimbursed by third party payors, including private insurers, local, state and foreign transparency laws that require manufacturers to report information related to payments and transfers of value to other healthcare providers and healthcare entities, marketing expenditures, or drug pricing, state laws that require pharmaceutical companies to register certain employees engaged in marketing activities in the location and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations, agency guidance 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 such requirements, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time, and resources.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.

Even if we receive marketing and commercialization approval of a product candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after a product is made commercially available, both in the United States and any foreign jurisdiction in which we seek regulatory approval. The FDA and other regulatory authorities have significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product candidate from the market. The FDA and other regulatory authorities also have the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMP and cGTP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product candidate, manufacturer, or facility, including withdrawal of the product candidate from the market. We intend to rely on third-party manufacturers and we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the U.S. or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA, or other regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties, and criminal prosecution.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private health insurers is critical to new product acceptance.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private health insurers and health maintenance organizations. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be

available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

Cost-containment is a priority in the U.S. healthcare industry and elsewhere. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its product. Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the U.S. can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities, and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

In connection with the Business Combination, Estrella adopted a Code of Business Conduct and Ethics and we expect to prepare and implement policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with the Code of Business Conduct and Ethics or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension, or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

General Risk Factors

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and has employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency 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. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster

recovery plans may not adequately protect us from a serious disaster.

We share our facilities with Eureka ("Facilities") located in Emeryville, California, near major earthquake faults, fire zones and the shore of San Francisco Bay. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemics, including any potential effects from the current global spread of COVID-19, power shortage, telecommunication failure, or other natural or man-made accidents or incidents that result in us being unable to fully utilize the Facilities may have a material adverse effect on our ability to operate our business, particularly on a daily basis and have significant negative consequences on our financial and operating conditions. Loss of access to the Facilities may result in increased costs, delays in the development of our product candidates, or interruption of our business operations. Natural disasters or pandemics such as the COVID-19 outbreak could further disrupt our operations and have a material adverse effect on our business, financial condition, results of operations, and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of the Facilities, that damaged critical infrastructure, such as research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. In the event of an accident or incident at the Facilities, we cannot assure our investors that the amounts of insurance payable, if any, will be sufficient to satisfy any damages and losses. If the Facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of preclinical studies and clinical trials or funding support by us or potential future collaborators;
- our execution of any collaboration, licensing, or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any of our existing or potential future collaboration, licensing, or similar arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments, or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our Common Stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. 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 our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, financial condition, and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our management team is not subject to non-competition restrictions if they terminate their employment with us.

The employment agreements with Dr. Liu and Mr. Xu do not contain non-competition covenants limiting their ability to compete with us if they terminate their employment. Although the employment agreements contain customary confidentiality and non-solicitation covenants, the departure of one or more of the members of our management team, followed by such departing member competing with us could diminish our strategic advantages and could have an adverse effect on our business, results of operations, financial condition, and prospects. In addition, Dr. Liu's employment agreement does not contain invention assignment provisions. As a result, any invention by Dr. Liu would remain his intellectual property and we would have no right to

ownership of such invention.

Risks Related to our Securities

Our Common Stock price may be volatile.

Our Common Stock price is likely to be volatile. The market price for our Common Stock may be influenced by many factors, including the other risks described in this section of the Annual Report entitled "*Risk Factors*" and the following:

- Estrella's ability to advance its current or potential future product candidates into the clinic;
- results of preclinical studies and clinical trials for Estrella's current or potential future product candidates, or those of its competitors or potential future collaborators;
- the impact of the ongoing COVID-19 pandemic on Estrella's business;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to Estrella's future products;
- the success of competitive products or technologies;
- introductions and announcements of new products by Estrella, its future commercialization collaborators, or its competitors, and the timing of these introductions or announcements;
- actions taken by regulatory authorities with respect to Estrella future products, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in Estrella's financial results or those of companies that are perceived to be similar to Estrella;
- the success of Estrella's efforts to acquire or in-license additional technologies, products, or product candidates;
- developments concerning any future collaborations, including, but not limited to, those with any sources of manufacturing supply and future commercialization collaborators;
- market conditions in the pharmaceutical and biotechnology sectors;
- market conditions and sentiment involving companies that have recently completed a business combination with a special purpose acquisition company ("SPAC");

- announcements by Estrella or its competitors of significant acquisitions, strategic alliances, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and Estrella's ability to obtain patent protection for its products;
- Estrella's ability or inability to raise additional capital and the terms on which it is raised;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our Common Stock, other comparable companies or the industry generally;
- Estrella's failure or the failure of its competitors to meet analysts' projections or guidance that Estrella or its competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to Estrella;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our Common Stock;
- sales of our Common Stock by Estrella or its stockholders, including the negative pressure potential sales of shares issued in the deSPAC transaction and registered pursuant to the registration statement relating to the offer and resale from time to time of an aggregate of 3,829,338 shares of Common Stock;
- the concentrated ownership of our Common Stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, public health crises and other calamities; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for SPAC post-business combination businesses, pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility, including since the public announcement of the Merger Agreement in October 2022. This volatility can often be unrelated to the operating performance of the underlying business. These broad market and industry factors may

seriously harm the market price of our Common Stock, regardless of Estrella's operating performance.

Estrella may incur significant costs from class action litigation due to the expected stock volatility.

Estrella's stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of development efforts for Estrella's platform and product candidates, the development efforts of future collaborators or competitors, the addition or departure of key personnel, variations in quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to Estrella because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years, including since the public announcement of the Merger Agreement in October 2022. In addition, recently there has been significant stock price volatility involving the shares of companies that have recently completed a business combination with a SPAC. When the market price of a stock has been volatile, as Estrella's stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. Additionally, there has recently been a general increase in litigation against companies that have recently completed a business combination with a SPAC alleging fraud and other claims based on inaccurate or misleading disclosures. If any Estrella stockholders were to bring a lawsuit of this type against Estrella, even if the lawsuit is without merit, Estrella could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of management.

We are a "controlled company" within the meaning of Nasdaq listing rules and, as a result, can rely on exemptions from certain corporate governance requirements that provide protection to shareholders of other companies.

As a result of Eureka Therapeutics, Inc. holding more than 50% of the voting power of our board of directors, we will be a "controlled company" within the meaning of Nasdaq's listing rules. Therefore, we are not required to comply with certain corporate governance rules that would otherwise apply to us as a listed company on Nasdaq including the requirement that compensation committee and nominating and corporate governance committee be composed entirely of "independent" directors (as defined by Nasdaq's listing rules). As a "controlled company" the Estella Board is not required to include a majority of "independent" directors. We do not intend to rely on those exemptions. However, we cannot guarantee that this may not change going forward.

Should the interests of Eureka Therapeutics, Inc. differ from those of other stockholders, it is possible that the other shareholders might not be afforded such protections as might exist if the board of directors of us, or such committees, were required to have a majority, or be composed exclusively, of directors who were independent of Eureka Therapeutics, Inc. or our management.

Estrella is an "emerging growth company" and it cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our Common Stock less attractive to investors and may make it more difficult to compare performance with other public companies.

Estrella is an emerging growth company as defined in the JOBS Act, and it intends to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in 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. Investors may find our Common Stock less attractive because Estrella will continue to rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock, and the stock price may be more volatile.

An emerging growth company may elect to delay the adoption of new or revised accounting standards. Section 102(b)(2) of the JOBS Act allows Estrella to delay adoption of new or revised accounting standards until those standards apply to non-public business entities. As a result, the financial statements contained in this Annual Report and those that Estrella will file in the future may not be comparable to companies that comply with the effective dates of revised accounting standards for public entities.

Future sales and issuances of Common Stock or rights to purchase Common Stock could result in additional dilution of the percentage ownership of Estrella stockholders and could cause Common Stock price to fall.

Significant additional capital will be needed in the future to continue Estrella's planned operations, including further development of Estrella's product candidates, payments under the Services Agreement in connection with preparing regulatory filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, Estrella may sell Common Stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner as determined from time to time. If Estrella sells Common Stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of Common Stock.

Pursuant to the Incentive Plan, the Estrella Board or a committee appointed by the Estrella Board to administer the Incentive Plan (the "Incentive Plan Administrator"), is authorized to grant stock options to Estrella's employees, directors, and consultants. Initially, the maximum aggregate number of shares of Common Stock that may be issued pursuant to stock awards under the Incentive Plan will be equal to the number of shares of Common Stock initially reserved under the Incentive Plan. The number of shares authorized for issuance under the Incentive Plan is approximately 3,520,123 shares of Common Stock. In addition, annually on the first trading day of the calendar year beginning in calendar year 2024, such share reserve will automatically increase by 10% of the total number of shares of Common Stock outstanding as of the last day of the immediately preceding calendar year, unless the Incentive Plan Administrator acts prior to January 1 of such year to provide that there will be no increase or a lesser increase in the share reserve for that year. Unless the Incentive Plan Administrator acts not to increase the number of shares available for issuance under the Incentive Plan, Estrella stockholders may experience additional dilution, which could cause Estrella's stock price to fall.

Estrella's issuance of additional shares of common stock or other equity securities of equal or senior rank would, all else being equal, have the following effects:

- existing stockholders' proportionate ownership interest in Estrella would decrease;
- the amount of cash available per share, including for payment of dividends in the future, may decrease;

- the relative voting strength of each previously outstanding share of common stock would be diminished; and

- the market price of shares of Common Stock may decline.

The exercise by Estrella of its right to issue Common Stock pursuant to the Common Stock Purchase Agreement could cause substantial dilution, which could materially affect the trading price of Common Stock.

In connection with the closing of the Business Combination, the Common Stock Purchase Agreement granted Estrella the right, but not the obligation, to require White Lion to purchase, from time to time, up to the lesser of (i) $50,000,000 of newly issued shares of Common Stock and (ii) the Exchange Cap, subject to satisfaction of certain conditions. To the extent Estrella exercises its right to sell such shares under the Common Stock Purchase Agreement, Estrella will need to issue new shares to White Lion. Although we cannot predict the number of shares of Common Stock that would actually be issued in connection with any such sales, such issuances could result in substantial dilution and decreases to the stock price of Common Stock.

We may be unable to sell shares to White Lion pursuant to the Common Stock Purchase Agreement if our Common Stock is delisted.

One of the conditions precedent to the commencement of the Common Stock Purchase Agreement is that Common Stock must be listed on a Principal Market and must not be suspended from trading or delisted. If our Common Stock is delisted, we will not be able to sell Equity Line Shares to White Lion and Estrella will lose a significant source of potential financing for its business. This could adversely affect our ability to fund our operations and obtain regulatory approval for our product candidates and could materially harm our business, financial condition and results of operations. Furthermore, if our Common Stock is delisted, we may face other negative consequences, such as reduced liquidity and trading volume of our shares, lower investor interest and confidence in our company, decreased analyst coverage and market making activity, limited availability of capital or financing options, and increased volatility in our stock price.

Our Warrants may never be in the money, and they may expire worthless.

The exercise price for our Private Warrants is $11.50 per-share (subject to adjustment as described herein), which exceeds the market price of our Common Stock, which was $1.01 per share based on the closing price of our Common Stock on the Nasdaq Capital Market on July 1, 2024. If all of our Warrants were exercised in full for cash, we would receive an aggregate of approximately $25,472,500. We do not expect warrant holders to exercise their Warrants and, therefore, we do not expect to receive cash proceeds from any such exercise, for so long as the Warrants remain out-of-the money. There can be no assurance that the Warrants will ever be in the money prior to their expiration and, as such, the Warrants may expire worthless.

We may redeem unexpired warrants prior to their exercise at a time that is disadvantageous to investors, thereby making our Warrants worthless.

We have the ability to redeem outstanding Warrants at any time after they become exercisable and prior to their expiration, at $0.01 per warrant, provided that the last reported sales price (or the closing bid price of our Common Stock in the event the shares of our Common Stock are not traded on any specific trading day) of the Common Stock equals or exceeds $16.50 per share (as adjusted for stock splits, stock dividends, reorganizations and the like) on each of 20 trading days within the 30 trading-day period ending on the third business day prior to the date on which we send proper notice of such redemption, provided that on the date we give notice of redemption and during the entire period thereafter until the time we redeem the warrants, we have an effective registration statement under the Securities Act covering the Common Stock issuable upon exercise of the warrants and a current prospectus relating to them is available. The registration statement registering the shares of Common Stock issuable upon exercise of the Warrants was declared effective on December 28, 2023. If and when the Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Warrants could force a warrant holder: (i) to exercise its warrants and pay the exercise price therefor at a time when it may be disadvantageous for it to do so, (ii) to sell its warrants at the then-current market price when it might otherwise wish to hold its Warrants or (iii) to accept the nominal redemption price which, at the time the outstanding Public Warrants are called for redemption, will be substantially less than the market value of its Warrants.

Our warrant agreement designates the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of our Warrants, which could limit the ability of warrant holders to obtain a favorable judicial forum for disputes with us.

Our warrant agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the warrant agreement including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We will waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

Notwithstanding the foregoing, these provisions of the warrant agreement will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum. Any person or entity purchasing or otherwise acquiring any interest in any of our Warrants shall be deemed to have notice of and to have consented to the forum provisions in our warrant agreement. If any action, the subject matter of which is within the scope the forum provisions of the warrant agreement is filed in a court other than a court of the State of New York or the United States District Court for the Southern District of New York (for purposes of this subsection, a “foreign action”) in the name of any holder of our Warrants such holder shall be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (for purposes of this subsection, an “enforcement action”), and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder’s counsel, as applicable, in the foreign action as agent for such warrant holder.

This choice-of-forum provision may limit the ability of warrant holders to bring a claim in a judicial forum that they find favorable for disputes with our company, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our warrant agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and the Estrella Board.

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

Outstanding Warrants to purchase an aggregate of 2,215,000 shares of Common Stock became exercisable on the completion of the Business Combination and the registration statement registering the shares of Common Stock underlying the Warrants becoming effective on December 28, 2023. Each Warrant entitles the holder thereof to purchase one share of our Common Stock at a price of $11.50 per whole share, subject to adjustment.

Warrants may be exercised only for a whole number of shares of Common Stock. To the extent such Warrants are exercised, additional shares of Common Stock will be issued, which will result in dilution to the then existing 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.

Estrella's internal control over financial reporting may not prevent or detect all errors or acts of fraud.

Estrella must design its internal control over financial reporting to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Estrella has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of Estrella's consolidated financial statements, and have other adverse consequences.

In connection with the audits of Estrella's financial statements for the years ended June 30, 2023 and 2024, material weaknesses in Estrella's internal control over financial reporting were identified in relation to: (i) Estrella's lack of qualified full-time personnel with appropriate levels of accounting knowledge and experience to address complex U.S. GAAP accounting issues and to prepare and review financial statements and related disclosures under U.S. GAAP. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis.

The identified material weaknesses, if not corrected, could result in a material misstatement to Estrella's consolidated financial statements that may not be prevented or detected.

The Company has implemented certain changes in its internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to remediate the material weaknesses identified in fiscal year 2023. The implementation of the material aspects of this plan took place during the second and third quarters of fiscal year 2024. Additional qualified out-sourced personnel with appropriate levels of accounting knowledge and experience to address U.S. GAAP accounting issues have been added to prepare and review financial statements and related disclosures under U.S. GAAP. Non-routine transactions are analyzed by the chief financial officer and third-party consultants to ensure proper accounting treatment. Narratives and policies for business processes that relate to financial statements have been put in place to establish proper segregation of duties and internal controls. While the Company has remediated certain previously identified material weaknesses, our chief executive officer and chief financial officer concluded that as of June 30, 2024, our disclosure controls and procedures were not effective at the reasonable assurance level. If Estrella fails to establish and maintain proper internal financial reporting controls, its ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Estrella is a public company in the United States subject to the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that Estrella include a report from management on Estrella's internal control over financial reporting in Estrella's annual report on Form 10-K beginning with Estrella's annual report for the fiscal year ended June 30, 2024. In addition, if Estrella ceases to be an "emerging growth company," Estrella's independent registered public accounting firm may be required to attest to and report on the effectiveness of Estrella's internal control over financial reporting.

If Estrella fails to implement any required improvements to its disclosure controls and procedures to address any material weaknesses in its internal control over financial reporting, such material weaknesses could result in inaccuracies in Estrella's financial statements and could also impair its ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis.

In addition, Estrella's reporting obligations may place a significant strain on its management, operational, and financial resources and systems for the foreseeable future. Estrella may be unable to timely complete its evaluation testing and any required remediation.

Reports published by analysts, including projections in those reports that differ from Estrella's actual results, could adversely affect the price and trading volume of our Common Stock.

Estrella currently expects that securities research analysts will establish and publish their own periodic financial projections for the business of Estrella. These projections may vary widely and may not accurately predict the results that Estrella will actually achieve. Estrella's stock price may decline if its actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on Estrella downgrades its stock or publishes inaccurate or unfavorable research about its business, Estrella's stock price could decline. If one or more of these analysts ceases coverage of Estrella or fails to publish reports on Estrella regularly, its stock price or trading volume could decline. If no analysts commence coverage of Estrella, the trading price and volume for our Common Stock could be adversely affected.

The obligations associated with being a public company will involve significant expenses and will require significant resources and management attention, which may divert from Estrella's business operations.

As a public company, Estrella is subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly, and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. As a result, Estrella will incur significant legal, accounting, and other expenses that Estrella did not previously incur as a private company prior to the Business Combination. Estrella's entire management team and many of its other current or future employees will be required to devote substantial time to compliance, and Estrella may not effectively or efficiently manage its transition into a public company.

These rules and regulations have and will continue to result in Estrella incurring substantial legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for Estrella to obtain and maintain director and officer liability insurance, and it may be required to accept reduced policy limits and coverage or incur substantially higher costs

to obtain or maintain the same or similar coverage in the future. As a result, it may be difficult for Estrella to attract and retain qualified people to serve on its board of directors, its board committees, or as executive officers.

Provisions in Estrella's Amended Charter Estrella's amended and restated bylaws (the "Amended Bylaws") and Delaware law may have anti-takeover effects that could discourage an acquisition of Estrella by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management, which could depress the trading price of our Common Stock.

Estrella's Amended Charter, the Amended Bylaws, and Delaware law contain provisions that may have the effect of discouraging, delaying, or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Estrella's Amended Charter and the Amended Bylaws include provisions that:

- permit the Estrella Board to issue up to 10,000,000 shares of preferred stock, with any rights, preferences, and privileges as they may designate, including the right to approve an acquisition or other change of control;
- provide that the number of directors of Estrella may be changed only by resolution of Estrella Board;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may be removed only for cause by the holders of two-thirds (66 and 2/3%) of the voting power of all of the then outstanding shares of voting stock of Estrella entitled to vote generally at an election of directors;
- provide that all vacancies, subject to the rights of any series of preferred stock, including newly created directorships, may, except as otherwise required by law, be filled exclusively by the affirmative vote of a majority of the directors then in office, even though less than a quorum, or by a sole remaining director;
- provide that stockholders seeking to present proposals before a meeting of stockholders or seeking to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and specify requirements as to the form and content of such notice;
- provide that special meetings of Estrella's stockholders may be called by the Estrella Board; and
- provide that the Estrella Board will be divided into three classes of directors, with only one class of directors being elected each year and each individual director serving a three-year term, therefore making it more difficult for stockholders to change the composition of the board of directors.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock, thereby depressing the market price of our Common Stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

Estrella has adopted cybersecurity principles modeled after its parent company, Eureka, which outsources its IT support to a third-party provider. Estrella's IT infrastructure is limited due to its size and scope, and it has not conducted a formal standalone IT risk assessment. Because it has not conducted a formal standalone IT risk assessment, Estrella's process for assessing, identifying, and managing material risks from cybersecurity threats has not been fully integrated into its overall risk management system or process. Estrella does not have a formal process established to oversee and identify cybersecurity threats and risks associated with its reliance on the third-party IT support provider of Eureka. However, it has implemented several key cybersecurity measures, focusing heavily on cloud-based solutions to protect its financial data and communications.

Key cybersecurity risk management strategies include:

- Data Backup and Recovery: Estrella stores all critical data in the cloud and does not maintain on-premise servers. Daily backups are conducted and monitored to protect financial and operational data from loss or breach. Periodic restore tests are also performed to verify the integrity of the data.
- Two-Factor Authentication: Access to Estrella's data and email, hosted on Office 365, is protected by two-factor authentication, providing an additional layer of security against unauthorized access.
- Data Access Control: Financial data is stored on a dedicated SharePoint site, with access restricted to relevant personnel only, ensuring tight control over sensitive information.

- Email Protection: Estrella employs Exchange Online Protection (EOP) for email filtering, Data Loss Prevention (DLP) to prevent accidental sharing of sensitive information, and basic email encryption to secure communications.

Governance

Cybersecurity oversight at Estrella is integrated into Eureka's IT governance framework. Eureka's IT Governance Committee, which consists of the CEO from the third-party IT provider and Eureka's operations team, oversees cybersecurity risk assessments and controls. The third-party IT provider has more than three decades of experience in providing strategic planning and IT outsourcing to companies, with cybersecurity professionals on staff that specialize in NIST compliance.

Estrella's CEO is responsible for ensuring that cybersecurity measures relevant to Estrella are in place and effective. Estrella's management works closely with Eureka's IT Governance Committee to ensure that Estrella benefits from Eureka's comprehensive cybersecurity practices. Although Estrella does not have a dedicated cybersecurity officer, Eureka's IT Governance Committee, oversees the IT support provided by the third-party IT provider to Estrella. Any critical cybersecurity incidents or risks identified are communicated to Estrella's board for review and action. In the event of a cybersecurity incident, the board is promptly informed, and measures are taken in coordination with Eureka's IT Governance Committee and third-party IT provider to address and mitigate any risks. Estrella's board is committed to ensuring that cybersecurity remains a priority and that all necessary steps are taken to protect the company's data and operations.

During the year ended June 30, 2024, we did not identify any cybersecurity threats that have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition. However, we may not be aware of all vulnerabilities or might not accurately assess the risks of incidents, and such preventative measures cannot provide absolute security and may not be sufficient in all circumstances or mitigate all potential risks.

Item 2. Properties.

Our principal executive office in the U.S., which we lease, is located at 5858 Horton Street, Suite 370, Emeryville, CA 94608. The Company does not own any real estate. We believe that our existing office space is sufficient for our current needs.

Item 3. Legal Proceedings.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We currently are not a party to any material litigation or other material legal proceedings.

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 warrants trade on the Nasdaq Global Market under the symbols "ESLA" and "ESLAW," respectively, since October 2, 2023.

Holders

As of June 30, 2024, there were 20 registered holders of record of our Common Stock and 1 holder of record of our warrants. This does not include the number of shareholders that hold shares in "street name" through banks or broker-dealers.

Dividends

We have not paid any cash dividends to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of the Board at such time. Our ability to declare dividends may also be limited by restrictive covenants pursuant to any debt financing agreements.

Unregistered Sales of Equity Securities

The Company has not sold any within the past three years which were not registered under the Securities Act except as follows:

Private Placements in Connection with UPTD IPO

Substantially concurrently with the closing of the IPO, the Company completed the private sale of 295,000 Private Shares to the Founders at a purchase price of $10.00 per Private Placement Share, among which, the Sponsor purchased 236,000 Private Shares and Tradeup INC. purchased 59,000 Private Shares, generating gross proceeds to the Company of $2,950,000. The Private Shares are identical to the shares of Common Stock sold as part of the Units in the IPO, except that the Founders have agreed not to transfer, assign or sell any of the Private Shares (except to certain permitted transferees) until 30 days after the completion of the Company's initial business combination. The issuance of the Private Shares was made pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended.

Subscription Agreements

In connection with the execution of the Merger Agreement, UPTD entered into subscription agreements (the "Subscription Agreements") with each of Plentiful Limited, a Samoan limited company ("Plentiful Limited") and Lianhe World Limited, a company incorporated in the People's Republic of China ("Lianhe World" and together with Plentiful Limited, the "Subscribers") pursuant to which the Subscribers have agreed to purchase, and UPTD has

agreed to sell to the Subscribers, an aggregate of 1,000,000 shares of UPTD common stock for an aggregate purchase price of $10 million (the "Equity Financing"). The Equity Financing closed concurrently with the Business Combination on the Closing Date.

Pursuant to the Subscription Agreements, within thirty days following the Closing Date, each Subscriber also became entitled to receive 704,819 shares of Common Stock, which were issued to each Subscribe in January 2024. In addition, within five days following the date that is 24 months following the Closing (the "24-Month Date"), if the VWAP of Common Stock for the fifteen trading days prior to the 24-Month Date (the "24-Month Date VWAP") is less than $8.30, then each of them will be entitled to a number of shares of Common Stock equal to (i) (A) 8.30 minus (B) the 24-Month Date VWAP multiplied by (ii) (A) the number of Shares held by the Investor on the 24-Month Date minus (B) the number of shares acquired by the Investor following the Closing divided by 10.00.

The Equity Subscription Line

On April 20, 2023, the Company entered into the Common Stock Purchase Agreement and a related registration rights agreement (the "White Lion RRA") with White Lion. Pursuant to the Common Stock Purchase Agreement, the Company has the right, but not the obligation to require White Lion to purchase, from time to time, up to the lesser of (i) $50,000,000 in aggregate gross purchase price of newly issued shares of Common Stock and (ii) the Exchange Cap, in each case, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement.

The Common Stock Purchase Agreement contains customary representations, warranties, covenants and indemnification provisions. Subject to the satisfaction of certain customary conditions, the Company's right to sell shares to White Lion has commenced on December 28, 2023, the effective date of the registration statement relating to the offer and resale from time to time of an aggregate of 3,829,338 shares of Common Stock (the "Commencement") and extend until December 30, 2024. During such term, subject to the terms and conditions of the Common Stock Purchase Agreement, the Company shall notify White Lion when the Company exercises its right, in its sole discretion, to sell shares (the effective date of such notice, a "Notice Date").

The number of shares sold pursuant to any such notice will be equal to the lesser of (a) the number of shares of Common Stock which would result in White Lion beneficially owning more than 4.99% of the number of shares of Common Stock outstanding, (b) the number of shares equal to the product of (i) the Average Daily Trading Volume (as defined in the Common Stock Purchase Agreement) and (ii) 30% and, (c) the number of shares of Common Stock equal to the quotient obtained by dividing (i) the lower of (A) $1,000,000 and (B) Closing Sale Price (as defined in the Common Stock Purchase Agreement) of the Common Stock on the day prior to the Purchase Notice Date (as defined in the Common Stock Purchase Agreement).

The aggregate number of Equity Line Shares that Estrella can sell to White Lion under the Common Stock Purchase Agreement may in no case exceed the maximum number of shares of Common Stock that Estrella can issue or sell to White Lion under the Common Stock Purchase Agreement pursuant to the applicable rules of the Principal Market (the "Exchange Cap") without getting approval from its stockholders. If stockholder approval is obtained to issue Equity Line Shares above the Exchange Cap, the Exchange Cap will no longer apply.

The purchase price to be paid by White Lion for any Equity Line Shares will equal (i) until an aggregate of $25,000,000 in shares have been purchased under the Common Stock Purchase Agreement, 97% of the lowest daily volume-weighted average price of Common Stock during the three consecutive trading days following the Notice Date, and (ii) thereafter, 98% of the lowest daily volume-weighted average price of Common Stock during the three consecutive trading days following the Notice Date.

The Common Stock Purchase Agreement will terminate automatically on the earliest of (i) December 30, 2024; (ii) the date when White Lion buys all the Equity Line Shares it agreed to buy under the Common Stock Purchase Agreement; (iii) the date when Estrella files for bankruptcy, has a bankruptcy case filed against it, has a custodian appointed for it or its property, or assigns its assets to its creditors.

The Common Stock Purchase Agreement may be terminated by (i) Estrella with three days' notice to White Lion after the Commencement, provided that Estrella pays the Commitment Fee (as defined below) and consults with White Lion before announcing the termination; (ii) the parties by mutual written consent at any time; or (iii) White Lion with three days' notice to the Company if any of the following events occurs: (a) a material adverse effect on Estrella or its business; (b) a Fundamental Transaction involving Estrella or its securities; (c) a material breach or default by Estrella of the White Lion RRA that is not cured within 15 days; (d) a lapse or unavailability of a registration statement for more than 45 consecutive days or 90 days in a year, unless caused by White Lion; (e) a suspension of trading of Common Stock on the Principal Market for more than five days; or (f) a material breach or default by Estrella of the Common Stock Purchase Agreement that is not cured within 15 days. The Company must notify White Lion and, if required, the public of any of these events within 24 hours.

In consideration for the commitments of White Lion, UPTD agreed to cause Estrella to issue to White Lion, immediately prior to the Closing, an aggregate of 250,000 shares of Estrella Series A Preferred Stock, which the parties have acknowledged has a value of $250,000 (the "Commitment Fee"). Accordingly, concurrently on April 20, 2023, Estrella and White Lion entered into a Joinder to the Estrella Series A Preferred Stock Purchase Agreement (the "Joinder"), pursuant to which Estrella agreed to issue the 250,000 shares of Estrella Series A Preferred Stock comprising the Commitment Fee immediately prior to Closing, subject to the Closing occurring on or before July 19, 2023 or such later date as may be mutually agreed upon in writing by Estrella and White Lion. Additionally, pursuant to the Joinder, White Lion agreed to purchase 500,000 shares of Estrella Series A Preferred Stock for $500,000 in cash immediately prior to the Closing, subject to the Closing occurring on or before July 19, 2023 or such later date as may be mutually agreed upon by Estrella and White Lion. Upon closing of the transactions contemplated by the Joinder, the 750,000 shares of Series A Preferred Stock of Estrella issued to White Lion automatically converted into 750,000 shares of common stock of Estrella immediately prior to the Effective Time and then into Common Stock based on the exchange ratio determined by the total number of shares of common stock of Estrella outstanding at the Effective Time in accordance with the Merger Agreement.

Estrella Series A Preferred Stock Purchase Agreements

On June 28, 2022, Estrella entered into a Series A Preferred Stock Purchase Agreement with an accredited third-party investor to raise gross proceeds of $5,000,000 by issuing 5,000,000 shares of its Series A Preferred Stock. The shares of Series A Preferred Stock were sold for $1.00 per share. On the Closing Date, immediately prior to the Effective Time, such shares of Estrella Series A Preferred Stock were converted into shares of Common Stock and then into Merger Consideration Shares at an exchange ratio of approximately 0.2407 in accordance with the Merger Agreement.

On each of July 31, 2023 and September 18, 2023, an aggregate of six third party investors executed joinders to Estrella's Series A Preferred Stock Purchase Agreement. Pursuant to the joinders, such investors agreed to purchase an aggregate of 9,250,000 shares of Estrella's Series A Preferred Stock for $9,250,000 ($730,000 of which was comprised of funds in the trust account delivered to Estrella at the closing of the Business Combination that would have otherwise been paid to US Tiger Securities, Inc. as a deferred underwriting fee in connection with UPTD's IPO) immediately prior to the effective time of Estrella's Merger with UPTD. Subsequently and immediately prior to the effective time of the Merger with UPTD, such shares of Estrella's Series A Preferred Stock converted into Estrella common stock and then into Merger Consideration Shares at an exchange ratio of approximately 0.2407 in accordance with the Merger Agreement.

In addition, immediately prior to the Effective Time, 500,000 shares of Estrella's Series A Preferred Stock were issued to White Lion for $500,000

and 250,000 shares of Estrella's Series A Preferred Stock were issued to White Lion in consideration for its commitments under the Common Stock Purchase Agreement pursuant to the Joinder to the Series A Preferred Stock Purchase Agreement between Estrella and White Lion, dated April 20, 2023, as further described in in the preceding section. Subsequently, immediately prior to the Effective Time, such shares of Estrella Series A Preferred Stock were converted into shares of Common Stock and then into Merger Consideration Shares at an exchange ratio of approximately 0.2407 in accordance with the Merger Agreement.

The securities described above were offered and sold pursuant to the exemption from the registration provided by Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder.

The following table provides information with respect to repurchases of Common Stock during each month of the quarter ended June 30, 2024.

Issuer Purchases of Common Stock [(i)]

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs
April 1, 2024 – April 30, 2024	136,569	$ 1.16	211,459	$ 757,382.60
May 1, 2024 – May 31, 2024	60,429	$ 1.05	271,888	$ 693,792.06
June 1, 2024 – June 30, 2024	49,906	$ 0.97	321,794	$ 645,560.09
Total	246,904			

(i) All shares of Common Stock repurchased during the quarter ended June 30, 2024 were made in open-market transactions pursuant to the authorization of the Company's board of directors to repurchase up to $1,000,000 of the Company's common stock as publicly announced in the Company's press release issued on January 30, 2024 and included as Exhibit 99.1 to the Company's Current Report on Form 8-K filed on the same date. The authorization does not have an expiration date. While the Company anticipates as of the date hereof that it will continue to repurchase shares of Common Stock pursuant to the authorization, the Company is not obligated to repurchase any particular amount of Common Stock pursuant to the authorization and the timing, method and amount of any repurchases made pursuant to the authorization in the future may depend on market conditions and other factors.

Item 6. [Reserved]

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

Unless the context otherwise requires, for purposes of this section, the terms "Company," "we," "us," "our," refer to Immunopharma, Inc. collectively with its subsidiary Estrella Biopharma, Inc., while the term "Estrella" refers to Estrella Biopharma, Inc. prior to closing of the business combination (the "Business Combination") with TradeUP Acquisition Corp. ("UPTD") on September 29, 2023. The following discussion and analysis of our results of operations and financial condition should be read together with our audited financial statements and the notes thereto, which are included elsewhere in this Report and our audited financial statements as exhibit 99.1 on Form 8-K filed with the SEC on October 5, 2023 and the section entitled "Management's Discussion and Analysis of Financial Conditions and Results of Operations" included in the Company's Registration Statement on Form S-1, filed with the SEC on October 11, 2023 and amended on November 13, 2023 and December 18, 2023. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Overview

The Company is a clinical-stage biopharmaceutical company developing T-cell therapies with the capacity to address treatment challenges for patients with blood cancers and solid tumors. We believe T-cell therapy continues to represent a revolutionary step towards providing a potential solution for many forms of cancer, including cancers poorly addressed by current approaches.

On June 28, 2022, pursuant to the Contribution Agreement, Eureka contributed certain assets related to T-cell therapies targeting CD19 and/or CD22 to Estrella in exchange for 105,000,000 shares of Series AA Preferred Stock of Estrella (the "Separation"). Eureka determined that the Separation would allow for the flexibility to create a capital structure tailored to Estrella's strategic goals, provide increased access to capital markets, allow for greater focus on the product candidates contributed to Estrella, and result in a dedicated management team.

As part of the Separation, Estrella entered into a License Agreement with Eureka and Eureka Therapeutics (Cayman) Ltd., an affiliate of Eureka, and a Services Agreement with Eureka, and Eureka contributed and assigned the Collaboration Agreement between Eureka and Imugene to Estrella. The License Agreement grants Estrella an exclusive license to develop CD19 and CD22-targeted T-cell therapies using Eureka's ARTEMIS® platform. Under the Services Agreement, Eureka has agreed to perform certain services for us in connection with the development of our product candidates, EB103 and EB104, and researching the use of EB103 in conjunction with CF33-CD19t. The Collaboration Agreement establishes our collaboration with Imugene related to the development of solid tumor treatments using CF33-CD19t in conjunction with EB103.

On March 2, 2023, the FDA cleared the IND application for EB103, allowing Estrella to proceed with the Phase I/II STARLIGHT-1 Clinical Trial.

On March 4, 2024, Estrella and Eureka entered into Statement of Work No. 001 ("SOW") relating to the clinical trial services to be performed by Eureka in connection with STARLIGHT-1, the Phase I/II clinical trial of Estrella's product candidate, EB103, a T-cell therapy targeting CD19 using ARTEMIS® T cell technology licensed by Estrella from Eureka. Pursuant to the SOW, Estrella agrees to pay Eureka non-refundable net fees in connection with the achievement of certain milestones set forth in the SOW, with total fees of $33,000,000 for achievement of all milestones. As of June 30, 2024, Estrella has paid $3,500,000 to Eureka for covering the fees associated with milestones that have been achieved.

To date, Estrella has funded its operations primarily from the June 28, 2022 issuance of $5.0 million of our Series A Preferred Stock, and net proceeds of approximately $20.1 million raised from completion of the Business Combination on September 29, 2023. We have a limited operating history. Since our inception, our operations have focused on preparing for the Business Combination, regulatory filings (including the INDs), planning preclinical and clinical studies, and building our management team. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

As of June 30, 2024, we had an accumulated deficit of approximately $19.5 million. We have remitted payment of approximately $11.2 million to Eureka, consisting of the upfront payment incurred under the License Agreement and monthly service provided by Eureka under the Services Agreement on October 10, 2023. In addition, in March 2024, we have paid $3,500,000 to Eureka for covering the fees associated with the milestones achieved.

We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue to advance preclinical and clinical development of our product candidates and preclinical programs;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- scale up our clinical and regulatory capabilities;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand, and protect our intellectual property portfolio;
- add 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 in operating as a public company.

Recent Developments

The Business Combination and Public Company Costs

On September 29, 2023, we consummated the previously announced Business Combination with UPTD pursuant to the terms of the Merger Agreement by and among UPTD, Merger Sub and Estrella. No closing conditions set forth in the Merger Agreement were waived by either UPTD or Estrella. Moreover, concurrently with closing of the Merger, Estrella consummated the following transactions: (i) sales of 9.25 million shares of Estrella Series A Preferred Stock for $9.25 million ($730,000 of which was comprised of funds in the trust account delivered to the Company at the closing of the Business Combination that would have otherwise been paid to US Tiger Securities, Inc as a deferred underwriting fee in connection with UPTD's initial public offering), which shares were converted to shares of Estrella Common Stock and subsequently exchanged for Merger Consideration Shares of UPTD immediately prior to the effective time of the merger at an exchange ratio of 0.2407, with such shares becoming shares of New Estrella Common Stock from and after the effective time of the Merger; (ii) issuance of 500,000 shares of Estrella's Series A Preferred Stock to White Lion for $500,000 and 250,000 shares of Estrella Series A Preferred Stock to White Lion in consideration for its commitments under the Common Stock Purchase Agreement, dated April 20, 2023, between UPTD and White Lion and in accordance with the Joinder to the Series A Preferred Stock Purchase Agreement between Estrella and White Lion, dated April 20, 2023, which shares were subsequently converted to shares of Estrella Common Stock and exchanged for Merger Consideration Shares of UPTD at an exchange ratio of 0.2407, with such Merger Consideration Shares becoming shares of New Estrella Common Stock from and after the effective time of the Merger and (iii) issued an unsecured promissory note to a third party for $300,000 at 12% interest per annum, which will be payable 30 days after the closing date of the Merger of September 29, 2023 and subsequently settled on October 26, 2023.

While the legal acquirer in the Business Combination was UPTD, for financial accounting and reporting purposes under U.S. GAAP, Estrella was the accounting acquirer, and the Business Combination was accounted for as a "reverse recapitalization." A reverse recapitalization (i.e., a capital transaction involving the issuance of stock by UPTD for the stock of Estrella) does not result in a new basis of accounting, and the consolidated financial statements of the combined company represent the continuation of the consolidated financial statements of Estrella in many respects. Accordingly, the consolidated assets, liabilities and results of operations of Estrella became the historical consolidated financial statements of the combined company, and UPTD's assets, liabilities, and results of operations were consolidated with Estrella beginning on the Closing Date. Operations prior to the Business Combination are presented as those of Estrella. The net assets of UPTD are recognized at historical cost (which is expected to be consistent with carrying value), with no goodwill or other intangible assets recorded upon execution of the Business Combination.

As a consequence of the Merger, Estrella became the successor to an SEC-registered and Nasdaq-listed company which will require Estrella to hire additional personnel and implement procedures and processes to address public company regulatory requirements and customary practices. Estrella expects to incur additional annual expenses as a public company for, among other things, directors' and officers' liability insurance, director fees and additional internal and external accounting and legal and administrative resources, including increased audit and legal fees.

Estrella's future results of consolidated operations and financial position may not be comparable to historical results as a result of the Business Combination.

On June 26 2024, the Company filed a Certificate of Ownership and Merger with the Delaware Secretary of State to effect a merger (the "Merger 1") with its wholly-owned subsidiary, Estrella, pursuant to Section 253 of the Delaware General Corporation Law. The Merger 1 was approved by resolutions duly adopted by the unanimous written consent of the Company's board of directors. The Merger 1 became effective at 11:59 PM Eastern Time on June 30, 2024, at which time the separate existence of Estrella ceased, and the Company became the surviving corporation.

Results of Operations

Estrella was formed on March 30, 2022, and has not commenced revenue-producing operations. To date, our operations have consisted of the development and early-stage testing of our initial product candidates, EB103 and EB104, preparation and submission of the IND Application for and researching the use of EB103 in conjunction with CF33-CD19t.

The results of operations for the year ended June 30, 2024 represented our results of operations to be comparable with the same period in 2023.

There are two major expenses incurred for the operation:

Research and Development Expenses

Research and development expenses consist primarily of costs related to conducting work related to IND-enabling, IND-filing and clinical trial preparation, which were mainly performed by Eureka. For the years ended June 30, 2024 and 2023, we incurred approximately $4.1 million and $10.5 million of research and development expenses, respectively. All research and development expense incurred for the periods presented above were dedicated to the development of ARTEMIS® T-cell therapies targeting CD19 and CD22. The decrease in research and development expenses was mainly due to Estrella incurring lower service fees with Eureka due to a lower volume of service rendered under the Services Agreement for the year ended June 30, 2024 compared to the same period in 2023. In addition, for the year ended June 30, 2024, we have incurred $3.5 million R&D expense from Eureka for achieving the milestones related to SOW.

Our breakdown of research and development expenses by categories for the years ended June 30, 2024 and 2023 are summarized below:

	For year Ended June 30, 2024	For year Ended June 30, 2023
Consulting and laboratory related fee	$ 3,654,957	$ 10,295,566
Stock based compensation	453,968	155,646
Total research and development	$ 4,108,925	$ 10,451,212

General and administrative expense

For the years ended June 30, 2024 and 2023, we incurred approximately $3.2 million and $0.7 million of general and administrative expenses, respectively. The increase in general and administrative expenses for the year ended June 30, 2024, was mainly due to an increase in professional fee, and recognition of the acceleration of the stock-based compensation upon consummation of the Business Combination. The increase was also attributable to approximately $0.5 million of bonus granted to our executive officers in recognition of their service.

Net Loss

We incurred a net loss of approximately $7.3 million and $11.1 million for the years ended June 30, 2024 and 2023, respectively. We expect our research and development expenses to continue to increase as we continue to work with Eureka to advance the IND filings, preclinical and clinical development of our product candidates and preclinical programs, seek regulatory approval for any product candidates that successfully complete clinical trials, scale up our clinical and regulatory capabilities, adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products, maintain, expand, and protect our intellectual property portfolio, add 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 in operating as a public company.

Liquidity and Capital Resources

As of June 30, 2024, we had cash of approximately $4.2 million. Our ability to fund our operations is dependent on the amount of cash on hand, our ability to raise debt or additional equity financing, and ultimately our ability to generate sufficient revenue. We have expended substantial funds on research and development, have experienced losses and negative cash flows from operations since our inception, and expect losses and negative cash flows from operations to continue until such time that our product candidates receive regulatory approval and we generate sufficient revenue and positive cash flow from operations, if ever.

To date, we have not generated any revenue from any source, and we do not expect to generate revenue for at least the next few years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be adversely affected. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates.

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue research and development, and seek marketing approval for, our product candidates. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing, and distribution. Furthermore, following the completion of the Business Combination, we expect to incur additional costs associated with operating as a public company.

On September 29, 2023, the Business Combination and several concurrent financing transactions were consummated, with Estrella receiving net proceeds of approximately $20.1 million, after deducting $5.07 million payable to redeem 467,122 shares of UPTD Common Stock at $10.86 per share in connection with the special meeting of UPTD stockholders related to the Business Combination held on July 31, 2023, $1.6 million for transaction expenses and $0.7 million for repayment of working capital loans, consisting of: (i) $9.75 million from the issuance of shares of Estrella Series A Preferred Stock immediately prior to the closing of the Business Combination ($0.7 million of which was comprised of funds in the trust account delivered to Estrella at the closing of the Business Combination that would have otherwise been paid to US Tiger Securities, Inc. as a deferred underwriting fee in connection with UPTD's IPO); (ii) $0.3 million from the issuance of an unsecured promissory note by us to a third party investor; (iii) $0.7 million from the funds held in UPTD's trust account; and (iv) $10 million from the PIPE investors pursuant to the Subscription Agreements.

On October 10, 2023, we remitted approximately $9.3 million to Eureka upon consummation of the Business Combination. We expect to devote the remaining net proceeds from the Business Combination to the preclinical and clinical development of our product candidates and our public company compliance costs. Based on our current operating plan, we expect that the net proceeds from the Business Combination and our ability to raise funds in the future through the issuance and sale of Equity Line Shares to White Lion will allow us to fund our operating expenses and capital requirements through one year from the issuance of these consolidated financial statements. However, this estimate is subject to various uncertainties and risks, some of which are beyond our control. We may use our available capital resources sooner than we currently anticipate, and we may need to seek additional funds sooner than planned. Our estimate as to how long we expect such proceeds to be able to fund our operating expenses and capital requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could result in fewer cash and cash equivalents available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

On March 4, 2024, the Company and Eureka entered into Statement of Work No. 001 ("SOW") relating to the clinical trial services to be performed by Eureka in connection with STARLIGHT-1, the Phase I/II clinical trial of Estrella's product candidate, EB103, a T-cell therapy targeting CD19 using ARTEMIS® T cell technology licensed by Estrella from Eureka. Pursuant to the SOW, Estrella agreed to pay Eureka non-refundable net fees in connection with the achievement of certain milestones set forth in the SOW, with total fees of $33,000,000 for achievement of all milestones. As of June 30, 2024, the Company had expensed $3,500,000 to Eureka for covering the fees associated with the milestones achieved.

On May 13, 2024, the Company and Eureka entered into Amendment No. 1 to the SOW, effective as of March 4, 2024, to clarify that in the event that Estrella exercises its right to terminate or suspend the engagement with Eureka by providing written notice to Eureka in accordance with the SOW, Estrella will only be obligated to compensate Eureka for (i) services provided by Eureka pursuant to the SOW ("Services") in connection with milestones that were achieved prior to the date and time of such written notice, (ii) reasonable and documented pass-through costs incurred by Eureka on behalf of Estrella prior to the date and time of such written notice in connection with providing the Services and (iii) amounts payable to third parties pursuant to commitments reasonably entered into by Eureka on behalf of Estrella prior to the date and time of such written notice in connection with providing the Services, provided that Eureka shall make commercially reasonable efforts to cancel or reduce any such amounts.

Our future operations are highly dependent on a combination of factors, including but not necessarily limited to (1) the success of our research and development programs; (2) the timely and successful completion of any additional financing; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies; (4) our ability to manage growth of the organization; (5) our ability to protect our technology and products; and, ultimately (6) regulatory approval and successful commercialization and market acceptance of our product candidates.

In addition, there is no assurance that the Warrant holders will exercise their Warrants because they are currently out of the money. As of June 30, 2024, the closing price of our Common Stock was $1.05 per share, which is significantly lower than the exercise price of the Warrants of $11.50 per share. Therefore, it is unlikely that the warrant holders will exercise their warrants unless the market price of our Common Stock increases substantially above the exercise price. The cash proceeds associated with the exercise of the Warrants are dependent on the stock price and the number of Warrants being exercised. We cannot predict when or if any Warrants will be exercised, and it is possible that none or only a small number of Warrants will ever be exercised. Therefore, we may not be able to rely on the warrant exercise as a source of liquidity or capital resources.

Furthermore, although the Common Stock Purchase Agreement with White Lion provides that the Company may, in its discretion, from time to time, direct White Lion to purchase shares of up to $50,000,000 of Common Stock ("Equity Line Shares") from the Company in one or more purchases in accordance with the Common Stock Purchase Agreement, the Company is not permitted to issue any Equity Line Shares under the Common Stock Purchase Agreement without obtaining majority stockholder approval if such issuance would equal 20% or more of the Company's outstanding common stock, which had not been obtained as of the date hereof and may not be obtained in the future. On December 28, 2023, the Company's registration statement on Form S-1 related to the Equity Line Shares was declared effective. As of the date hereof, no Equity Line Shares have been issued to White Lion under the Common Stock Purchase Agreement.

We plan to raise additional capital in the future in order to continue our research and development programs and fund operations. However, our ability to raise additional capital in the equity or debt markets is dependent on various factors, and there is no assurance that such financing will be available on acceptable terms, or at all. The market demand of our equity is subject to a number of risks and uncertainties, including but not limited to, negative economic conditions, adverse market conditions, and adverse financial results.

Cash Flows

Operating activities

Net cash used in operating activities was approximately $16.1 million for the year ended June 30, 2024, and was primarily attributable to (a) a net loss of approximately $7.3 million, approximately $9.3 million decrease in accounts payable, related party, as we remitted approximately $9.4 million payment to Eureka, consisting of the upfront payment incurred under the License Agreement and monthly service provided by Eureka under the Services Agreement on October 10, 2023, (b) approximately $0.1 million increase in prepaid expense as we prepaid various service providers and insurance which we expect to be amortized within the next 12 months, and (c) approximately $0.4 million decrease in other payables and accrued liabilities as we paid off accrued professional fee over the previous period, offset by approximately $1.2 million increase in non-cash items such as stock-based compensation as we incurred amortization for the year ended June 30, 2024 related to the stock options granted to our employees, board of directors, and other consultants under the Incentive Plan.

Net cash used in operating activities was approximately $1.3 million for the year ended June 30, 2023, and was primarily attributable to a net loss of approximately $11.1 million, offset by (a) approximately $8.4 million increase in account payable related party which related to service fee incurred from the Services Agreement, (b) approximately $0.4 million increase in non-cash item such as stock-based compensation as we incurred amortization for year ended June 30, 2023 related to the stock options granted to our employees, board of directors, and other consultants under the Incentive Plan, (c) approximately $0.8 million decrease in prepaid expenses – related party as we utilized prior prepaid service fees from the Services Agreement in the current period, and (d) an approximately $0.1 million increase in other payables and accrued liabilities as we accrued various legal, consulting, and research and development expenses related to the Business Combination.

Investing activities

Net cash provided by investing activities was approximately $5.0 million for the year ended June 30, 2024, and was primarily attributable to approximately $5.1 million cash released from trust account as a result of the consummation of the Business Combination, offset by approximately $0.1 million loan to UPTD as Monthly Extension Payment before merger.

Net cash used in investing activities was approximately $0.3 million for the year ended June 30, 2023, and was primarily attributable to loan to UPTD as Monthly Extension Payment.

Financing activities

Net cash provided by financing activities was approximately $12.8 million for the year ended June 30, 2024, and was primarily attributable to approximately $20.0 million net proceed received from the consummation of the Business Combination, which included approximately $9.0 million in gross proceeds raised through sales of Estrella Series A Preferred Stock immediately prior to the effective time of the Merger, approximately $0.3 million raised through issuance of an unsecured promissory note by Estrella to a third party investor, approximately $0.7 million proceeds raise from the reverse recapitalization, and $10.0 million net proceeds from the PIPE Investment that closed concurrently with the consummation of the Business Combination, offset by approximately $1.5 million payments of transaction cost related to the Merger, approximately $5.1 million payment to UPTD's stockholder for stock redemption before the Business Combination, approximately $0.3 million repayment of promissory note, and approximately $0.3 million payment in

stock repurchase.

Off-Balance Sheet Arrangements

As of June 30, 2024 and 2023, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

Commitments & Contingencies

In the normal course of business, we are subject to loss contingencies, such as legal proceedings and claims arising out of our business, that cover a wide range of matters, including, among others, government investigations and tax matters. In accordance with ASC No. 450-20, "Loss Contingencies", we will record accruals for such loss contingencies when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated.

License Agreement

Pursuant to the License Agreement, we were obligated to make (i) a one-time, non-refundable, non-creditable payment of $1,000,000, payable in twelve equal monthly installments, (ii) certain one-time, non–refundable, non-creditable development "milestone" payments upon the occurrence of certain events related to development and sales, with potential aggregate multi-million dollar payments upon FDA approval, and (iii) royalty payments of a single digit percentage on net sales during any consecutive 12-month period.

As of June 30, 2024, we have fully paid the license fee to Eureka.

On January 30, 2023, one development milestone payment in the amount of $50,000 related to the submission of EB103 to the FDA was earned by Eureka under the Agreement, which was paid on October 10, 2023. No other development milestone, sales milestone, or royalty payment has been earned as we do not have any product candidates approved for sale and have not generated any revenue from product sales.

Collaboration Agreement

Pursuant to the Collaboration Agreement, we and Imugene will be separately responsible for all qualified full-time person ("FTE") and other internal costs incurred in the performance of its research, as well as the full cost of procurement of leukopaks and purification of T-cells from two donors, and of manufacturing and quality control of EB103 T-cells under the research plan. Any joint cost will be shared equally. If either we or Imugene incurs out-of-pocket costs in excess of the amount budgeted for such costs in the applicable research budget plus allowable overruns, then the other party will not be responsible for its 50% share of the excess of such budgeted amount plus allowable overruns, unless the joint steering committee approves such excess costs (either before or after such costs have been incurred). The research plan under the Collaboration Agreement was completed as of August 30, 2023.

Services Agreement

Pursuant to the Services Agreement, we agreed to (i) pay Eureka $10,000,000 in connection with the services thereunder payable in 12 equal monthly installments and (ii) reimburse Eureka on a monthly basis for reasonable pass-through costs incurred or paid to providers by Eureka in providing the services. In addition, we will be charged for other services performed by Eureka outside the scope of the services set forth in the Services Agreement, at a flat rate, by time or materials or as mutually agreed upon the parties in writing. As of June 30, 2024, we had remitted to Eureka a total of $10,000,000 and $117,920 of pass-through costs for services provided pursuant to the Services Agreement.

Statement of Work

Pursuant to the SOW, Estrella agreed to pay Eureka total fees of $33,000,000 in connection with the Phase I/II clinical trial of Estrella's product candidate, EB103, a T-cell therapy targeting CD19 using ARTEMIS® T cell technology licensed by Estrella from Eureka. As of June 30, 2024, we have paid $3,500,000 to Eureka for covering the fees associated with the milestones achieved.

Equity Financing Commitment

On April 20, 2023, UPTD entered into a Common Stock purchase agreement (as amended on April 26, 2023 and from time to time, the "Common Stock Purchase Agreement") and a related registration rights agreement (the "White Lion RRA") with White Lion. Pursuant to the Common Stock Purchase Agreement, following the Closing, the Company has the right, but not the obligation to require White Lion to purchase, from time to time up to $50,000,000 in aggregate gross purchase price of newly issued shares of Common Stock of the Company, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement, including, among others, the initial and any subsequent registration statement for the Equity Line Shares being declared effective by the SEC and remaining effective during the term of the Common Stock Purchase Agreement. In addition, under Nasdaq listing rules, the Company is not permitted to issue any Equity Line Shares under the Common Stock Purchase Agreement if such issuance would equal 20% or more of the Company's outstanding common stock without obtaining majority approval by our stockholders, which had not been obtained as of the date hereof. On December 28, 2023, the Company's registration statement on Form S-1 related to the Equity Line Shares was declared effective by the SEC. As of the date hereof, no Equity Line Shares have been issued to White Lion pursuant to the Common Stock Purchase Agreement.

Registration Rights

The holders of 312,200 shares of common stock that were issued to the initial stockholders of UPTD (the "Founder Shares") and of 1,107,500 shares of Common Stock issued to certain investors in a private placement in connection with UPTD's initial public offering (the "Private Shares") are entitled to registration rights pursuant to a registration rights agreement, dated July 14, 2021, among UPTD, TradeUP Acquisition Sponsor LLC and certain security holders named therein. The Company assumed the obligations of UPTD under such agreement upon consummation of the Business Combination. The holders of the majority of these securities are entitled to make up to three demands, excluding short form demands, that the Company registers such securities. In addition, the holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to the completion of the initial Business Combination and rights to require the Company to register for resale such securities pursuant to Rule 415 under the Securities Act. We are also obligated to file a registration statement for the (i) Equity Line Shares that we may issue to White Lion pursuant to the

Common Stock Purchase Agreement and White Lion RRA, (ii) up to 2,225,000 shares of Common Stock issuable upon exercise of the Warrants and (iii) the shares issued or that will be issued pursuant to the Subscription Agreements. The Company will bear the expenses incurred in connection with the filing of any such registration statements. The Company filed a registration statement on Form S-1 with the SEC on October 10, 2023 and subsequently filed Amendment No. 1 and Amendment No. 2 thereto on November 13, 2023 and December 18, 2023, respectively, with respect to the Founder Shares, Private Shares, Equity Line Shares, the shares of Common Stock issuable upon exercise of the Warrants and certain shares issuable under the Subscription Agreements. The registration statement was declared effective by the SEC on December 28, 2023.

Critical Accounting Policies

Our financial statements accompanying notes have been prepared in accordance with U.S. GAAP. The preparation of these financial statements and accompanying notes requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We have identified certain accounting estimates that are significant to the preparation of our financial statements. These estimates are important for an understanding of our financial condition and results of operation. Certain accounting estimates are particularly sensitive because of their significance to financial statements and because of the possibility that future events affecting the estimate may differ significantly from management's current judgments. We believe no critical accounting estimate was identified other than below listed significant estimate and accounting policies.

Stock-Based Compensation

We recognize compensation costs resulting from the issuance of stock-based awards to employees, non-employees, and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option granted is estimated as of the date of grant using the Black-Scholes-Merton option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. The Black-Scholes-Merton option-pricing model includes various assumptions, including the fair market value of Estrella Common Stock, expected life of stock options, the expected volatility, and the expected risk-free interest rate, among others. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside of our control.

As a result, if other assumptions had been used, stock-based compensation expense, as determined in accordance with authoritative guidance, could have been materially impacted. Furthermore, if we use different assumptions on future grants, stock-based compensation expense could be materially affected in future periods.

We account for the fair value of equity instruments issued to non-employees using either the fair value of the services received or the fair value of the equity instrument, whichever is considered more reliable. We utilize the Black-Scholes-Merton option-pricing model to measure the fair value of options issued to non-employees.

We record compensation expense for the awards with graded vesting using the straight-line method. We recognize compensation expense over the requisite service period applicable to each individual award, which generally equals the vesting term. Forfeitures are recognized when realized.

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

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report.

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

Estrella, at the direction of the Board, and upon the recommendation of the audit committee of the Board, dismissed its independent registered public accountant Marcum LLP ("Marcum"), effective as of January 30, 2024. Marcum was initially engaged on November 3, 2022 by Estrella to serve as Estrella's auditor for its fiscal year ended June 30, 2023.

Marcum's report on Estrella's financial statements for the fiscal year ended June 30, 2023 did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope, or accounting principles, except that Marcum's report contained an explanatory paragraph expressing substantial doubt about the ability of Estrella to continue as a going concern.

During the fiscal year ended June 30, 2023 and subsequent interim periods through the date of Marcum's dismissal, there were (i) no disagreements with Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, any of which, if not resolved to Marcum's satisfaction, would have caused it to make reference to the subject matter of any such disagreement in connection with its reports for such years and (ii) no "reportable events" requiring disclosure pursuant to paragraph (a)(1)(v) of Item 304 of Regulation S-K and the related instructions to Item 304 of Regulation S-K.

At the direction of the Board, and upon the recommendation of the audit committee, Estrella appointed Macias Gini & O'Connell, LLP ("MGO") as Estrella's new independent registered public accounting firm for the fiscal year ending June 30, 2024, effective as of January 30, 2024. During the Company's two most recent fiscal years ended June 30, 2022, and June 30, 2023, and the subsequent interim period through the date of MGO's engagement, neither the Company nor anyone on its behalf has consulted with MGO regarding (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, where either a written report or oral advice was provided to the Company that MGO concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue, (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K or (iii) any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Evaluation of Disclosure Controls and Procedures

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 June 30, 2024. Based upon their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15 (e) and 15d-15 (e) under the Exchange Act) were not effective.

Management's Annual Report on Internal Control over Financial Reporting

As required by SEC rules and regulations implementing Section 404 of the Sarbanes Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting.

Our disclosure controls and procedures are designed to ensure that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of such date, our disclosure controls and procedures were, in design and operation, not effective as of June 30, 2024 at a reasonable assurance level.

We believe, however, that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls systems are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, within a company have been detected.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

The Company has implemented certain changes in its internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to remediate the material weaknesses identified in fiscal year 2023. The implementation of the material aspects of this plan took place during the second and third quarters of fiscal year 2024. Additional qualified personnel with appropriate levels of accounting knowledge and experience to address U.S. GAAP accounting issues have been added to prepare and review financial statements and related disclosures under U.S. GAAP. Non-routine transactions are analyzed by in-house staff and third-party consultants to ensure proper accounting treatment. Narratives and policies for business processes that relate to financial statements have been put in place to establish proper segregation of duties and internal controls. While the Company has remediated certain previously identified material weaknesses, our chief executive officer and chief financial officer concluded that as of June 30, 2024, our disclosure controls and procedures were not effective at the reasonable assurance level.

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated herein by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders, which is expected to be filed with the SEC within 120 days after the close of our fiscal year.

Item 11. Executive Compensation.

The information required by this Item is incorporated herein by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders, which is expected to be filed with the SEC within 120 days after the close of our fiscal year.

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

The information required by this Item is incorporated herein by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders, which is expected to be filed with the SEC within 120 days after the close of our fiscal year.

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

The information required by this Item is incorporated herein by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders, which is expected to be filed with the SEC within 120 days after the close of our fiscal year.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated herein by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders, which is expected to be filed with the SEC within 120 days after the close of our fiscal year.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

The following documents are included on pages F-1 through F-31 attached hereto and are filed as part of this Annual Report on Form 10-K.

Index to Financial Statement

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits.

The following is a list of exhibits filed, furnished, or incorporated by reference as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
2.1*	Agreement and Plan of Merger, dated as of September 30, 2022, by and among TradeUP Acquisition Corp., Tradeup Merger Sub Inc. and Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on October 3, 2022, File No. 001-40608)
3.1	Amended and Restated Certificate of Incorporation of Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on October 5, 2023, File No. 001-40608)
3.2	Amended and Restated Bylaws of Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on October 5, 2023, File No. 001-40608)
4.1	Specimen Unit Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 9 to the Registration Statement on Form S-1/A filed with the SEC on July 9, 2021, File No. 333-253322)
4.2	Specimen Common Stock Certificate. (incorporated by reference to Exhibit 4.2 to Amendment No. 9 to the Registration Statement on Form S-1/A filed with the SEC on July 9, 2021, File No. 333-253322)
4.3	Specimen Warrant Certificate (included as Exhibit A to Exhibit 4.4 below)
4.4	Warrant Agreement, dated July 14, 2021, between TradeUP Acquisition Corp. and VStock Transfer, LLC, as warrant agent (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on July 19, 2021, File No. 001-40608)
4.5	Description of Registrant's Securities
10.1	Promissory Note, dated July 25, 2022, issued by TradeUP Acquisition Corp. to Running Lion Holdings Limited (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on July 27, 2022, File No. 001-40608)
10.2	Promissory Note, dated July 25, 2022, issued by TradeUP Acquisition Corp. to Tradeup INC. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on July 27, 2022, File No. 001-40608)
10.3	Contribution Agreement, dated June 28, 2022, by and between Eureka Therapeutics, Inc. and Estrella Immunopharma, Inc. incorporated by reference to Exhibit 10.3 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.4†	License Agreement, dated June 28, 2022, by and among Eureka Therapeutics, Inc., Eureka Therapeutics (Cayman) Ltd. and Estrella Immunopharma, Inc. incorporated by reference to Exhibit 10.4 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)

10.5†	Services Agreement, dated June 28, 2022, by and between Eureka Therapeutics, Inc. and Estrella Immunopharma, Inc. incorporated by reference to Exhibit 10.5 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.6†	Collaboration Agreement, dated October 29, 2021, by and between Estrella Immunopharma, Inc. (as successor to Eureka Therapeutics, Inc.) and Imugene Limited incorporated by reference to Exhibit 10.6 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.7	Amendment to Executive Offer Letter, by and between Estrella Immunopharma, Inc. and Dr. Cheng Liu incorporated by reference to Exhibit 10.16 to the Current Report on Form 8-K filed with the SEC on October 5, 2023
10.8	Amendment to Employment Agreement, by and between Estrella Immunopharma, Inc. and Jiandong (Peter) Xu incorporated by reference to Exhibit 10.17 to the Current Report on Form 8-K filed with the SEC on October 5, 2023
10.9	Amendment to Employment Agreement, by and between Estrella Immunopharma, Inc. and Qian (Vicky) Yang incorporated by reference to Exhibit 10.18 to the Current Report on Form 8-K filed with the SEC on October 5, 2023
10.10*	Support Agreement, dated September 30, 2022, by and among TradeUP Acquisition Corp., Estrella Immunopharma, Inc., TradeUP Acquisition Sponsor LLC, Tradeup INC. and the officers and directors of TradeUP Acquisition Corp. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on October 3, 2022, File No. 001-40608)

Exhibit Number	Description of Exhibit
10.11	Estrella Immunopharma, Inc. 2023 Omnibus Incentive Plan incorporated by reference to Annex C to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.12	Estrella Immunopharma, Inc. Option Grant Notice, including 2022 Equity Incentive Plan incorporated by reference to Exhibit 10.12 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.13	Business Combination Marketing Agreement, dated July 14, 2021, among TradeUP Acquisition Corp., US Tiger Securities, Inc. EF Hutton, division of Benchmark Investments, LLC, and R. F. Lafferty & Co., Inc. (incorporated by reference to Exhibit 1.2 to the Current Report on Form 8-K filed with the SEC on July 19, 2021, File No. 001-40608)
10.14	Registration Rights Agreement, dated July 14, 2021, among TradeUP Acquisition Corp., TradeUP Acquisition Sponsor LLC and certain security holders named therein (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on July 19, 2021, File No. 001-40608)
10.15	Amendment No. 1 to Services Agreement, effective October 1, 2022, by and between Eureka Therapeutics, Inc. and Estrella Immunopharma, Inc. incorporated by reference to Exhibit 10.15 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.16	Amendment No. 1 to License Agreement, effective October 1, 2022, by and between Eureka Therapeutics, Inc. and Estrella Immunopharma, Inc. incorporated by reference to Exhibit 10.16 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.17	Promissory Note, dated January 19, 2023, issued by TradeUP Acquisition Corp. to TradeUP Acquisition Sponsor LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on January 24, 2023, File No. 001-40608)
10.18	Extension Promissory Note, dated January 19, 2023, issued by TradeUP Acquisition Corp. to Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 24, 2023, File No. 001-40608)
10.19	Extension Promissory Note, dated February 19, 2023, issued by TradeUP Acquisition Corp. to Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on February 21, 2023, File No. 001-40608)
10.20	Extension Promissory Note, dated March 17, 2023, issued by TradeUP Acquisition Corp. to Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on March 17, 2023, File No. 001-40608)
10.21	Extension Promissory Note, dated April 12, 2023, issued by TradeUP Acquisition Corp. to Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 13, 2023, File No. 001-40608)
10.22	Common Stock Purchase Agreement, dated as of April 20, 2023, by and between TradeUP Acquisition Corp. and White Lion Capital LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 24, 2023, File No. 001-40608)
10.23	Registration Rights Agreement, dated as of April 20, 2023, by and between TradeUP Acquisition Corp. and White Lion Capital LLC. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on April 24, 2023, File No. 001-40608)
10.24	Amendment to the Common Stock Purchase Agreement, dated as of April 26, 2023, by and between TradeUP Acquisition Corp. and White Lion Capital LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 26, 2023, File No. 001-40608)
10.25	Extension Promissory Note, dated May 19, 2023, issued by TradeUP Acquisition Corp. to Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on May 19, 2023, File No. 001-40608)

Exhibit Number	Description of Exhibit
10.26	Promissory Note, dated June 6, 2023, issued by TradeUP Acquisition Corp. to Tradeup INC. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 6, 2023, File No. 001-40608)
10.27	Amendment No. 2 to Services Agreement, effective March 1, 2023, by and between Eureka Therapeutics, Inc. and Estrella Immunopharma, Inc. incorporated by reference to Exhibit 10.27 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.28	Amendment No. 2 to License Agreement, effective March 1, 2023, by and between Eureka Therapeutics, Inc. and Estrella Immunopharma, Inc. incorporated by reference to Exhibit 10.28 to the registration statement on Form S-4/A filed with the SEC on July 7, 2023 (File No. 333-267918)
10.29	Extension Promissory Note, dated June 16, 2023, issued by TradeUP Acquisition Corp. to Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 20, 2023, File No. 001-40608)
10.30	Subscription Agreement dated September 14, 2023 by and among TradeUP Acquisition Corp. and Plentiful Limited (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 20, 2023)
10.31	Subscription Agreement dated September 14, 2023 by and among TradeUP Acquisition Corp. and Lianhe World Limited (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on September 20, 2023)
10.32	Joinder to the Estrella Series A Purchase Agreement by and between Estrella Biopharma, Inc. and Lianhe World Limited (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.33	Joinder to the Estrella Series A Purchase Agreement by and between Estrella Biopharma, Inc. and CoFame Investments, LLC (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)

10.34	Joinder to the Estrella Series A Purchase Agreement by and between Estrella Biopharma, Inc. and US Tiger Securities, Inc. (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.35	Joinder to the Estrella Series A Purchase Agreement by and between Estrella Biopharma, Inc. and Smart Crest International Limited (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.36	Joinder to the Estrella Series A Purchase Agreement by and between Estrella Biopharma, Inc. and Yangbing Xiao (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.37	Joinder to the Estrella Series A Purchase Agreement by and between Estrella Biopharma, Inc. and Yuandong Wang (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.38	Stock Transfer Agreement by and among Cheng Liu, Jiandong (Peter) Xu and Qian (Vicky) Yang, Yuandong Wang and Estrella Biopharma, Inc. (incorporated by reference to Exhibit 10.10 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.39	Stock Transfer Agreement by and among Cheng Liu, Jiandong (Peter) Xu and Qian (Vicky) Yang, Yangbing Xiao and Estrella Biopharma, Inc. (incorporated by reference to Exhibit 10.11 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.40	Stock Transfer Agreement by and among Cheng Liu, Jiandong (Peter) Xu and Qian (Vicky) Yang, Smart Crest International Limited and Estrella Biopharma, Inc. (incorporated by reference to Exhibit 10.12 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.41	Unsecured Promissory Note by and between Hongbin Zhang and Estrella Biopharma Inc. (incorporated by reference to Exhibit 10.15 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.42	Employment agreement by and between Dr. Cheng Liu and Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.19 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.43	Employment Agreement by and between Peter Xu and Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.20 to the Current Report on Form 8-K filed with the SEC on October 5, 2023)
10.44	Registration Rights Agreement, dated as of April 20, 2023, by and between TradeUP Acquisition Corp. and White Lion Capital LLC. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on April 24, 2023, File No. 001-40608)

Exhibit Number	Description of Exhibit
10.45	Amendment to the Common Stock Purchase Agreement, dated as of April 26, 2023, by and between TradeUP Acquisition Corp. and White Lion Capital LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 26, 2023, File No. 001-40608)
10.46	Private Placement Shares Purchase Agreement, dated July 14, 2021, among the TradeUP Acquisition Corp., TradeUP Acquisition Sponsor LLC and Tradeup INC. (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on July 19, 2021)
10.47	Securities Subscription Agreement, between the TradeUP Acquisition Corp. and TradeUP Acquisition Sponsor LLC dated February 12, 2021 (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 filed with the SEC on July 9, 2021 File No. 333-253322)
10.48	Securities Subscription Agreement, between the TradeUP Acquisition Corp. and Tradeup INC. dated February 12, 2021(incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 filed with the SEC on July 9, 2021 File No. 333-253322)
10.49	Form of Share Purchase Agreement between the TradeUP Acquisition Corp. and the founders (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 filed with the SEC on June 11, 2021 File No. 333-253322)
10.50	Letter Agreement, dated July 14, 2021, among the TradeUP Acquisition Corp., TradeUP Acquisition Sponsor LLC, Tradeup INC. and certain security holders named therein (incorporated by reference to Exhibit 10.1 to the Current Report on 8-K filed with the SEC on July 19, 2021 File No. 001-40608)
10.51	Statement of Work No. 001, dated and effective as of March 4, 2024, by and among Estrella Biopharma, Inc., Eureka Therapeutics, Inc and Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on 8-K filed with the SEC on March 7, 2024, File No. 001-40608)
10.52	Amendment No. 1 to Statement of Work No. 001, dated May 13, 2024 and effective as of March 4, 2024, by and among Estrella Biopharma, Inc., Eureka Therapeutics, Inc. and Estrella Immunopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on 8-K filed with the SEC on May 13, 2024, File No. 001-40608)
16.1	Letter from Marcum LLP, dated February 1, 2024 (incorporated by reference to Exhibit 16.1 to the Current Report on Form 8-K filed with the SEC on February 2, 2024, File No. 001-40608)
31.1**	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Clawback Policy.
101.INS	Inline XBRL Instance 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 (formatted as Inline XBRL and contained in Exhibit 101).

* Annexes, schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted attachment to the Securities and Exchange Commission on a confidential basis upon request.

† Portions of this exhibit (indicated by asterisks) have been omitted because the registrant has determined that the information is both not material and is the type that the registrant treats as private or confidential.

** These certifications are furnished to the SEC pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 16. Form 10-K Summary

None.

INDEX TO FINANCIAL STATEMENT

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Estrella Immunopharma Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Estrella Immunopharma Inc. (the "Company") as of June 30, 2024, the related consolidated statement of operations, stockholders' equity and cash flows for the year then ended, 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 June 30, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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 suffered recurring losses from operations and has negative cash flows from operating activities. These matters raise 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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 audit 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 audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2024.

/s/ Macias Gini & O'Connell LLP

Walnut Creek, CA
September 26, 2024
PCAOB ID No. 324

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Estrella Immunopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Estrella Biopharma, Inc. (the "Company", now known as Estrella Immunopharma, Inc.) as of June 30, 2023, the related statements of operations, stockholders' deficit and cash flows for the year ended June 30, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2023, and the results of its operations and its cash flows for the year ended June 30, 2023, in conformity with accounting

principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit 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 audit 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 audit 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 audit 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/ Marcum LLP

Marcum LLP

We served as the Company's auditor from 2022 through 2024.

Costa Mesa, CA

October 5, 2023, except for the sixth paragraph of Note 3, as to which the date is September 26, 2024

ESTRELLA IMMUNOPHARMA, INC
CONSOLIDATED BALANCE SHEETS

	As of June 30, 2024	As of June 30, 2023
Assets		
Current assets:		
Cash and cash equivalent	$ 4,165,428	$ 2,479,146
Prepaid expenses and other receivable	288,761	-
Extension note receivable	-	273,066
Total current assets	4,454,189	2,752,212
Other Assets		
Deferred transaction costs	-	276,187
Total Assets	$ 4,454,189	$ 3,028,399
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable - related party	$ -	$ 9,333,146
Other payables and accrued liabilities	131,823	398,781
Accrued liability - related party	4,000	22,000
Franchise tax payables	4,134	4,297
Income tax payables	40,744	-
Total current liabilities	180,701	9,758,224
Non-current liabilities:		
Other liability	-	12,725
Total non-current liabilities	-	12,725
Total Liabilities	180,701	9,770,949
Commitments and Contingencies (Note 7)		
Preferred Stock*		
Series A Preferred Stock, $0.0001 par value, 15,000,000 shares authorized;	-	5,000,000
0 and 1,203,695 shares issued and outstanding as of June 30, 2024 and 2023, respectively		
Series AA Preferred Stock, $0.0001 par value, 105,000,000 shares authorized;	-	-
0 and 25,277,591 shares issued and outstanding as of June 30, 2024 and 2023, respectively		

Stockholders' Equity (Deficit):		
Common stock, $0.0001 par value; 250,000,000 shares authorized;		
36,610,870 and 978,243 shares issued as of June 30, 2024 and 2023, respectively*	3,661	98
Additional paid-in capital	24,124,543	445,905
Accumulated deficit	(19,500,276)	(12,188,553)
Treasury stock, at cost 321,794 and 0 shares as of June 30, 2024 and 2023, respectively	(354,440)	-
Total Stockholders' Equity (Deficit)	4,273,488	(11,742,550)
Total Liabilities, Preferred Stock and Stockholders' Equity (Deficit)	$ 4,454,189	$ 3,028,399

***** Giving retroactive effect to reverse recapitalization effected on September 29, 2023 to reflect exchange ratio of approximately 0.2407 as described in Note 3

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

ESTRELLA IMMUNOPHARMA, INC
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended June 30, 2024	For the Year Ended June 30, 2023
Operating expenses		
Research and development	$ 4,108,925	$ 10,451,212
General and administrative	3,201,173	663,190
Total operating expenses	7,310,098	11,114,402
Loss from Operations	(7,310,098)	(11,114,402)
Loss before income taxes	(7,310,098)	(11,114,402)
Income taxes provision	(1,625)	-
Net loss	$ (7,311,723)	$ (11,114,402)
Net loss applicable to common stock per share, basic and diluted	$ (0.27)	$ (36.35)
Weighted average common stock outstanding, basic and diluted*	27,103,964	305,748

***** Giving retroactive effect to reverse recapitalization effected on September 29, 2023 to reflect exchange ratio of approximately 0.2407 as described in Note 3

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

ESTRELLA IMMUNOPHARMA, INC
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Series A Preferred Stock		Series AA Preferred Stock		Common Stock		Treasury	Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares*	Amount	Shares*	Amount	Shares*	Amount	Stock	Capital	Deficit	(Deficit)
Balance, July 1, 2022	5,000,000	$ 5,000,000	105,000,000	$ -	176,000	$ 18	$ -	$ 34,290	$ (1,074,151)	$ (1,039,843)
Recapitalization	(3,796,305)	-	(79,722,409)	-	(133,630)	(14)	-	14	-	-
Balance, July 1, 2022	1,203,695	5,000,000	25,277,591	-	42,370	4	-	34,304	(1,074,151)	(1,039,843)
Vesting of early exercised stock options	-	-	-	-	935,873	94	-	2,006	-	2,100
Stock-based compensation	-	-	-	-	-	-	-	409,595	-	409,595
Net loss	-	-	-	-	-	-	-		(11,114,402)	(11,114,402)
Balance, June 30, 2023	1,203,695	5,000,000	25,277,591	-	978,243	98	$ -	445,905	(12,188,553)	(11,742,550)
Issuance of series A preferred stock	2,407,390	9,750,000	-	-	-	-	-	-	-	-
Conversion of series A and series AA preferred stock into common stock	(3,611,085)	(14,750,000)	(25,277,591)	-	28,888,675	2,889	-	14,747,111	-	14,750,000
Vesting of early exercised stock options	-	-	-	-	2,633,082	263	-	12,462	-	12,725
Stock-based compensation	-	-	-	-	-	-	-	1,194,653	-	1,194,653

Issuance of common stock for PIPE investment	-	-	-	-	1,000,000	100	-	9,999,900	-	10,000,000
Issuance of common stock upon completion of business combination	-	-	-	-	1,701,232	170	-	(474,147)	-	(473,977)
Transactions cost	-	-	-	-	-	-	-	(1,801,200)	-	(1,801,200)
Issuance of common stock for PIPE investment	-	-	-	-	1,409,638	141	-	(141)	-	-
Purchase of treasury stock	-	-	-	-	-	-	(354,440)	-	-	(354,440)
Net loss	-	-	-	-	-	-	-	-	(7,311,723)	(7,311,723)
Balance, June 30, 2024	-	$ -	-	$ -	36,610,870	$ 3,661	$ (354,440)	$24,124,543	$ (19,500,276)	$ 4,273,488

* Giving retroactive effect to reverse recapitalization effected on September 29, 2023 to reflect exchange ratio of approximately 0.2407 as described in Note 3

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

ESTRELLA IMMUNOPHARMA, INC
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended June 30, 2024	For the Year Ended June 30, 2023
Cash Flows from Operating Activities:		
Net loss	$ (7,311,723)	$(11,114,402)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,194,653	409,595
Changes in operating assets and liabilities:		
Prepaid expenses and other receivable	(149,994)	-
Prepaid expenses - related party	-	833,333
Accounts payable - related party	(9,333,146)	8,387,559
Other payables and accrued liabilities	(449,958)	122,594
Accrued liability - related party	(18,000)	22,000
Franchise tax payable	(138)	3,200
Net cash used in operating activities	(16,068,306)	(1,336,121)
Cash Flows from Investing Activities:		
Loan to UPTD as extension note receivable prior to business combination	(112,298)	(273,066)
Cash released from trust account	5,072,945	-
Net cash provided by investing activities	4,960,647	(273,066)
Cash Flows from Financing Activities:		
Payments of transactions cost	(1,525,013)	-
Net proceeds from PIPE investment	10,000,000	-
Net proceeds from issuance of Series A Preferred Stock	9,020,000	-
Net proceeds from promissory note	300,000	-
Repayment of promissory note	(300,000)	-
Payment of redemption payable	(5,072,945)	-
Proceeds from business combination	726,339	-
Purchase of treasury stock	(354,440)	-
Net cash provided by financing activities	12,793,941	-
Net Change in Cash	1,686,282	(1,609,187)
Cash at beginning of the year	2,479,146	4,088,333
Cash at end of the year	$ 4,165,428	$ 2,479,146
Supplemental Cash Flow Information		
Cash paid for income tax	$ 1,600	$ -
Cash paid for interest	$ 2,663	$ -
Supplemental Disclosure of Non-cash Financing Activities		
Deferred transaction costs included in other payables and accrued liabilities	$ -	$ 276,187
Recognition of related party operating right-of-use asset and lease liability	$ -	$ 48,988
Conversion of Series A prefer stock into common stock	$ 5,000,000	$ -
Conversion of deferred underwriting commission payable into Series A preferred stock	$ 730,000	$ -

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

Note 1 — Organization and Business Operation

Description of business

Estrella Immunopharma, Inc., a Delaware corporation, is a clinical-stage biopharmaceutical company developing T-cell therapies with the capacity to cure patients with blood cancers and solid tumors.

As further discussed below and in Note 3, on September 29, 2023 (the " Closing Date"), Estrella Biopharma, Inc. ("Estrella") and TradeUP Acquisition Corp. ("UPTD") consummated the business combination (the "Business Combination") pursuant to the terms of the Agreement and Plan of Merger, dated as of September 30, 2022 (the "Merger Agreement"), by and among UPTD, Tradeup Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of UPTD ("Merger Sub"), and the Company. Pursuant to the terms of the Merger Agreement, Merger Sub merged with and into Estrella, with Estrella surviving as a wholly-owned subsidiary of UPTD. Upon closing of the Business Combination (the "Closing"), UPTD changed its corporate name to Estrella Immunopharma, Inc. ("New Estrella" or the "Company").

Estrella was incorporated in the State of Delaware on March 30, 2022 by Eureka Therapeutics, Inc. ("Eureka"), which was incorporated in California in February 2006 and reincorporated in Delaware in March 2018 and is the predecessor of Estrella. Estrella's fiscal year end is June 30, and the Company's fiscal year end changed from December 31 to June 30 effective as of the Closing Date.

On June 28, 2022, pursuant to a Contribution Agreement between Estrella and Eureka (the "Contribution Agreement"), Eureka contributed certain assets (the "Assets") related to T-cell therapies targeting CD19 and CD22, proteins expressed on the surface of almost all B-cell leukemias and lymphomas, in exchange for 105,000,000 shares of Estrella's Series AA Preferred Stock (the "Separation").

As part of the Separation, Estrella entered into a License Agreement (the "License Agreement") with Eureka and Eureka Therapeutics (Cayman) Ltd. ("Eureka Cayman"), an affiliate of Eureka, and a Services Agreement (the "Services Agreement") with Eureka, and Eureka contributed and assigned the Collaboration Agreement between Eureka and Imugene Limited ("Imugene") (the "Collaboration Agreement") to Estrella. The License Agreement grants the Company an exclusive license to develop CD19 and CD22 targeted T-cell therapies using Eureka's ARTEMIS® platform. Under the Services Agreement, Eureka has agreed to perform certain services for the Company in connection with the development of the Company's product candidates, EB103 and EB104. EB103, which is a T-cell therapy also called "CD19-Redirected ARTEMIS® T-Cell Therapy," utilizes Eureka's ARTEMIS ® technology to target CD19. The Company is also developing EB104, a T-cell therapy also called "CD19/22 Dual-Targeting ARTEMIS® T-Cell Therapy." Like EB103, EB104 utilizes Eureka's ARTEMIS® technology to target not only CD19, but also CD22. The Collaboration Agreement establishes the partnership between the Company and Imugene related to development of solid tumor treatments using Imugene's product candidate ("CF33-CD19t") in conjunction with EB103.

On March 2, 2023, the FDA cleared Estrella's IND application for EB103, allowing Estrella to proceed with the Phase I/II STARLIGHT-1 Clinical Trial "STARLIGHT-1". On March 4, 2024, the Company, Estrella and Eureka executed Statement of Work #001 relating to clinical trial services to be performed by Eureka in connection with the STARLIGHT-1 clinical trial (see Note 9). On May 13, 2024, the Company and Eureka entered into Amendment No. 1 to the Statement of Work, effective as of March 4, 2024 (see Note 9). As of June 30, 2024, the Company has begun enrolling patients into the STARLIGHT-1 clinical trial in the U.S.

Merger and reverse recapitalization

As described above and further discussed in Note 3, the Business Combination was consummated on September 29, 2023.

The Business Combination was accounted for as a "reverse recapitalization." Under this method of accounting, UPTD was treated as the "acquired" company for financial reporting purposes. Accordingly, the Business Combination was treated as the equivalent of Estrella issuing shares for the net assets of UPTD, accompanied by a recapitalization. The net assets of UPTD are stated at historical costs. No goodwill or other intangible assets are recorded.

On June 26, 2024, the Company filed a Certificate of Ownership and Merger with the Delaware Secretary of State to effect a merger (the "Merger 1") with its wholly-owned subsidiary, Estrella BioPharma Inc, pursuant to Section 253 of the Delaware General Corporation Law. The Merger 1 was approved by resolutions duly adopted by the unanimous written consent of the Company's board of directors. The Merger 1 became effective at 11:59 PM Eastern Time on June 30, 2024, at which time the separate existence of Estrella ceased, and the Company became the surviving corporation.

Liquidity and Going Concern

The accompanying financial statements have been prepared on a basis which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As of June 30, 2024, the Company had cash of approximately $4.2 million, and accumulated deficit of approximately $ 19.5 million. For the year ended June 30, 2024, loss from operations was approximately $7.3 million. The Company's ability to fund its operations is dependent on the amount of cash on hand and its ability to raise debt or additional equity financing. The Company has expended substantial funds on its research and development business, has experienced losses and negative cash flows from operations since its inception and expects losses and negative cash flows from operations to continue until its technology receives regulatory approval and the Company generates sufficient revenue and positive cash flow from operations, if ever.

On September 29, 2023, the Business Combination and several concurrent financing transactions were consummated, with the Company receiving net proceeds of approximately $20.1 million, after deducting $5.1 million payable to redeem 467,122 shares of UPTD Common Stock at $ 10.86 per share in connection with the special meeting of UPTD stockholders related to the Business Combination held on July 31, 2023, $1.6 million for UPTD's transaction expenses and $0.7 million for repayment of working capital loans, consisting of: (i) $ 9.75 million from the issuance of shares of the Company's Operating Series A Preferred Stock immediately prior to the closing of the Business Combination ($0.7 million of which was comprised of funds in the trust account delivered to the Company at the closing of the Business Combination that would have otherwise been paid to US Tiger Securities, Inc. as a deferred

underwriting fee in connection with UPTD's IPO); (ii) $0.3 million from the issuance of an unsecured promissory note by us to a third party investor; (iii) $0.7 million from the funds held in UPTD's trust account; and (iv) $ 10 million from the PIPE investors pursuant to the Subscription Agreements.

On April 20, 2023, UPTD entered into the Common Stock Purchase Agreement and the White Lion RRA with White Lion. Subsequently, on April 26, 2023, UPTD and White Lion entered into an amendment to the Common Stock Purchase Agreement. Pursuant to the Common Stock Purchase Agreement, following the Closing, New Estrella will have the right, but not the obligation, to require White Lion to purchase, from time to time up to $50,000,000 in aggregate gross purchase price of newly issued shares of Common Stock (the "Equity Line Shares"), subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement as further described in Note 8.

On October 10, 2023, the Company used a portion of the net proceeds from the Business Combination to pay $ 8.3 million due to Eureka under the Services Agreement and approximately $0.9 million aggregate amount due to Eureka under the License Agreement, comprised of the outstanding portion of the upfront fee as well as a milestone payment in connection with the submission of the IND application for EB103. The Company intends to devote the remaining net proceeds from the Business Combination to the preclinical and clinical development of the Company's product candidates and the public company compliance costs.

On March 4, 2024, Estrella and Eureka entered into Statement of Work No. 001 ("SOW") relating to the clinical trial services to be performed by Eureka in connection with STARLIGHT-1, the Phase I/II clinical trial of Estrella's product candidate, EB103, a T-cell therapy targeting CD19 using ARTEMIS ® T cell technology licensed by Estrella from Eureka. Pursuant to the SOW, Estrella agrees to pay Eureka non-refundable net fees in connection with the achievement of certain milestones set forth in the SOW, with total fees of $33,000,000 for achievement of all milestones. As of June 30, 2024, Estrella has paid $3,500,000 to Eureka for covering the fees associated with the milestones that have been achieved.

On May 13, 2024, the Company and Eureka entered into Amendment No. 1 to the Statement of Work, effective as of March 4, 2024, to clarify that in the event that Estrella exercises its right to terminate or suspend the engagement with Eureka by providing written notice to Eureka in accordance with the SOW, Estrella will only be obligated to compensate Eureka for (i) services provided by Eureka pursuant to the SOW ("Services") in connection with milestones that were achieved prior to the date and time of such written notice, (ii) reasonable and documented pass-through costs incurred by Eureka on behalf of Estrella prior to the date and time of such written notice in connection with providing the Services and (iii) amounts payable to third parties pursuant to commitments reasonably entered into by Eureka on behalf of Estrella prior to the date and time of such written notice in connection with providing the Services, provided that Eureka shall make commercially reasonable efforts to cancel or reduce any such amounts.

The Company's future operations are highly dependent on a combination of factors, including but not necessarily limited to (1) the success of our research and development programs; (2) the timely and successful completion of any additional financing; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies; (4) our ability to manage growth of the organization; (5) our ability to protect our technology and products; and, ultimately (6) regulatory approval and successful commercialization and market acceptance of our product candidates.

However, management believes that the Company has sufficient funds on hand and ability to raise funds in the future through the issuance and sale of Equity Line Shares to White Lion in order to meet its working capital requirements and debt obligations, for at least the next 12 months from the filing date of these financial statements.

Note 2 — Significant accounting policies

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC").

Emerging Growth Company Status

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, (the "Securities Act"), as modified by the Jumpstart The Company's Business Startups Act of 2012, (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its 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.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's financial statements with another public company difficult because of the potential differences in accounting standards used.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Accordingly, the actual results could differ significantly from those estimates. Significant items subject to such estimates and assumptions include stock-based compensation, and deferred income tax asset valuation and allowances.

Cash and cash equivalent

The Company maintains its operating accounts in a single financial institution. The balance is insured by the United States Federal Deposit Insurance Corporation ("FDIC") but only up to specified limits. The Company's cash is maintained in a checking and a saving account and Certificates of Deposits. Cash equivalents consist of funds held at the third-party broker's account for stock repurchase purpose, and the fund are unrestricted and immediately available for withdrawal and use. The balance held at the third-party broker's account is insured by the United States Securities Investor Protection Corporation ("SIPC") but only up to specified limits.

Basic and Diluted Loss per Common Stock

Basic net loss per Common Stock is calculated by dividing the net loss by the weighted–average number of Common Stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted–average number of Common Stock and dilutive share equivalents outstanding for the period, determined using the treasury stock and if–converted methods. Since the Company has had net losses for all periods presented, all potentially dilutive securities are anti–dilutive.

As of June 30, 2024 and 2023, the Company had the following potential Common Stock outstanding which were not included in the calculation of diluted net loss per Common Stock because inclusion thereof would be anti-dilutive:

	As of June 30, 2024	As of June 30, 2023
Series A Preferred Stock*	-	1,203,695
Series AA Preferred Stock*	-	25,277,591
Unvested early-exercised stock option*	-	2,633,082
Public warrant	2,214,993	-
Total	2,214,993	29,114,368

* Giving retroactive effect to reverse recapitalization effected on September 29, 2023 to reflect exchange ratio of approximately 0.2407 as described in Note 3

Stock-Based Compensation

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option granted is estimated as of the date of grant using the Black-Scholes-Merton option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. The Black-Scholes-Merton option-pricing model includes various assumptions, including the fair market value of the Common Stock of the Company, expected life of stock options, the expected volatility and the expected risk-free interest rate, among others. These assumptions reflect the Company's best estimates, but they involve inherent uncertainties based on market conditions generally outside the control of the Company.

As a result, if other assumptions had been used, stock-based compensation expense, as determined in accordance with authoritative guidance, could have been materially impacted. Furthermore, if the Company uses different assumptions on future grants, stock-based compensation expense could be materially affected in future periods.

Mezzanine Equity

Mezzanine equity represents the Series A Preferred Stock and Series AA Preferred Stock (collectively known as "Preferred Stock") issued by the Company. The shares of Preferred Stock were mandatorily redeemable upon the occurrence of Deemed Liquidation Events outside of the Company's control. Therefore, the Company classifies the Preferred Stock as mezzanine equity. Refer to Note 11.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares and whether the warrant 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, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. The Company determined that upon further review of the warrant agreements, the Company concluded that its warrants qualify for equity accounting treatment.

Upon completion of the business combination, all of UPTD's public warrants that remained outstanding were replaced by the Company's public warrants. The Company treated such warrants replacement as a warrant modification and no incremental fair value was recognized.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of two cash accounts in a financial institution located in the United States. The Company has not experienced losses on these accounts, and management believes the Company is not exposed to significant risks. The Federal Deposit Insurance Corporation (FDIC) provides standard insurance coverage of $250,000 per insured bank for each account ownership category. As of June 30, 2024, and 2023, the Company had not experienced losses on these accounts. As of June 30, 2024, and 2023, the Company had deposited $4,019,813 and $2,479,146, respectively, with financial institutions in the United States. Of these balances, $ 3,758,670 and $2,229,146, respectively, were not covered by deposit insurance. While management believes that these financial institutions are of high credit quality, it also continually monitors their creditworthiness.

The Securities Investor Protection Corporation (SIPC) provides standard insurance coverage of $ 500,000 per brokerage account, which includes $250,000 for cash balances. As of June 30, 2024, and 2023, the Company maintained $ 145,615 and $0, respectively, in its brokerage account, with the entire balance covered by SIPC insurance.

Risks and Uncertainties

Management continues to evaluate the impact of inflation rates, the continuing military action in Ukraine, and Israel's war against Hamas on the industry and has concluded that these factors could have a negative effect on the Company's financial position and/or results of its operations. The specific impact of these factors is not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

The Company's future success depends on the Company and Eureka's ability to retain key employees, directors, and advisors and to attract, retain and motivate qualified personnel. The Company relies on Eureka to provide certain technical assistance to facilitate the Company's exploitation of the intellectual property licensed by Eureka, and Eureka will be solely responsible for the manufacture and supply of clinical quantities of the licensed products and final filled and finished (including packaged) drug product form of the licensed products. Pursuant to the Services Agreement, Eureka currently performs or supports the Company's important research and development activities. The Statement of Work (see Note 9) may be terminated by mutual agreement at any time. Following the termination of, or the expiration of the term of, the Statement of Work, the Company may not be able to replace the research and development-related services that Eureka provides or enter into appropriate third-party arrangements on terms and conditions, including cost, comparable to those that the Company will receive from Eureka. Additionally, after the Statement of Work terminates, the Company may be unable to sustain the research and development-related services at the same levels or obtain the same benefits as when the Company was receiving such services and benefits from Eureka. If the Company is required to operate these research and development functions separately in the future, or are unable to obtain them from other providers, the Company may not be able to operate the Company's business effectively and could result in a material adverse effect.

Fair Value of Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC Topic 820, "Fair Value Measurements and Disclosures," approximates the carrying amounts represented in the accompanying balance sheet, primarily due to their short-term nature. The Company measures the fair value of certain of its financial assets and liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value which is not equivalent to cost will be classified and disclosed in one of the following three categories:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets and liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Income Taxes

The Company recognizes deferred tax assets and liabilities for both the expected impact of differences between the financial statement and tax basis of assets and liabilities and for the expected future tax benefit to be derived from tax loss and tax credit carry forwards and establishes a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized.

Accounting for uncertainty in income taxes is recognized based on a recognition threshold and measurement process for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of June 30, 2024 and 2023. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company may be subject to potential examination by federal and state taxing authorities in the areas of income taxes. These potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with federal and state tax laws. The Company's management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

The Company is incorporated in the State of Delaware and is required to pay franchise taxes to the State of Delaware on an annual basis.

Research and Development Expenses

The Company charges research and development costs to operations as incurred. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials when applicable, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered. Research and development expenses for the years ended June 30, 2024 and 2023 primarily consisted of personnel costs for the design and development of clinical trials, legal and professional fees and, facilities related fees. Refer to Note 9 for the terms of the License Agreement, the Service Agreement, and the Statement of Work.

Deferred transaction costs

Deferred transaction costs consist primarily of expenses paid to attorneys, consultants, underwriters, and others related to the Merger, which were charged to shareholders' equity upon the completion of the Merger. The Company completed the Merger on September 29, 2023.

Lease

Effective July 1, 2022, the Company adopted ASU 2016-02, "Leases" (Topic 842), and elected the practical expedients that does not require us to reassess: (1) whether any expired or existing contracts are, or contain, leases, (2) lease classification for any expired or existing leases and (3) initial direct costs for any expired or existing leases. For lease terms of twelve months or fewer, a lessee is permitted to make an accounting policy election not to recognize lease assets and liabilities.

If any of the following criteria are met, the Company classifies the lease as a finance lease:

- The lease transfers ownership of the underlying asset to the lessee by the end of the lease term;
- The lease grants the lessee an option to purchase the underlying asset that the Company is reasonably certain to exercise;
- The lease term is for a major part of the remaining economic life of the underlying asset;
- The present value of the sum of the lease payments and any residual value guaranteed by the lessee, that is not otherwise included in the lease payments substantially exceeds all of the fair value of the underlying asset; or
- The underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term.

Leases that do not meet any of the above criteria are accounted for as operating leases.

The Company combines lease and non-lease components in its contracts under Topic 842, when permissible.

Operating lease right-of-use ("ROU") asset and lease liability were recognized at the adoption date of July 1, 2022, based on the present value of lease payments over the lease term. Since the implicit rate for the Company's leases is not readily determinable, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow, on a collateralized basis, an amount equal to the lease payments, in a similar economic environment and over a similar term.

In the event of lease modification, the Company followed ASC 842-10-25 through 25-12, "lessee accounting for a modification that is not accounted for as a separate contract," to remeasure and reallocate the remaining consideration in the lease agreement and reassess the classification of the lease at the effective date of the modification.

The Company reviews the impairment of its ROU asset consistent with the approach applied for its other long-lived assets. The Company reviews the recoverability of its long-lived assets when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on its ability to recover the carrying value of the asset from the expected undiscounted future pre-tax cash flows of the related operations. The Company has elected to include the carrying amount of operating lease liability in any tested asset group and includes the associated operating lease payments in the undiscounted future pre-tax cash flows.

Segment reporting

The Company accounted for segment reporting in accordance with ASC 280, "Segment Reporting". Based on qualitative and quantitative criteria established by ASC 280, the Company considers itself to be operating within one reportable segment.

Recent Accounting Pronouncements

The Company considers the applicability and impact of all accounting standards updates ("ASUs"). Management periodically reviews new accounting standards that are issued. Under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with new or revised accounting standards, which delays the adoption of these accounting standards until they would apply to private companies.

In October 2023, the FASB issued ASU 2023-06, Disclosure Improvements — codification amendments in response to SEC's disclosure Update and Simplification initiative which amend the disclosure or presentation requirements of codification subtopic 230-10 Statement of Cash Flows—Overall, 250-10 Accounting Changes and Error Corrections— Overall, 260-10 Earnings Per Share— Overall, 270-10 Interim Reporting— Overall, 440-10 Commitments—Overall, 470-10 Debt—Overall, 505-10 Equity—Overall, 815-10 Derivatives and Hedging—Overall, 860-30 Transfers and Servicing—Secured Borrowing and Collateral, 932-235 Extractive Activities— Oil and Gas—Notes to Consolidated Financial Statements, 946-20 Financial Services — Investment Companies— Investment Company Activities, and 974-10 Real Estate—Real Estate Investment Trusts—Overall. The amendments represent changes to clarify or improve disclosure and presentation requirements of above subtopics. Many of the amendments allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the SEC's requirements. Also, the amendments align the requirements in the Codification with the SEC's regulations. For entities subject to existing SEC disclosure requirements or those that must provide financial statements to the SEC for securities purposes without contractual transfer restrictions, the effective date aligns with the date

when the SEC removes the related disclosure from Regulation S-X or Regulation S-K. Early adoption is not allowed. For all other entities, the amendments will be effective two years later from the date of the SEC's removal. The Company is currently evaluating the impact of the update on the Company's consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, which is an update to Topic 740, Income Taxes. The amendment in this update enhances the transparency and decision usefulness of income tax disclosures. ASU 2023-09 will be effective for fiscal years beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The amendments in this Update should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating the impact the adoption of ASU 2023-07 will have on its annual and interim disclosures.

The Company does not believe recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the Company's consolidated financial statements.

Note 3 — Reverse recapitalization

Upon the consummation of the Business Combination, the following transactions (collectively, the "Transactions") were completed, based on the Company's capitalization as of September 29, 2023:

- each share of common stock, par value $ 0.0001 per share, of Merger Sub issued and outstanding immediately prior to the effective time of the Business Combination ("Effective Time") was no longer outstanding and thereupon were converted into and become one validly issued fully paid and non-assessable share of Common Stock, par value $0.001 per share, of the Company and all such shares constituted the only outstanding shares of capital stock of the Company as of immediately following the Effective Time;
- The UPTD Units were automatically separated into underlying Common Stock and UPTD Warrants and are no longer be traded on the open market following the Closing;
- Estrella issued 500,000 shares of Series A Preferred Stock to White Lion for $ 500,000 and 250,000 shares of Series A Preferred Stock to White Lion as commitment fee pursuant to the Common Stock Purchase Agreement immediately prior to the Effective Time;
- Estrella issued (i) 1,520,000 shares of Series A Preferred Stock were issued to Lianhe World for $1,520,000, (ii) 1,000,000 shares of Series A Preferred Stock were issued to CoFame for $1,000,000, (iii) 730,000 shares of Series A Preferred Stock were issued to Tiger for $730,000 for deferred commission, (iv) 2,000,000 shares of Series A Preferred Stock were issued to Smart Crest for $2,000,000; (v) 2,000,000 shares of Series A Preferred Stock were issued to Xiao for $2,000,000 and (vi) 2,000,000 shares of Series A Preferred Stock were issued to Wang for $2,000,000, immediately prior to the Effective Time;
- Estrella issued an unsecured 30-day promissory note to Hongbing Zhang in the principal amount of $ 0.3 million with an interest rate of 12% per annum;
- Each share of Series A Preferred Stock and Series AA Preferred Stock that was issued and outstanding immediately prior to the Effective Time was automatically converted into a number of shares of Estrella Common Stock (See Note 12);
- Each share of Estrella Common Stock was converted into 0.2407 shares of Company Common Stock; and
- The Company issued 500,000 shares of Common Stock to each of Plentiful Limited and Lianhe World, respectively.

The following table presents the number of the Company's Common Stock issued and outstanding immediately following the Reverse Recapitalization:

	Common Stock
UPTD's Common Stock outstanding prior to Reverse Recapitalization	2,329,920
Less: redemption of UPTD's Common Stock	(628,688)
Common Stock issued to PIPE investment	1,000,000
Conversion of Estrella's Common Stock into UPTD's Common Stock	32,500,000
Total Common Stock outstanding	35,201,232

Estrella was determined to be the accounting acquirer given that Estrella effectively controlled the Company upon consummation of the Business Combination. The transaction is accounted for as a reverse recapitalization, which is equivalent to the issuance of Common Stock by Estrella for the net monetary assets of UPTD, accompanied by a recapitalization. Estrella was determined as the accounting acquirer and the historical financial statements of Estrella became the Company's historical financial statements, with retrospective adjustments to give effect of the reverse recapitalization. The net assets of UPTD were recognized as of the Closing Date at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Closing Date are those of Estrella and Estrella's operations are the only ongoing operations of the Company.

In connection with the Reverse Recapitalization, the Company raised approximately $ 726,339 of proceeds, presented as cash flows from financing activities, which included the contribution of $8,138,230 of funds held in UPTD's trust account, $ 9,782 of cash held in UPTD's operating cash account, net of $5,072,945 payable to UPTD's public stockholders to redeem 467,122 public shares of UPTD's Common Stock, $ 1,640,128 in transaction costs incurred by UPTD, and $708,600 prepayment of working capital loans issued to UPTD's related parties.

The following table reconcile the elements of the Reverse Recapitalization to the statements of cash flows and the changes in shareholders' equity (deficit):

	September 29, 2023
Funds held in UPTD's trust account	$ 8,138,230
Funds held in UPTD's operating cash account	9,782
Less: amount payable to redeem public shares of UPTD's Common Stock	(5,072,945)
Less: payments of transaction costs incurred by UPTD	(1,640,128)
Less: repayments of working capital loan – related parties of UPTD	(708,600)
Proceeds from the Reverse Recapitalization	726,339
Less: non-cash net deficit assumed from UPTD	(1,200,316)
Net distributions from issuance of Common Stock upon the Reverse Recapitalization	$ (473,977)

The shares and corresponding capital amounts and all per share data related to the Company's outstanding Common Stock prior to the Reverse Recapitalization have been retroactively adjusted using the Exchange Ratio of 0.2407.

Note 4 — Cash Held in Trust Account

The Company had cash held in a trust account, carried over from UPTD upon the consummation of the Business Combination. Such balance held in trust account was designated to pay UPTD's shareholders who redeemed public shares of UPTD's Common Stock before the consummation of the business combination. On October 3, 2023, the remaining balance of cash held in trust account was disbursed to the UPTD's shareholder as mentioned above.

Note 5 — Extension Note Receivable

Pursuant to Merger Agreement, Estrella agreed to, upon request by UPTD, deposit the agreed reasonable amount to UPTD's trust account in order to effectuate extension of UPTD's deadline to consummate a business combination. Pursuant to the Merger Agreement, as of June 30, 2023, a total of $273,066 of six-monthly extension payments, each in the principal amount of $ 45,511, would be deposited into the Trust Account of UPTD, all of which were sourced by loans from Estrella (the "Extension Notes"). The Extension Notes bore no interest and were settled between Estrella and UPTD upon the consummation of the Business Combination on September 29, 2023.

Note 6 — Other payables and accrued liabilities

	As of June 30, 2024	As of June 30, 2023
Accrued professional fees (i)	$ 121,235	$ 398,781
Salary and payroll taxes payable	10,241	
Others	347	-
Total other payables and accrued liabilities	$ 131,823	$ 398,781

(i) The balance of accrued professional fees represented amount due to third party service providers which include, legal and consulting fee related to research and development, and others.

Note 7 — Stock redemption payable

Stock redemption payable represents the balance payable to UPTD's shareholders related to the redemption of public shares of UPTD's Common Stock before the consummation of the business combination. On October 3, 2023, such balance was paid in full through the Company's investment held in trust account. (see Note 4).

Note 8 — Commitments and contingencies

Manufacturing Commitment

On June 28, 2022, Eureka and the Company entered into the License Agreement under which Eureka granted to the Company a license under certain intellectual property controlled by Eureka for exploitation by the Company in the Company's territory under the License Agreement (the "Licensed Territory"). Eureka will be solely responsible for the manufacture and supply of clinical quantities of the licensed products and final filled and finished (including packaged) drug product form of the licensed products for development and commercialization purposes in the field both in the Licensed Territory and elsewhere. Refer to Note 9.

Equity Financing Commitment

On April 20, 2023, UPTD entered into a Common Stock purchase agreement (as amended on April 26, 2023 and from time to time, the "Common Stock Purchase Agreement") and a related registration rights agreement (the "White Lion RRA") with White Lion. Pursuant to the Common Stock Purchase Agreement, following the Closing, the Company has the right, but not the obligation to require White Lion to purchase, from time to time, up to $50,000,000 in aggregate gross purchase price of newly issued shares of Common Stock of the Company, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement, including, among others, the initial and any subsequent registration statement for the Equity Line Shares being declared effective by the SEC and remaining effective during the term of the Common Stock Purchase Agreement. In addition, under Nasdaq listing rules, the Company is not permitted to issue any Equity Line Shares under the Common Stock Purchase Agreement if such issuance would equal 20% or more of the Company's outstanding common stock without obtaining majority approval by our stockholders, which had not been obtained as of the date hereof. On December 28, 2023, the Company's registration statement on Form S-1 related to the Equity Line Shares was declared effective by the SEC. As of the date hereof, no Equity Line Shares have been issued to White Lion pursuant to the Common Stock Purchase Agreement.

Registration Rights

The holders of 312,200 shares of Common Stock that were issued to the initial stockholders of UPTD (the "Founder Shares") and of 1,107,500 shares of Common Stock issued to certain investors in a private placement in connection with UPTD's initial public offering (the "Private Shares") are entitled to registration rights pursuant to a Registration Rights Agreement, dated July 14, 2021, among UPTD, TradeUP Acquisition Sponsor LLC and certain security holders named therein. The Company assumed the obligations of UPTD under such agreement upon consummation of the Business Combination. The holders of the majority of these securities are entitled to make up to three demands, excluding short form demands, that the Company registers such securities. In addition, the holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to the completion of the initial Business Combination and rights to require the Company to register for resale such securities pursuant to Rule 415 under the Securities Act. The Company is also obligated to file a registration statement for the (i) Equity Line Shares that we may issue to White Lion pursuant to the Common Stock Purchase Agreement and White Lion RRA, (ii) up to 2,225,000 shares of Common Stock issuable upon exercise of the Warrants and (iii) the shares issued or that will be issued pursuant to the Subscription Agreements. The Company will bear the expenses incurred in connection with the filing of any such registration statements.

Contingencies

From time to time, the Company is or may be party to certain legal proceedings, as well as certain asserted and un-asserted claims. Amounts accrued, as well as the total amount of reasonably possible losses with respect to such matters, individually and in the aggregate, are not deemed to be material to the financial statements.

In some instances, the Company may be required to indemnify its licensors for the costs associated with any such adversarial proceedings or litigation. Third parties may assert infringement claims against the Company, its licensors or its strategic collaborators based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with the Company, its licensors or its strategic collaborators to enforce or otherwise assert their patent rights.

Collaboration Agreement

On October 29, 2021, Eureka, entered into a Collaboration Agreement with Imugene Ltd, a clinical stage immune-oncology company to evaluate Imugene's CF33-CD19t, its oncolytic virus onCARlytics technology in combination with Eureka's CD19 ARTEMIS® T-cell therapy for the treatment of solid tumors.

On June 28, 2022, as part of the Separation, Eureka contributed and assigned the Collaboration Agreement to Estrella. Pursuant to the Collaboration Agreement, Estrella and Imugene have each granted to the other a royalty free, non-exclusive, worldwide license, with the right to grant and authorize sublicenses, to their respective technologies to conduct the research activities each is responsible for performing under the research plan set forth in the Collaboration Agreement. The research plan is required to be reviewed no less frequently than every six to eight months by a joint steering committee comprised of participants from each of Estrella and Imugene.

Allocation of Costs, unless otherwise agreed by the Parties in connection with a given Research Plan and associated Research Budget:

(a) Eureka Costs: Eureka will be responsible for all FTE and other internal costs incurred in the performance of all Eureka Research Activities, as defined in the Collaboration Agreement;

(b) Imugene Costs: Imugene will be responsible for all FTE and other internal costs incurred in the performance of all Imugene Research Activities, as defined in the Collaboration Agreement; and

(c) Joint Costs: Eureka and Imugene will share equally (50:50) the out-of-pocket costs set forth in the applicable Research Budget plus Allowable Overruns, as defined in the Collaboration Agreement. If either Party incurs out-of-pocket costs in excess of the amount budgeted therefor in the applicable Research Budget plus Allowable Overruns, then the other Party will not be responsible for its 50% share to the extent in excess of such budgeted amount plus Allowable Overruns, unless the joint steering committee ("JSC") approves such excess costs (either before or after such costs have been incurred).

The research plan under the Collaboration Agreement was completed as of August 30, 2023. The Company and Eureka recorded the costs associated with the Collaboration Agreement as research and development expenses in the amount of $0 and $24,186, For the years ended June 30, 2024 and 2023, respectively.

On May 15, 2023, Estrella assigned a cost reimbursement receivable of $ 27,169 from Imugene under the Collaboration Agreement to Eureka. There was no impact on Estrella's statements of operations.

Note 9 — Related Party Transactions

License Agreement

On June 28, 2022, in connection with the Contribution Agreement, Eureka, Eureka Cayman and Estrella entered a License Agreement under which Eureka and Eureka Cayman granted to Estrella a license under certain intellectual property controlled by Eureka for exploitation by Estrella in the Licensed Territory, which primarily includes the United States and the rest of the world, excluding China and the Association of Southeast Asian Nations.

Pursuant to the License Agreement, (1) Eureka will be solely responsible for the manufacture and supply of clinical quantities of the licensed products and

final filled and finished (including packaged) drug product form of the licensed products ("Drug Product") for development and commercialization purposes in the field both in the Licensed Territory and elsewhere, and (2) during the term of the License Agreement, Eureka will manufacture and supply, either itself or through an affiliate or a third party contract manufacturer, all of Estrella's and its related parties' clinical quantities requirements of Drug Product for Estrella's and its related parties' development activities with respect to the licensed products in the field in the Territory conducted in accordance with this agreement. Eureka and Estrella will use good faith efforts to negotiate and enter into a clinical supply agreement on reasonable and customary terms for the supply of Drug Product by Eureka to Estrella at a price equal to the fully burdened cost (the "Clinical Supply Agreement"), and a related quality agreement, which agreements will govern the terms and conditions of the manufacturing and clinical supply of Drug Product to Estrella. Furthermore, Eureka and Estrella's collaboration will be overseen by a JSC. Eureka and Estrella will initially appoint one representative to the JSC, with each representative having knowledge and expertise in the development and commercialization of products similar to the licensed products and having sufficient seniority within the applicable party to provide meaningful input and make decisions arising within the scope of the JSC's responsibility.

The License Agreement requires Estrella to make certain payments, including (a) an "upfront" payment of $ 1,000,000, payable in 12 equal monthly installments, (b) "milestone" payments upon the occurrence of certain events related to development and sales, with potential aggregate multi-million dollar payments upon FDA approval, and (c) royalty payments of a single digit percentage on net sales.

As of June 30, 2024 and 2023, Estrella had remaining balance of account payable - related party amounted to $ 0 and $833,333, respectively, related to License Agreement's upfront payment. As of June 30, 2024, one development milestone payment in the amount of $50,000 related to the submission of EB103 to the FDA was earned by Eureka under the Agreement. Such amount was accrued by Estrella and outstanding as of June 30, 2023 and payment was made on October 10, 2023 with $0 outstanding as of June 30, 2024.

Services Agreement

On June 28, 2022, Estrella entered a Services Agreement with Eureka. Pursuant to the Services Agreement, Eureka will perform certain services for Estrella related the transfer of certain technology and the provision of certain technical assistance to facilitate Estrella's exploitation of the intellectual property licensed by Eureka to Estrella under the License Agreement, and Eureka will perform such services for Estrella (the "Services"). Under the Services Agreement, Estrella shall pay Eureka (1) $10,000,000 in connection with the Services payable in 12 equal monthly installments with the first payment to be made no later than five days after the Effective date and (2) reimburse Eureka on a monthly basis for reasonable pass-through costs incurred or paid to providers by Eureka in providing the Services. In addition, Estrella will be charged for other services performed by Eureka outside the scope of the Services per the Service Agreement, at a flat rate, by time or materials or as mutually agreed upon the parties in writing.

Eureka's service covered a period of 12 months and the service commenced on June 28, 2022. As of June 30, 2024 and June 30, 2023, Estrella had account payable balance - related party of $0 and $8,333,331 related to Service Agreement with Eureka, respectively.

As of June 30, 2024 and 2023, Estrella accrued $ 0 and $116,482 for pass-through costs related to clinical trials incurred by Eureka in account payable-related party, respectively.

For the years ended June 30, 2024 and 2023, Estrella incurred $ 54,957 and $116,482 pass-through costs related to clinical trials, respectively.

After the closing of the business combination on September 29, 2023, on October 10, 2023 Estrella remitted $ 9,334,475 to Eureka.

Statement of Work

On March 4, 2024, the Company, Estrella and Eureka entered into Statement of Work No. 001 ("SOW") relating to the clinical trial services to be performed by Eureka in connection with STARLIGHT-1, the Phase I/II clinical trial of Estrella's product candidate, EB103, a T-cell therapy targeting CD19 using ARTEMIS® T cell technology licensed by Estrella from Eureka. The trial is designed to assess the safety, tolerability, recommended Phase II dose, and preliminary anti-cancer activity of EB103 for the treatment of relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (NHL) patients.

The SOW is governed by the terms of the Services Agreement, dated June 28, 2022, between Estrella and Eureka (as amended by Amendment No. 1, effective as of October 1, 2022, and Amendment No. 2, effective as of March 1, 2023), and incorporates all the terms of the Services Agreement by reference. Notwithstanding the foregoing, the terms and conditions of the SOW govern in the event of any conflict with the terms and conditions of the Services Agreement.

The scope of work set forth in the SOW includes study start-up, patient dosing and related activities, study close-out, and reporting. Additionally, the SOW sets forth the various services Eureka will provide in connection with the clinical trial, including regulatory document development, site activation, patient enrollment and consent management, data collection, and pharmacovigilance.

Pursuant to the SOW, Estrella agrees to pay Eureka non-refundable net fees in connection with the achievement of certain milestones set forth in the SOW, with total fees of $33,000,000 for achievement of all milestones, excluding additional pass-through costs and expenses incurred by Eureka and payable by Estrella as further described below. Such amount assumes 20 patients to be dosed and one clinical site is activated. An additional $500,000 will become payable to Eureka if a second site is activated following mutual agreement of Estrella and Eureka. In addition to the milestone payments, Eureka will invoice Estrella quarterly for additional pass-through costs and expenses incurred in connection with its services under the SOW. Estrella is required to settle invoices within 30 days, with Eureka reserving the right to impose monthly interest charges of 1.5% for undisputed amounts unpaid after 30 days. Estrella will also be responsible for payment of any taxes, fees, duties or charges imposed by any governmental authority in connection with the services provided by Eureka under the SOW, other than any taxes on Eureka's income.

The first invoice payable to Eureka issuable upon execution of the SOW is for $ 3.5 million, covering the fees associated with the initiation of the study, the preparation and activation of the first study site, and the First Patient First Visit (FPFV) milestones. Prior to the commencement of the patient dosing phase, a deposit of $1.5 million is required to be delivered to Eureka to ensure the readiness for patient treatment expenses and will be applied against the final invoice, and any unused portion will be returned to Estrella following collection of all outstanding fees and costs payable to Eureka under the SOW. Additional invoices will be issued in connection with the patient dosing milestone, amounting to $1,375,000 per patient and a total cost $27,500,000 for 20 patients, excluding any pass-through costs and additional expenses. The SOW provides an estimated dosing timeline of 6 patients by the end of 2024 and an additional 14 patients by the end of 2025. Lastly, a $2,000,000 milestone fee will become due in connection with the study close-out phase, estimated to be completed by the end of 2025. Services provided in connection with this milestone include finalizing patient data, trial data cleaning, statistical analysis, and preparing and submitting the final study report.

As of June 30, 2024, Estrella has paid $ 3,500,000 to Eureka for covering the fees associated with milestones achieved.

ESTRELLA IMMUNOPHARMA, INC

Notes to Consolidated Financial Statements

On May 13, 2024, the Company and Eureka entered into Amendment No. 1 to the SOW, effective as of March 4, 2024, to clarify that in the event that Estrella exercises its right to terminate or suspend the engagement with Eureka by providing written notice to Eureka in accordance with the SOW, Estrella will only be obligated to compensate Eureka for (i) services provided by Eureka pursuant to the SOW ("Services") in connection with milestones that were achieved prior to the date and time of such written notice, (ii) reasonable and documented pass-through costs incurred by Eureka on behalf of Estrella prior to the date and time of such written notice in connection with providing the Services and (iii) amounts payable to third parties pursuant to commitments reasonably entered into by Eureka on behalf of Estrella prior to the date and time of such written notice in connection with providing the Services, provided that Eureka shall make commercially reasonable efforts to cancel or reduce any such amounts.

Series AA Preferred Stock

On June 28, 2022, Estrella and Eureka entered into the Contribution Agreement pursuant to which Eureka agreed to contribute and assign to Estrella all rights, title and interest in and to the Assets in exchange for 105,000,000 shares of Estrella's Series AA Preferred Stock (refer to Note 11). As of June 30, 2024 and 2023, Eureka collectively owned 69.7% and 92.1% of Estrella on a fully diluted basis, respectively.

Lease

On July 6, 2022, Estrella entered into an office lease contract with Eureka, to lease a 428 square feet office with a $ 2,000 payment. Under the original lease contract, the sublease agreement commenced on August 1, 2022 and expired on September 30, 2023. In November 2022, the sublease's expiration date was amended to July 31, 2023. Therefore, such lease contained a lease term for 12 months and less after amendment. Estrella elected not to apply the ROU and lease liability recognition requirements to above mentioned short-term lease as the modified lease term was less than twelve months. As a result of the lease amendment, Estrella then reduced the corresponding ROU and lease liability to $0 and continued to recognize the lease monthly payments in profit or loss on a straight-line basis over the remaining lease term period.

On October 1, 2023 Estrella entered into an office lease contract with Eureka, to lease 180 square feet of office space with $ 2,000 monthly lease payments for nine months without any renewal option.

For the years ended June 30, 2024 and 2023, the Company incurred $ 20,000 and $22,000 rent expense from Eureka. Refer to Note 14.

As of June 30, 2024 and 2023, the outstanding balance of lease payments of $ 4,000 and $22,000 was recorded as accrued liability - related party on the Company's consolidated balance sheets, respectively.

Note 10 — Promissory note

On September 29, 2023, Estrella issued an unsecured promissory note to Hongbing Zhang, in the aggregate principal amount of $ 300,000 (the "Unsecured Note"). Interest shall begin accruing on September 29, 2023 at a rate of 12% per annum until the outstanding amount has been paid in full. The Unsecured Note matures on October 30, 2023 and was paid in full on October 27, 2023.

Note 11 — Preferred Stock

Series AA Preferred Stock

On June 28, 2022, Estrella and Eureka entered into the Contribution Agreement pursuant to which Eureka contributed and assigned to Estrella all right, title and interest in and to the Assets in exchange for 105,000,000 shares of Estrella's Series AA Preferred Stock. In accordance with ASC 805 "Common control transactions." The transfer of the Assets was accounted for by Estrella at historical carrying values.

ESTRELLA IMMUNOPHARMA, INC

Notes to Consolidated Financial Statements

Series A Preferred Stock

On June 28, 2022, Estrella entered into a Series A Preferred Stock Purchase Agreement with an accredited third-party investor to raise gross proceeds of $5,000,000 by issuing 5,000,000 shares of its Series A Preferred Stock. The shares of Series A Preferred Stock were sold for $ 1.00 per share.

On each of July 31, 2023 and September 18, 2023, an aggregate of six third party investors executed joinders to Estrella's Series A Preferred Stock Purchase Agreement. Pursuant to the joinders, such investors agreed to purchase an aggregate of 9,250,000 shares of Estrella's Series A Preferred Stock for $9,250,000 immediately prior to the effective time of Estrella's merger with UPTD. Subsequently and immediately prior to the effective time of the merger with UPTD, such shares of Estrella's Series A Preferred Stock converted into Estrella Common Stock and then into Merger Consideration Shares based on an exchange ratio of 0.2407 determined by the total number of shares of Estrella Common Stock outstanding immediately prior to the Effective Time in accordance with the Merger Agreement. In addition, immediately prior to the Effective Time, 500,000 shares of Estrella's Series A Preferred Stock were issued to White Lion for $500,000 and 250,000 shares of Estrella's Series A Preferred Stock were issued to White Lion in consideration for its commitments under the Common Stock Purchase Agreement pursuant to the Joinder to the Series A Preferred Stock Purchase Agreement between Estrella and White Lion, dated April 20, 2023, as further described in Note 8 above.

The significant terms of the Series A, Series AA Preferred Stocks issued by Estrella are as follows:

Dividend Rights

Each holder of Preferred Stock shall be entitled to receive only when, as and if declared by the board of directors, out of any funds and assets legally available therefor, dividends on a pari passu basis at the rate of 8% of the original issue price of $ 1.00 per share. The dividend shall be non-cumulative and non-compounding.

Liquidation Rights

Series A Preferred Stock – In the event of any voluntary or involuntary liquidation, dissolution or winding up of Estrella, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of Estrella available for distribution to its stockholders or, in the case of a Deemed Liquidation Event (as defined below), out of the consideration payable to stockholders in such Deemed Liquidation Event or the Available Proceeds, before any payment shall be made to the holders of Series AA Preferred Stock or Common Stock by reason of their ownership thereof, and amount per share equal to the applicable Original Issue Price, plus any dividends declared but unpaid thereon.

Series AA Preferred Stock – After payment of the full liquidation preference of the Series A Preferred Stock, then in the event of any voluntary or involuntary liquidation, dissolution or winding up of Estrella, the holders of shares of Series AA Preferred Stock then outstanding shall be entitled to be paid out of the assets of Estrella available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, out of the consideration payable to stockholders in such Deemed Liquidation Event or the Available Proceeds. Before any payment shall be made to the holders of Common Stock by reason of their ownership, an amount per share equal to the applicable Original Issue Price, plus any dividends declare but unpaid thereon.

Distribution of Remaining Assets – If there are any remaining assets of the Estrella, such assets shall be distributed among the holders of the shares of Series A Preferred Stock and Common Stock, prorated based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock.

Voting Rights

Each holder of outstanding shares of Series A Preferred Stock shall be entitled to cast two (2) votes for each share of Series A Preferred Stock held by such holder and each holder of outstanding shares of Series AA Preferred Stock shall be entitled to cast one (1) vote for each share of Series AA Preferred Stock held by such holder. Except as provided by law or by the other provisions of the amended and restated certificate of incorporation, holders of Preferred Stock shall vote together with holders of Common Stock as a single class.

Conversion Rights

Each share of Preferred Stock shall be convertible, at the option of the holder at any time and from time to time, and without the payment of additional consideration by the holder into such number of fully paid and non – assessable shares of Common Stock as is determined by dividing the Original Issue Price by the Conversion Price in effect at the time of conversion. The Series A Conversion Price applicable to the Series A Preferred Stock shall initially be equal to $1.00. The Series AA Conversion Price applicable to the Series AA Preferred Stock shall initially be equal to $ 1.00. The Series A Conversion Price and the Series AA Conversion Price are referred to as "Conversion Price." The initial Conversion Prices and the rate at which shares of applicable Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment in connection with certain dilutive issuances, share split, combinations, dividends, distributions, recapitalizations, mergers, consolidations, reclassifications, exchanges, and substitutions.

Pursuant to the Estrella's amended and restated certificate of incorporation, holders of the Estrella's Preferred Stock have the following methods of conversion: Automatic conversion upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $1.00 per share (subject to appropriate adjustment in the event of any stock dividend, stock splits, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50,000,000 of gross proceeds to Estrella and in connection with such offering the Common Stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved by the board of directors or (b) the date and time, or the occurrence of an event, specified by vote or written consent of (i) the holders of at least a majority of the outstanding shares of Series A Preferred Stock and (ii) the holders of at least a majority of the outstanding shares of Series AA Preferred Stock, voting separately, then (x) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate (y) such shares may not be reissued by Estrella.

Redemption Rights

Both Series A Preferred Stock and Series AA Preferred Stock were mandatorily redeemable upon the occurrence of a "Deemed Liquidation Event" which includes the following: (1) a merger or consolidation in which (a) Estrella is a constituent party or (b) a subsidiary of Estrella is a constituent party and Estrella issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of Estrella outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (i) the surviving or resulting corporation; or (ii) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or (2) (a) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by Estrella or any subsidiary of Estrella of all or substantially all the assets of Estrella and its subsidiaries taken as a whole, or (b) the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of Estrella if substantially all of the assets of Estrella and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of Estrella.

Estrella shall use the consideration received by Estrella for such Deemed Liquidation Events mentioned above (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the board of directors of Estrella)**,** together with any other assets of Estrella available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "Available Proceeds"), to redeem all outstanding shares of Preferred Stock at a price per share equal to the applicable liquidation amount, which is equal to the original issue price of the Preferred Stock plus any declared but unpaid dividends. The Series A Preferred Stock must receive its liquidation amount prior to the Series AA Preferred Stock receives any payment.

The Series A Preferred Stock and the Series AA Preferred Stock were accounted for under Section 480-10-S99 — Distinguishing Liabilities from Equity (FASB Accounting Standards Codification 480) as amended by ASU 2009-04 — for Redeemable Equity Instruments ("ASU 2009-04"). Under ASU 2009-04, a redeemable equity security is to be classified as temporary equity if it is conditionally redeemable upon the occurrence of an event that is not solely within the control of the issuer. Therefore, the Company classified the Series A Preferred Stock and Series AA Preferred Stock as temporary equity in the consolidated balance sheet as of June 30, 2023.

Immediately prior to the consummation of the business combination on September 29, 2023, all shares of Estrella Series A and Series AA Preferred Stock were converted into Estrella Common Stock and each share of Estrella Common Stock was exchanged for shares of Common Stock at an exchange ratio of 0.2407.

Note 12 — Stockholders' Equity (Deficit)

Before reverse recapitalization

Given the consideration of retroactive adjustments, upon incorporation on March 20, 2022, the Company's authorized shares were 145,000,000 shares of Common Stock with a par value of $0.0001 per share.

After reverse recapitalization

Upon consummation of the business combination on September 29, 2023, each share of Estrella's Common Stock was converted into 0.2407 shares of the Company's Common Stock.

The Company's authorized shares of Common Stock is 250,000,000 with a par value of $ 0.0001 per share (the "Common Stock"). Given the retroactive effect of the reverse recapitalization, as of June 30, 2023, there were 978,243 shares of Common Stock issued and outstanding.

Issuance of Common Stock upon the reverse recapitalization (see Note 3)

On September 29, 2023, upon the consummation of the Business Combination, the Company issued an aggregate total of 1,701,232 Common Stock to UPTD's shareholders.

The following table presents the number of the Company's ordinary shares issued upon the Reverse Recapitalization:

	Ordinary Shares
UPTD's Common Stock outstanding prior to Reverse Recapitalization	2,329,920
Less: redemption of UPTD's Common Stock	(628,688)
Total shares issued upon the Reverse Recapitalization	1,701,232

Conversion of Series A Preferred Stock and the Series AA Preferred Stock

Immediately prior to the consummation of the business combination on September 29, 2023, all shares of Estrella Series A and Series AA Preferred Stock were converted into Estrella Common Stock and then into Merger Consideration Shares which is amounted to 28,888,675 shares of Common Stock based on an exchange ratio of 0.2407 determined by the total number of shares of Estrella Common Stock outstanding at the Effective Time in accordance with the Merger Agreement.

PIPE investment shares

In connection with the Merger, on September 14, 2023, UPTD entered into subscription agreements (the "Subscription Agreements") with each of Plentiful Limited, a Samoan limited company ("Plentiful Limited") and Lianhe World Limited ("Lianhe World," together with Plentiful Limited, collectively, the "PIPE Investors"). Concurrently with the closing of the Business Combination, the Company issued 500,000 shares of Common Stock to each of Plentiful Limited and Lianhe World, respectively, for aggregate proceeds of $10,000,000.

Within thirty days following the date of the Closing, each PIPE Investor will also be entitled to receive 704,819 shares of Common Stock. Within five days following the date that is 24 months following the Closing (the "24-Month Date"), if the VWAP of Common Stock for the fifteen trading days prior to the 24-Month Date (the "24-Month Date VWAP") is less than $8.30, then each of them will be entitled to a number of shares of Common Stock equal to (i) (A) 8.30 minus (B) the 24-Month Date VWAP multiplied by (ii) (A) the number of Shares held by the Investor on the 24-Month Date minus (B) the number of Shares acquired by the Investor following the Closing divided by 10.00.

On January 22, 2024, the Company completed the issuance of an additional 704,819 shares of Common Stock to each of the two PIPE Investors. The shares were issued as part of the consideration that each PIPE Investor was entitled to receive thirty days following the date of the closing of the Business Combination.

Warrants

In connection with the reverse recapitalization, the Company has assumed 2,214,993 Public Warrants outstanding. Public Warrants met the criteria for equity classification.

Each whole Warrant entitles the registered holder to purchase one whole share of the Company's Common Stock at a price of $ 11.50 per share. Pursuant to the warrant agreement, a warrant holder may exercise its Warrants only for a whole number of shares of Common Stock. This means that only a whole Warrant may be exercised at any given time by a warrant holder. No fractional Warrants will be issued upon separation of the Units and only whole Warrants will trade. The Warrants will expire five years after the completion of the Company's initial Business Combination, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

The Company has agreed that as soon as practicable, but in no event later than 30 business days, after the closing of the initial Business Combination, it will use its reasonable commercially reasonable efforts to file, and within 60 business days following its initial Business Combination to have declared

effective, a registration statement for the registration, under the Securities Act, of the shares of Common Stock issuable upon exercise of the Warrants. The Company will use its commercially reasonable efforts to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the Warrants in accordance with the provisions of the warrant agreement. 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 shares of Common Stock. Notwithstanding the above, if the Company's Common Stock is at the time of any exercise of a Warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, the Company may, at its option, require holders of Warrants who exercise their Warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event it so elect, it will not be required to file or maintain in effect a registration statement, but it will be required to use its commercially reasonable efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available.

Once the Warrants become exercisable, the Company may call the Warrants for redemption:

- in whole and not in part;
- at a price of $0.01 per Warrant;
- upon not less than 30 days' prior written notice of redemption (the " 30-day redemption period") to each warrant holder; and
- if, and only if, the reported last sale price of the Common Stock equals or exceeds $ 16.50 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending on third business day before the Company send the notice of redemption to the warrant holders.

The Company accounted for the 2,214,993 public Warrants assumed from the merger as equity instruments in accordance with ASC 480, "Distinguishing Liabilities from Equity" and ASC 815-40, "Derivatives and Hedging: Contracts in Entity's Own Equity".

Stock Repurchase Program

On January 30, 2024, the Company issued a press release announcing that its board of directors has authorized share repurchases of up to $ 1 million of its common stock. The authorization does not constitute a formal or binding commitment to make any share repurchases and the timing, amount and method of any share repurchases made pursuant to the authorization will be determined at a future date depending on market conditions and other factors. As of June 30, 2024, $645,560 remained available for repurchases.

For the year ended June 30, 2024, the Company repurchased 321,794 shares of its Common stock in open market transactions for $ 354,440 at a weighted average price per share of $1.10. The Company did not repurchase any shares of its Common stock during the same period in 2023.

Note 13 — Stock Based Compensation

At the special meeting of UPTD stockholders related to the Business Combination held on July 31, 2023, UPTD's shareholders approved the adoption of the Company's 2023 Omnibus Incentive Plan (the "2023 Plan"), which became effective on the Closing Date. Upon the closing of the Business Combination, 3,520,123 shares of Common Stock became authorized for issuance under the 2023 Plan. As of the date hereof, no shares of Common Stock have been issued under the Incentive Plan.

On May 27, 2022, Estrella's board of directors approved its 2022 Equity Incentive Plan (the "2022 Plan"). The 2022 Plan provides for the grant of (i) options, (ii) share appreciation rights, (iii) restricted share awards, (iv) restricted share unit awards, and (v) other share awards. The aggregate number of shares of Common Stock that may be issued pursuant to the 2022 Plan will not exceed 15,000,000 shares of Common Stock. On May 27, 2022, the Company granted options under the 2022 Plan to purchase 15,000,000 shares of its Common Stock to its employees, board of directors, and other consultants. The total fair value of these stock options was approximately $1,638,381.

The stock-based compensation expense recorded in the Company's results of operations. For the years ended June 30, 2024 and 2023 were $ 1,194,653 and $409,595, respectively.

The breakdown of stock-based compensation by categories for the years ended June 30, 2024 and 2023 are summarized below:

	For the Year Ended June 30, 2024	For the Year Ended June 30, 2023
Research and development	$ 453,968	$ 155,646
General and administrative	740,685	253,949
Total stock-based compensation	$ 1,194,653	$ 409,595

The intrinsic value of the granted options was approximately $ 1.6 million. Upon completion of the business combination on September 29, 2023, the unvested options were vested upon consummation of the merger, under which the Company recognized the remaining unrecognized fair value as expense.

The Company estimated the fair value of the stock options using the Black-Scholes option pricing model. The fair value of employee stock options issued was estimated using the following assumptions:

Grant date	May 27, 2022
Exercise price	$ 0.001
Estimated stock price	$ 0.11
Expected volatility	120.0%
Expected term (in years)	4.00
Risk-free interest rate	3.00%

The risk-free interest rate was obtained from U.S. Treasury rates for the applicable periods. The Company's expected volatility was based upon the implied volatility of a portfolio of comparable companies. The expected life of the Company's options was determined using the actual remaining life of the stock option. The fair value of the Common Stock input was determined by the board of directors based on a variety of factors, including valuation prepared by a third party, the Company's financial position, the status of development efforts within the Company, the current climate in the marketplace and the prospects of a liquidity event, among others.

For the year ended June 30, 2024, no additional stock options were granted.

On May 27, 2022, all employees, the board of directors, and other consultants elected to exercise the stock options granted by the Company early. The total proceeds received by the Company amounted to $15,000 and was recorded as other liability due to the terms of the early exercised shares, which are subject to repurchase until such shares are vested and are required to be returned to the Company if the vesting conditions are not satisfied. Such other liability account should be cleared at the time the exercised shares are vested or repurchased. As of June 30, 2024 and June 30, 2023, the unamortized balance of the above mentioned other liability amounted to $0 and $12,725, respectively, based on the vesting period.

A summary of early-exercised stock option's vesting activity for the years ended June 30, 2024 and 2023, are as follows:

	Number of Shares*	Weighted-Average Grant Date Fair Value per share
Balance of unvested early-exercised stock option at June 30, 2022	3,568,955	$ 0.46
Vested early-exercised stock option	(935,873)	$ 0.46
Balance of unvested early-exercised stock option at June 30, 2023	2,633,082	$ 0.46
Vested early-exercised stock option	(2,633,082)	$ 0.46
Balance of unvested early-exercised stock option at June 30, 2024	-	$ -

* Giving retroactive effect to reverse recapitalization effected on September 29, 2023 to reflect exchange ratio of approximately 0.2407 as described in Note 3

ESTRELLA IMMUNOPHARMA, INC

Notes to Consolidated Financial Statements

Note 14 — Income Taxes

The Company has no income tax expense except state minimum taxes, due to operating losses incurred for the years ended June 30, 2024 and 2023. Loss before income taxes were $7,310,098, and $11,114,402 for the year ended June 30, 2024 and 2023, respectively.

The provision for income taxes for the years ended June 30, 2024 and 2023 consisted of the following:

Income tax expense	For the year ended June 30, 2024	For the year ended June 30, 2023
Current income tax expense		
Federal	$ —	$ —
State	1,625	—
Total	$ 1,625	$ —

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows as of June 30, 2024 and 2023

	For the year ended June 30, 2024	For the year ended June 30, 2023
Statutory rate	21.0%	21.0%
State income tax rate	6.2%	-%
Stock-based compensation	(3.4)%	-%
Acquired Intangible	4.4%	-%
Research and development tax credit rate difference	-%	-%
Prior year true-ups	(1.9)%	0.6%
Changes in valuation allowance	(26.3)%	(21.6)%
Total	—	—

The Company's net deferred tax assets were as follows as of June 30, 2024 and 2023

	As of June 30, 2024	As of June 30, 2023
Deferred tax assets:		
Net operating loss carryover	$ 1,838,655	$ 354,895
Accruals and reserves	336	-
Stock-based compensation	-	93,183
Capitalized Research and development and intangibles	2,640,159	2,111,518
Total deferred tax assets	4,479,150	2,559,596
Valuation allowance	(4,479,150)	(2,559,596)
Deferred tax asset, net of allowance	$ —	$ —

As of June 30, 2024 and 2023, the Company had gross federal income tax net operating loss ("NOL") carry forwards of approximately $ 6.6 million and $1.7 million, respectively. As of June 30, 2024 and 2023, the Company had gross state income tax net operating loss ("NOL") carry forwards of approximately $6.5 million and $6.5 million, respectively. The federal net operating losses are carried forward indefinitely. The state net operating losses will begin to expire in 2042.

Under the Code, the NOL can be carried forward indefinitely and can be used to offset up to 80% of taxable income for losses arising in tax years beginning after June 30, 2022. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax asset will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during periods in which those temporary differences become deductible.

Due to the uncertainty surrounding the realization of the benefits of its deferred assets, including NOL carry forwards, stock-based compensation, research and development expense capitalization and federal research tax credit, the Company has provided a 100% valuation allowance on its deferred tax assets at June 30, 2024 and 2023. The valuation allowance increased from $2.6 million to $4.5 million in 2023. In terms of research and development expense capitalization attributed to deferred tax assets, the Company capitalized research and development expense of approximately $3.7 million and $10.3 million for the year end June 30, 2024 and 2023, respectively. The research and development expense capitalization were mainly derived from Eureka's license, service agreement and SOW would be amortized over 5 years for income tax purposes.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740, Income Taxes. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of June 30, 2024 and 2023, the Company had no uncertain tax positions, and no interest or penalties have been charged to the Company. If incurred, the Company will classify any interest and penalties as a component of interest expense and operating expense, respectively

The Company's ability to utilize the net operating loss and tax credit carryforwards in the future may be subject to substantial restrictions in the event of past or future ownership changes as defined in Section 382 of the Internal Revenue Code and similar state tax laws. In the event the Company should experience an ownership change, as defined under Section 382, utilization of the Company's net operating loss carryforward and tax credit could be limited.

The Company files corporation tax returns in the United States, California and other States. The Company has been in an overall net operating loss position since inception. Due to the significant federal and state tax attribute carryovers, the Company is subject to examination by taxing authorities for all tax years since inception.

Note 15 — Leases

On July 6, 2022, the Company entered into an office lease contract with Eureka, a related party ("Lease 1"). Under the original lease contract, the sublease agreement commenced on August 1, 2022 and expires on September 30, 2023. In November 2022, the sublease's expiration date was amended to July 31, 2023.

On October 1, 2023 Estrella entered into an office lease contract with Eureka, a related party ("Lease 2") for nine months without any renewal option.

The Company's office lease was classified as an operating lease. The Company's lease agreement does not contain any material residual value guarantees or material restrictive covenants.

The Company elected not to apply the ROU and lease liability recognition requirements to above mentioned short-term lease in accordance with ASC 842-20-25-2. As a result of the lease amendment, the Company then reduced the corresponding ROU and lease liability to $0 from Lease 1 and continued to recognize the lease monthly payments in profit or loss on a straight–line basis over the remaining lease term period.

Rent expense for the years ended June 30, 2024 and 2023 was $ 20,000 and $22,000, respectively.

Note 16 — Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date through the issuance date. Except as described below, there were no material subsequent events that required recognition or disclosure in the financial statements.

Stock Repurchase

From July 01, 2024 to September 20, 2024, the Company repurchased 98,180 shares of its Common Stock in open market transactions for $ 137,078 at a weighted average price per share of $1.40.

Office Sublease Agreement

On July 1, 2024, the Company entered into an office sublease agreement ("Sublease Agreement") with Eureka, a related party. Pursuant to the Sublease Agreement, the sublease commenced on July 1, 2024 and expires on December 31, 2024 with $2,000 sublease fee per month.

Consulting Agreement with One Nine

On July 3, 2024, the Company entered into a consulting agreement ("Consulting Agreement") with One Nine Limited (the "Consultant") with the Consultant to provide financing advice and service in connection with the sale of equity interests in the Company of no less than $30,000,000 on terms acceptable to the Company.

Development Milestones and Payments under the Licensing Agreement and Statement of Work #001

With the dosing of the first patient in July 2024 in the STARLIGHT-1 clinical trial, the development milestone pursuant to Section 8.2.1 (First Patient Dosed in the First Clinical Trial of a Licensed Product) in the Licensing Agreement with Eureka was met. As a result, Estrella made a payment of $ 50,000 to Eureka for this milestone. As of September 2024, two patients have been dosed in the STARLIGHT-1 clinical trial.

Appointment of Hong Zhang

In August 2024, Ms. Hong Zhang was appointed as a director and chairperson by the Board of Directors.

SIGNATURES

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

ESTRELLA IMMUNOPHARMA, INC.

Date: September 26, 2024

By: /s/ Cheng Liu
Name: Cheng Liu
Title: Chief Executive Officer

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

Name	Title	Date
/s/ Cheng Liu **Cheng Liu**	Chief Executive Officer and Director (Principal Executive Officer)	September 26, 2024
/s/ Peter Xu **Peter Xu**	Chief Financial Officer (Principal Financial and Accounting Officer)	September 26, 2024
/s/ Hong Zhang **Hong Zhang**	Chairperson and Director	September 26, 2024
/s/ Marsha Roberts **Marsha Roberts**	Director	September 26, 2024
/s/ Fan Wu **Fan Wu**	Director	September 26, 2024
/s/ Janelle Wu **Janelle Wu**	Director	September 26, 2024
/s/ Pei Xu **Pei Xu**	Director	September 26, 2024

Exhibit 4.5

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

DESCRIPTION OF CAPITAL STOCK

The following summary sets forth the material terms of our securities. The following summary is not intended to be a complete summary of the rights and preferences of such securities, and is qualified by reference to our amended and restated certificate of incorporation ("Amended Charter") and our amended and restated bylaws, a copy of each of which is filed as an exhibit to our Annual Report on Form 10-K of which this description forms a part. We urge you to read the Amended Charter and our amended and restated bylaws in their entirety for a complete description of the rights and preferences of our securities.

Authorized and Outstanding Stock

The Amended Charter authorizes the issuance of 260,000,000 shares, consisting of 250,000,000 shares of common stock, par value of $0.0001 per share ("Common Stock"), and 10,000,000 shares of preferred stock, par value of $0.0001 per share. As of September 20, 2024, there were 36,190,896 shares of Common Stock issued and outstanding. No shares of preferred stock are currently outstanding.

Common Stock

The Amended Charter provides the following with respect to the rights, powers, preferences, and privileges of the Common Stock.

Voting Power

Except as otherwise provided herein or expressly required by law, each holder of the Common Stock is entitled to one vote per share on matters to be voted on by stockholders. The holders of the Common Stock possess all voting power for the election of Estrella's directors and all other matters requiring stockholder action.

Dividends

Subject to applicable law and the rights and preferences of any holders of any outstanding series of preferred stock, holders of the Common Stock will be entitled to receive dividends when, as, and if declared by the Estrella Board in accordance with applicable law, in its discretion, out of funds legally available therefor. Estrella has not historically paid any cash dividends on its Common Stock to date and does not intend to pay cash dividends in the foreseeable future. Any payment of cash dividends in the future will be dependent upon Estrella's revenues and earnings, if any, capital requirements, and general financial conditions. In no event will any stock dividends, stock splits, or combinations of shares be declared or made on the Common Stock unless the shares of the Common Stock at the time outstanding are treated equally and identically.

Liquidation, Dissolution, and Winding Up

Subject to the rights and preferences of the holders of the shares of any outstanding series of preferred stock, in the event of a voluntary or involuntary liquidation, dissolution, or winding up of Estrella, the funds and assets of Estrella that may be legally distributed to Estrella's stockholders shall be distributed among the holders of then outstanding the Common Stock *pro rata* in accordance with the number of shares of the Common Stock held by each such holder.

Preemptive or Other Rights

There are no sinking fund provisions applicable to the Common Stock.

Preferred Stock

The Amended Charter provides that shares of preferred stock may be issued from time to time in one or more series. The Estrella Board will be authorized to fix designations, powers, including voting powers, full or limited, or no voting powers, preferences, and the relative participating, optional or other special rights of the shares of each series of preferred stock and any qualifications, limitations, and restrictions thereof. The Estrella Board will be able to, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of the Common Stock and could have anti-takeover effects. The ability of the Estrella Board to issue preferred stock without stockholder approval could have the effect of delaying, deferring, or preventing a change of control of Estrella or the removal of existing management. Estrella has no preferred stock currently outstanding.

Warrants

Each whole Warrant entitles the registered holder to purchase one whole share of our Common Stock at a price of $11.50 per share, subject to adjustment as discussed below.. Pursuant to the warrant agreement, a warrant holder may exercise its Warrants only for a whole number of shares of Common Stock. This means that only a whole Warrant may be exercised at any given time by a warrant holder. No fractional Warrants will be issued upon separation of the units and only whole Warrants will trade. The warrants will expire on October 2, 2028, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

We will not be obligated to deliver any shares of Common Stock pursuant to the exercise of a Warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the shares of Common Stock underlying the Warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration or a valid exemption from registration is available. No Warrant will be exercisable and we will not be obligated to issue shares of Common Stock upon exercise of a Warrant unless Common Stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the Warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a Warrant, the holder of such Warrant will not be entitled to exercise such Warrant and such Warrant may have no value and expire worthless. In no event will we be required to net cash settle any Warrant.

We have agreed that as soon as practicable, but in no event later than 30 business days, after October 2, 2023, we will use our commercially reasonable efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the shares of Common Stock issuable upon exercise of the Warrants, and we will use our commercially reasonable efforts to cause the same to become effective within 60 business days of October 2, 2023, and to maintain the effectiveness of such registration statement and a current prospectus relating to those shares of Common Stock until the Warrants expire or are redeemed, as specified in the warrant agreement; provided that if our Common Stock is at the time of any exercise of a

Warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, we may, at our option, require holders of Warrants who exercise their Warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event we so elect, we will not be required to file or maintain in effect a registration statement, but we will use our commercially reasonable efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available. If a registration statement covering the shares of Common Stock issuable upon exercise of the Warrants is not effective by the 60th day October 2, 2023, warrant holders may, until such time as there is an effective registration statement and during any period when we will have failed to maintain an effective registration statement, exercise Warrants on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act or another exemption, but we will use our commercially reasonable efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available. In such event, each holder would pay the exercise price by surrendering the warrants for that number of common stocks equal to the quotient obtained by dividing (x) the product of the number of common stocks underlying the warrants, multiplied by the excess of the "Fair Market Value" (defined below) less the exercise price of the warrants by (y) the Fair Market Value. The "Fair Market Value" as used in this paragraph shall mean the volume weighted average price of the common stocks for the 10 trading days ending on the trading day prior to the date on which the notice of exercise is received by the warrant agent.

Redemption of Warrants when the price per share of Common Stock equals or exceeds $16.50.

Once the warrants become exercisable, we may redeem the outstanding warrants:

- in whole and not in part;
- at a price of $0.01 per Warrant;
- upon a minimum of 30 days' prior written notice of redemption to each warrant holder; and
- if, and only if, the closing price of our Common Stock equals or exceeds $16.50 per share (including adjustments to the number of shares issuable upon exercise or the exercise price of a Warrant as described under the heading "— Warrants — Anti-Dilution Adjustments") for any 20 trading days within a 30-trading day period ending third business day before we send the notice of redemption to the warrant holders.

We will not redeem the Warrants as described above unless a registration statement under the Securities Act covering the issuance of shares of Common Stock issuable upon exercise of the Warrants is then effective and a current prospectus relating to those shares of Common Stock is available throughout the 30-day redemption period. If and when the Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws.

We have established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the Warrants, each warrant holder will be entitled to exercise its Warrant prior to the scheduled redemption date. However, the price of shares of our Common Stock may fall below the $16.50 redemption trigger price (including adjustments to the number of shares issuable upon exercise or the exercise price of a warrant as described under the heading "— Warrants — Anti-dilution Adjustments") as well as the $11.50 (for whole shares) warrant exercise price after the redemption notice is issued.

No fractional shares of Common Stock will be issued upon exercise. If, upon exercise, a holder would be entitled to receive a fractional interest in a share, we will round down to the nearest whole number of shares of Common Stock to be issued to the holder. If, at the time of redemption, the Warrants are exercisable for a security other than the Common Stock pursuant to the warrant agreement, the Warrants may be exercised for such security. At such time as the warrants become exercisable for a security other than shares of Common Stock, the Company will use its commercially reasonable efforts to register under the Securities Act the security issuable upon the exercise of the Warrants.

Redemption procedures.

A holder of a Warrant may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 9.8% (or such other amount as a holder may specify) of shares of Common Stock issued and outstanding immediately after giving effect to such exercise.

Anti-Dilution Adjustments.

If the number of outstanding shares of Common Stock is increased by a capitalization or share dividend paid in shares of Common Stock to all or substantially all holders of share of Common Stock, or by a split-up of shares of Common Stock or other similar event, then, on the effective date of such capitalization or share dividend, split-up or similar event, the number of common stocks issuable on exercise of each Warrant will be increased in proportion to such increase in the outstanding shares of Common Stock. A rights offering made to all or substantially all holders of shares of Common Stock entitling holders to purchase common stocks at a price less than the "historical fair market value" (as defined below) will be deemed a share dividend of a number of shares of Common Stock equal to the product of (i) the number of shares of Common Stock actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for shares of Common Stock) and (ii) one minus the quotient of (x) the price per share of Common Stock paid in such rights offering and (y) the historical fair market value. For these purposes, (i) if the rights offering is for securities convertible into or exercisable for shares of Common Stock, in determining the price payable for shares of Common Stock, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) "historical fair market value" means the volume weighted average price of shares of Common Stock as reported during the 10 trading day period ending on the trading day prior to the first date on which the shares of Common Stock trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the Warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to all or substantially all of the holders of shares of our Common Stock on account of such shares of Common Stock (or other securities into which the warrants are then convertible), other than (a) as described above, or (b) any cash dividends or cash distributions which, when combined on a per share basis with all other cash dividends and cash distributions paid on the shares of Common Stock during the 365-day period ending on the date of declaration of such dividend or distribution, does not exceed $0.50 (as adjusted to appropriately reflect any other adjustments and excluding cash

dividends or cash distributions that resulted in an adjustment to the exercise price or to the number of shares of Common Stock issuable on exercise of each Warrant) but only with respect to the amount of the aggregate cash dividends or cash distributions equal to or less than $0.50 per share.

If the number of outstanding shares of Common Stock is decreased by a consolidation, combination, reverse share split or reclassification of shares of Common Stocks or other similar event, then, on the effective date of such consolidation, combination, reverse share split, reclassification or similar event, the number of common stocks issuable on exercise of each Warrant will be decreased in proportion to such decrease in issued and outstanding Common Stock.

Whenever the number of shares of Common Stock purchasable upon the exercise of the Warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of Common Stocks purchasable upon the exercise of the warrants immediately prior to such adjustment and (y) the denominator of which will be the number of shares of Common Stock so purchasable immediately thereafter.

In case of any reclassification or reorganization of the issued and outstanding shares of Common Stock (other than those described above or that solely affects the par value of such shares of common stock), or in the case of any merger or consolidation of us with or into another entity (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our issued and outstanding shares of common stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the registered holders of the Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the Warrants and in lieu of the shares of Common Stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of common stocks or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the warrants would have received if such holder had exercised their warrants immediately prior to such event.

The Warrants were issued in registered form under a warrant agreement between VStock Transfer, LLC, as warrant agent, and us. The warrant agreement provides that the terms of the Warrants may be amended without the consent of any holder for the purpose of (i) curing any ambiguity or correct any mistake, including to conform the provisions of the warrant agreement to the description of the terms of the warrants and the warrant agreement set forth in this prospectus, or defective provision (ii) amending the provisions relating to cash dividends on common stocks as contemplated by and in accordance with the warrant agreement or (iii) adding or changing any provisions with respect to matters or questions arising under the warrant agreement as the parties to the warrant agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of the Warrants. You should review a copy of the warrant agreement, which will be filed as an exhibit to the registration statement of which this prospectus is a part, for a complete description of the terms and conditions applicable to the Warrants.

The warrant holders do not have the rights or privileges of holders of our Common Stock and any voting rights until they exercise their warrants and receive common stocks. After the issuance of shares of Common Stock upon exercise of the Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

We have agreed that, subject to applicable law, any action, proceeding or claim against us arising out of or relating in any way to the warrant agreement will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and we irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim. This provision does not apply to suits brought to enforce any liability or duty created under the Exchange Act or any claim for which the federal district courts of the United States of America are the sole and exclusive forum.

Anti-Takeover Provisions

Amended Charter and Amended Bylaws

Among other things, the Amended Charter and the Amended Bylaws (as amended from time to time) will:

- permit the Estrella Board to issue up to 10,000,000 shares of preferred stock, with any rights, preferences, and privileges as they may designate, including the right to approve an acquisition or other change of control;
- provide that the number of directors of Estrella may be changed only by resolution of the Estrella Board;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may be removed only for cause by the holders of two-thirds (66 and 2/3%) of the voting power of all of the then outstanding shares of voting stock of Estrella entitled to vote generally at an election of directors;
- provide that all vacancies, subject to the rights of any series of preferred stock, including newly created directorships, may, except as otherwise required by law, be filled exclusively by the affirmative vote of a majority of the directors then in office, even though less than a quorum, or by a sole remaining director;
- provide that stockholders seeking to present proposals before a meeting of stockholders or seeking to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and specify requirements as to the form and content of such notice;
- provide that special meetings of Estrella's stockholders may be called by the Estrella Board; and
- provide that the Estrella Board will be divided into three classes of directors, with only one class of directors being elected each year and each individual director serving a three-year term (see the section titled "*Management of Estrella*"), therefore making it more difficult for stockholders to change the composition of the board of directors.

The combination of these provisions will make it more difficult for the existing stockholders to replace the Estrella Board or for another party to obtain control of Estrella by replacing the Estrella Board. Because the Estrella Board will have the power to retain and discharge its officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock will make it possible for the Estrella Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of Estrella.

These provisions are intended to enhance the likelihood of continued stability in the composition of the Estrella Board and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce Estrella's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for Estrella's shares and may have the effect of delaying changes in our control or management. As a consequence, these

provisions may also inhibit fluctuations in the market price of Estrella's securities.

Certain Anti-Takeover Provisions of Delaware Law

Estrella is currently subject to the provisions of Section 203 of the DGCL. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of a corporation's assets. However, the above provisions of Section 203 would not apply if:

- the relevant board of directors approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of the corporation's voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the initial business combination is approved by the board of directors and authorized at a meeting of the corporation's stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

These provisions may have the effect of delaying, deferring, or preventing changes in control of Estrella.

Our Transfer Agent and Warrant Agent

The transfer agent for our common stock and warrant agent for our warrants is VStock Transfer, LLC 18 Lafayette Place Woodmere, NY 11598.

Listing of Securities

Our common stock and warrants are listed on Nasdaq under the symbols "ESLA" and "ESLAW," respectively.

Exhibit 31.1

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

I, Cheng Liu, certify that:

1. I have reviewed this Annual Report on Form 10-K of Estrella Immunopharma, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: September 26, 2024

By: /s/ Cheng Liu
Cheng Liu
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Peter Xu, certify that:

1. I have reviewed this Annual Report on Form 10-K of Estrella Immunopharma, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: September 26, 2024

By: /s/ Peter Xu
Peter Xu
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Estrella Immunopharma, Inc. (the "Registrant") on Form 10-K for the fiscal year ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, in the capacity and on the date indicated below, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: September 26, 2024

By: /s/ Cheng Liu
Cheng Liu
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Estrella Immunopharma, Inc. (the "Registrant") on Form 10-K for the fiscal year ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, in the capacity and on the date indicated below, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: September 26, 2024

By: /s/ Peter Xu
Peter Xu
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

ESTRELLA IMMUNOPHARMA, INC.

INCENTIVE BASED COMPENSATION RECOUPMENT POLICY

Effective as of October 2, 2023

1. Purpose. The purpose of the Estrella Immunopharma, Inc. Incentive Based Compensation Recoupment Policy (the " ***Policy***") is to set forth the circumstances in which Estrella Immunopharma, Inc. (the "***Company***") will recover the amount of Erroneously Awarded Compensation (as defined below) received by a current or former Executive Officer (as defined below) in the event that the Company is required to prepare an Accounting Restatement (as defined below).

2. Definitions. For purposes of this Policy, the following terms have the definitions set forth below:

A. "***Accounting Restatement***" shall mean the required revision of a previously issued financial statement for correction of an error in such financial statement that is (i) due to the material noncompliance of the Company with any applicable financial reporting requirement under the U.S. federal securities laws, including any required accounting restatement to correct an error in a previously issued financial statement that is material to such previously issued financial statement, or (ii) not material to a previously issued financial statement, but would result in a material misstatement if the error were corrected in the current period (i.e., as of the time of the Accounting Restatement) financial statements or left uncorrected in the current period financial statements.

B. "***Board***" shall mean the Board of Directors of the Company.

C. "***Committee***" shall mean the Compensation Committee of the Board, or in the absence of such committee, a group constituting the majority of the Board's independent directors.

D. "***Erroneously Awarded Compensation***" shall mean, with respect to each Executive Officer and in connection with any Accounting Restatement, the amount of Incentive Based Compensation received by such Executive Officer that exceeds the amount of Incentive Based Compensation that would have been received by such Executive Officer had it been determined based on the restated amounts set forth in the Accounting Restatement.

E. "***Executive Officer***" shall mean each individual designated as an "officer" of the Company in accordance with 17 C.F.R. 240.16a-1(f). Identification of an executive officer for purposes of this Policy would include, at a minimum, executive officers identified pursuant to 17 C.F.R. 229.401(b).

F. "***Financial Reporting Measures***" means financial measures that are used for evaluating the attainment of Incentive Based Compensation and that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, as well as any financial measures that are derived wholly or in part from such measures. For purposes of this Policy, the Company's stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the SEC.

G. "***Incentive Based Compensation***" means compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive Based Compensation is deemed received by an Executive Officer in the Company's fiscal year during which the Financial Reporting Measure specified in the Incentive Based Compensation award is attained, even if the payment or grant of the Incentive Based Compensation occurs after the end of that period.

H. "***Nasdaq***" shall mean the Nasdaq Stock Market LLC.

I. "***Required Restatement Date***" shall mean the earlier to occur of (i) the date upon which the Board, the Committee or the officers of the Company authorized to take such action, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date upon which a court, regulator or other legally authorized body directs the issuer to prepare an Accounting Restatement in a final, non-appealable order or judgment.

J. "***SEC***" shall mean the U.S. Securities and Exchange Commission.

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3. Application.

A. This Policy applies to all Incentive Based Compensation received by a current and former Executive Officer: (i) on or after October 2, 2023; (ii) after beginning service as an Executive Officer; (iii) who served as an Executive Officer at any time during the performance period for which Incentive Based Compensation was received; (iv) while the Company has a class of securities listed on a national securities exchange or a national securities association; and (v) during the three completed fiscal years immediately preceding the Required Restatement Date.

B. Notwithstanding Paragraph A of this Section 3, this Policy applies during any transition period that results from a change in the Company's fiscal year within or immediately following the three completed fiscal year period. For the avoidance of doubt any transition period between the last day of the Company's previous fiscal-year end and the first day of its new fiscal year that comprises a period of nine to 12 months would be deemed a completed fiscal year.

C. For the avoidance of doubt, references to Executive Officer throughout this Policy shall be read to refer to current or former Executive Officers in accordance with this Section 3, unless otherwise noted.

4. Recovery of Erroneously Awarded Incentive Based Compensation.

A. In the event of an Accounting Restatement, the Company shall promptly determine the amount of any Erroneously Awarded Compensation for each Executive Officer in connection with such Accounting Restatement and shall provide written notice to each Executive Officer of (i) the Required Restatement Date, (ii) the amount of Erroneously Awarded Compensation received, and (iii) the method, manner, and time for repayment or return or such Erroneously Awarded Compensation, as applicable. The amount of Incentive Based Compensation that is subject to recovery will be computed without regard to any taxes paid.

B. The Committee shall have the discretion to reasonably determine the appropriate means of recovery of such Erroneously Awarded Compensation based on applicable facts and circumstances. If an Executive Officer fails to repay Erroneously Awarded Compensation to the Company by the time and in the manner set forth in writing by the Committee, the Company shall take all actions reasonable and appropriate to recover the Erroneously Awarded Compensation from the Executive Officer. The Executive Officer shall be required to reimburse the Company for all expenses and attorney's fees reasonably incurred by the Company in recovering Erroneously Awarded Compensation to the extent permitted under applicable law.

C. For Incentive Based Compensation based on the Company's stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement:

i. the amount will be based on a reasonable estimate of the effect of the accounting restatement on the Company's stock price or total shareholder return upon which the Incentive Based Compensation was received; and

ii. the Company will maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq.

5. Recovery Exceptions. The Company will recover Erroneously Awarded Compensation in accordance with this Policy, except to the extent that any of the following conditions are met and applicable, and the Committee has determined that recovery would be impracticable:

A. the direct expense reasonably expected to be paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; *provided* that before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on the expense of enforcement, the Company will make a reasonable attempt to recover such Erroneously Awarded Compensation without incurring any third party expense, document such reasonable attempt(s) to recover and provide such documentation to Nasdaq;

B. recovery would violate home country law, applicable where the Company is incorporated outside of the United States, and that law was adopted prior to November 28, 2022; *provided* that before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company will obtain an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and provide such opinion to Nasdaq; or

C. recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

6. Reporting and Disclosure Requirements. The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by the applicable SEC filings.

7. Indemnification Prohibition. The Company will not indemnify any current or former Executive Officer against any losses stemming from the application of this Policy to Erroneously Awarded Compensation.

8. Other Recoupment Rights. This Policy is not intended to limit the Company's ability to pursue equitable relief or other means to recover monetary damages resulting from an Executive Officer's wrongdoing. The Company retains all rights it may have under applicable law.

9. Administration. The Committee shall have sole discretion in making all determinations under this Policy. Any determinations of the Committee shall be binding on the Executive Officer.

10. Amendment. This Policy may be amended from time to time in the Committee's sole discretion.

11. Compliance with the Exchange Act. Notwithstanding the foregoing, this Policy shall be interpreted and administered consistent with the applicable securities laws, including the requirements of (i) Section 10D of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), as added by Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, (ii) Rule 10D-1 under the Exchange Act, and (iii) the listing standards adopted by Nasdaq pursuant to Rule 10D-1, and, to the extent this Policy is in any manner deemed inconsistent with such requirements, this Policy shall be treated as retroactively amended to be compliant with such requirements.