UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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 001-41583

Coya Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-4017781**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5850 San Felipe St., Suite 500 Houston, TX	**77057**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (800) 587-8170

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	COYA	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 the shares of common stock on the Nasdaq Capital Market on June 30, 2023, was approximately $36,439,109.

The number of shares of Registrant's common stock outstanding as of March 11, 2024 was 14,542,579.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2024 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference in Part III of this Form 10-K.

Auditor Firm Id: 410 Auditor Name: Weaver and Tidwell, L.L.P. Auditor Location: Austin, Texas

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements made under the headings "Summary," "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K contain forward-looking statements that reflect our plans, beliefs, expectations and current views with respect to, among other things, future events and financial performance.

Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts and are often characterized by the use of words such as "believe," "can," "could," "potential," "plan," "predict," "goals," "seek," "should," "may," "may have," "would," "estimate," "continue," "anticipate," "intend," "expect" or by discussions of strategy, plans or intentions. Such forward-looking statements involve known and unknown risks, uncertainties, assumptions and other important factors that could cause our actual results, performance or achievements, or industry results, to differ materially from historical results or any future results, performance or achievements expressed, suggested or implied by such forward-looking statements. These include, but are not limited to, statements about:

- our ability to develop, obtain regulatory approval for and commercialize our product candidates;
- the timing of future investigational new drug ("IND") submissions, initiation of preclinical studies and clinical trials, and timing of expected clinical results for our product candidates;
- our success in early preclinical studies, which may not be indicative of results obtained in later studies or clinical trials;
- the outbreak of public health emergencies, epidemics, pandemics (like COVID-19), which could adversely impact our business, including our preclinical studies and any future clinical trials;
- the potential benefits of our product candidates;
- our ability to identify patients with the diseases treated by our product candidates, and to enroll patients in clinical trials;
- the success of our efforts to expand our pipeline of product candidates and develop marketable products through the use of our potential therapeutic modalities;
- our expectations regarding collaborations and other agreements with third parties and their potential benefits;
- our ability to obtain, maintain and protect our intellectual property;
- our reliance upon intellectual property licensed from third parties;
- our ability to identify, recruit and retain key personnel;
- our expected use of net proceeds from our initial public offering and the sufficiency of such net proceeds, together with our cash and cash equivalents, to fund our operations;
- our financial performance;
- developments or projections relating to our competitors or our industry;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; and
- other factors and assumptions described in this Annual Report on Form 10-K under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Our Business", and elsewhere in this Annual Report on Form 10-K.

These statements are based on our historical performance and on our current plans, estimates and projections in light of information currently available to us, and therefore you should not place undue reliance on them. The inclusion of this forward-looking information should not be regarded as a representation by us, the underwriters or any other person that the future plans, estimates or expectations contemplated by us will be achieved. Forward-looking statements made in this Annual Report on Form 10-K speak only as of the date of this Annual Report on Form 10-K, and we undertake no obligation to update them in light of new information or future events, except as required by law.

You should carefully consider the above factors, as well as the factors discussed elsewhere in this Annual Report on Form 10-K, including under "Risk Factors," before deciding to invest in our securities. The factors identified above should not be construed as an exhaustive list of factors that could affect our future results and should be read in conjunction with the other cautionary statements that are included in this Annual Report on Form 10-K. Furthermore, new risks and uncertainties arise from time to time, and it is impossible for us to predict those events or how they may affect us. If any of these trends, risks or uncertainties actually occurs or continues, our business, revenue and financial results could be harmed, the trading prices of our securities could decline and you could lose all or part of your investment. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by this cautionary statement.

PART I

ITEM 1. BUSINESS

All references in this report to "Coya," the "Company," "we," "us," or "our" mean Coya Therapeutics, Inc. unless stated otherwise or the context otherwise indicates.

Overview

We are a clinical-stage biotechnology company focused on developing proprietary new therapies to enhance the function of regulatory T cells ("Tregs"). Tregs are a subpopulation of T-lymphocytes consisting of CD4+CD25high hFOXP3+ cells that suppress inflammatory responses. Tregs were first discovered in 1995 by Dr. Shimon Sakaguchi and since their discovery, multiple lines of research have contributed to elucidate Treg biology and its role in health and disease. Tregs and their transcription factors have been shown to be essential to maintaining cellular homeostasis by regulating autoimmune and inflammatory responses and maintaining self-tolerance in mammals. Dysfunctional Tregs underlie numerous disease states, and this cellular dysfunction is driven by the chronic inflammatory environment and high levels of oxidative stress commonly observed in certain diseases. Further, the degree of Treg dysfunction is correlated with the severity and progression of serious and life-threatening conditions. These and other recent advances in the understanding of Treg biology, have made this subset of T-lymphocytes an important potential therapeutic target, which we believe may provide new treatments for serious diseases.

We have built a diversified product candidate pipeline that includes both *ex vivo* and *in vivo* approaches intended to restore the suppressive and immunomodulatory functions of Tregs. Our product candidate pipeline is based on our three distinct potential therapeutic modalities: Treg-enhancing biologics, Treg-derived exosomes, and autologous Treg cell therapy. "Autologous" means the treatment of a patient with human cells derived from the patient itself, whereas "Allogeneic" means the treatment of a patient with human cells derived from a donor other than the patient, where such donor is genetically non-identical. Our core focus is developing these therapies to target Treg dysfunction, which has been identified to be an important pathophysiological component of neurodegenerative, autoimmune, and metabolic diseases, where new and effective therapies are urgently needed.

Our lead assets are our Treg-enhancing biologics, which have been developed from key learnings established in our early work and discoveries of our autologous Treg cell therapy asset. Our autologous Treg cell therapy program has completed a Phase 1 and Phase 2a studies in amyotrophic lateral sclerosis, or ALS. The clinical data from these initial studies has served as an important confirmation of the underlying immunomodulatory properties of Tregs and their potential therapeutic benefits. These studies have also significantly expanded our own foundational knowledge of the biological activity of Tregs and key biomarkers of disease progression and drug effect, which we believe will be critical for the design of our future clinical and preclinical studies, the selection of future targeted diseases and the overall advancement of our development pipeline. We believe our findings have also established mechanistic benefits of combination biologics to address Treg dysfunction as well as highlighted important advantages of scalability and cost.

COYA 302 (our lead asset) is the combination of our proprietary low dose interleukin-2 (COYA 301, or LD IL-2) and the immunomodulatory drug CTLA4-Ig, and we believe this combination has the potential to provide a sustained and durable effect on our first series of indications (neurodegenerative disorders) through targeting of multiple pathways. Our research and clinical efforts have led us to believe that combination biologics using our LD IL-2 as a backbone modality could be the best way to treat neurodegenerative conditions that are inherently driven by a complexity of pathways. We believe COYA 302 represents the most clinically advanced of what we hope will be a family of combination therapies that all feature our LD IL-2. Moreover, given its growing list of indications, we can now refer to COYA 302 as a "Pipeline in a Product."

Our operations have consisted of developing our clinical and preclinical product candidates and we have devoted substantially all of our resources to developing product and technology rights, conducting research and development, organizing and staffing our company, business planning and raising capital. We have funded our operations primarily through the private and public sale of our securities. Our net losses were $8.0 million and $12.2 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $25.9 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and general and administrative expenditures. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our product candidates;

- initiate nonclinical studies and clinical trials for any additional product candidates that we may pursue;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- acquire or in-license other product candidates and technologies;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions. The financial statements included elsewhere in this Annual Report on Form 10-K have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business and do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Recent Developments

Development and License Agreement with Dr. Reddy's Laboratories

On December 5, 2023, we entered into a Development and License Agreement (the "DRL Development Agreement") with Dr. Reddy's Laboratories Ltd. ("DRL") and its affiliate, Dr. Reddy's Laboratories SA (collectively, "Dr. Reddy's"), pursuant to which, among other things, we granted to Dr. Reddy's an exclusive, royalty-bearing right and license to commercialize COYA 302 solely for use in patients with amyotrophic lateral sclerosis ("ALS") in the United States, Canada, the European Union and the United Kingdom (collectively, the "New Territories"). We previously granted Dr. Reddy's Laboratories Ltd. an exclusive license to obtain regulatory approval and commercialize COYA 302 for ALS and certain other indications in all other countries (other than the New Territories, Japan, Mexico, and in each country in South America), pursuant to the License and Supply Agreement entered with Dr. Reddy's Laboratories Ltd., effective as of April 1, 2023.

Upon execution of the DRL Development Agreement, Dr. Reddy's paid a non-refundable upfront payment of $7.5 million (the "DRL Upfront Payment"). Under the terms of the DRL Development Agreement, Dr. Reddy's will make development funding payments to us for development of COYA 302 as follows: (i) $4.2 million upon FDA acceptance of an Investigational New Drug ("IND") application for COYA 302 for the treatment of ALS and (ii) an additional $4.2 million payment upon the dosing of the first patient in the first phase 2 clinical trial for COYA 302 for the treatment of ALS in the United States. We anticipate that the IND filing will be made in the first half of 2024. The DRL Development Agreement also calls for up to an aggregate of $40.0 million in development milestones and up to an aggregate of $677.25 million in sales milestones, relating to the New Territories, should all such development and sales milestones be achieved. We will also be owed royalties by Dr. Reddy's on Net Sales (as defined in the DRL Development Agreement) of COYA 302 in the low to mid-teens (prior to paying royalties due pursuant to previously disclosed license agreements

related to COYA 302). We will have the responsibility for the clinical development of COYA 302 and for seeking regulatory approval in the United States for COYA 302 in ALS.

The foregoing summary of the DRL Development Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the DRL Development Agreement, which is filed as an exhibit to this Annual Report on Form 10-K for the year ended December 31, 2023.

Securities Purchase Agreement

On December 5, 2023, we entered into the Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of 4,370,382 shares of our common stock, or the 2023 Private Placement. The offering resulted in gross proceeds of approximately $26.5 million, at a price of $6.06 per share of common stock, before deducting placement agent commissions and other offering expenses. In connection with the 2023 Private Placement and as a form of payment for services provided by a co-placement agents and our financial advisor we issued warrants to purchase up to 319,004 shares of common stock at an exercise price of $7.58 per share. Such warrants have a term of four years from issuance, and will be exercisable beginning six months from the closing of the 2023 Private Placement.

The financing included participation by former U.S. Secretary of Commerce Wilbur Ross and other existing institutional investors. Secretary Ross joined the Board of Directors of Coya in January of 2024.

License Agreement with UneMed (the Technology Transfer Office of University of Nebraska Medical Center)

On February 13, 2024, we entered into a license agreement with UNeMed Corporation ("UNeMed"), the Technology Transfer Office of University of Nebraska Medical Center. The license covers the combination of COYA 301 with Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) and additional immune analogues and provides a next generation approach with a novel combination to synergistically modulate and reduce inflammation. UNeMed will receive payments upon achievement of certain milestones and will be eligible to receive tiered low single-digit royalty on net sales.

Proof of Concept Data

During the first half of 2023, our combination product for neurodegenerative diseases, or COYA 302, and our low dose IL-2, or COYA 301, showed positive results in a proof of concept (“POC”), open label study in ALS patients and in Alzheimer’s Disease ("Alzheimer's Disease" or “AD”), patients, respectively. Both POC studies were conducted with commercially available products as investigator-initiated trials.

The POC study in support of COYA 302, an open label study conducted in 4 ALS patients, evaluated the safety and tolerability, function of regulatory T-cells, biomarkers, and preliminary efficacy (as measured by the ALSFRS-R scale) utilizing commercially available IL-2 and abatacept. Study data showed no decline or minimal decline at 24 and 48 weeks respectively after initiation of treatment and appeared to be well tolerated in all study patients as no serious adverse events were reported. Twenty-four weeks is an important timepoint as this is the period that ALS studies are usually benchmarked to measure differences in the ALSFRS-R scale for a treatment versus placebo. Based on this POC data, we intend to design a well-powered and well-controlled study to demonstrate the safety and efficacy of COYA 302 (COYA 301 or low dose IL-2, plus an abatacept proposed biosimilar, licensed from Dr. Reddy's Laboratories, or DRL_AB) in patients with ALS and are preparing for an IND submission to the FDA in the first half of 2024. We intend to initiate a Phase 2 trial after the acceptance of our IND application by the FDA.

The POC study in support of COYA 301, an open label study conducted in 8 patients with AD, evaluated the safety and tolerability, biological activity, blood biomarkers, and preliminary efficacy of commercially available IL-2. Study data found that (i) cognitive function, as measured by 3 validated tools, either improved or did not decline, (ii) Treg function was significantly enhanced, (iii) pro-inflammatory blood cytokines and chemokines were significantly reduced with evidence of reduced neuroinflammation in the brain and (iv) the study treatment appeared to be well tolerated as no serious adverse events were reported. Currently, a double-blind, placebo-controlled, randomized trial is being conducted at Houston Methodist Hospital using low dose IL-2 in mild to moderate AD patients. We anticipate reporting top line data in Q3 2024. The study has enrolled 38 patients and is assessing Treg function, blood, and cerebrospinal fluid biomarkers, cognitive function, and safety.

We believe this study will strengthen support for COYA 302 (combination of low dose IL-2 and CTLA4-Ig) in AD; since the combination targets both the adaptive and innate immune system we would anticipate a more sustained and durable effect than just low dose IL-2 alone. This combination has been shown to have a sustained Treg anti-inflammatory suppressive function and an increase in Treg number when given to ALS patients. Further, this combination enhanced suppression of macrophage mediated oxidative stress and

proinflammatory cytokine biomarkers in this population. Taken together, we anticipate the results of the low dose IL-2 in AD as a proof of concept to support the combination therapy of COYA 302 in AD in addition to the planned studies in ALS, frontotemporal dementia ("FTD"), Parkinson's Disease ("PD"), and additional lifecycle programs in neurodegenerative disorders to be determined.

Pipeline Expansion

In January of 2024, we announced that we are expanding our pipeline in neurodegenerative conditions for COYA 302 beyond ALS to include FTD and PD. Our updated pipeline can be viewed below. More recently, in February of 2024, we announced our expansion of COYA 302 to AD. This expansion advances our approach of combination biologics with low dose IL-2 as a backbone which we believe may represent a new approach to target complex immune pathways in neurodegenerative diseases.

FTD, AD and PD share a similar disease pathogenesis to ALS that is associated with a heightened proinflammatory cascade involving dysfunctional Tregs and proinflammatory microglia and macrophages. We believe the biological redundancies in molecular immune pathways in these complex diseases limit the efficacy of many single drug therapies, requiring the development of novel therapeutics that can address this pathophysiologic complexity.

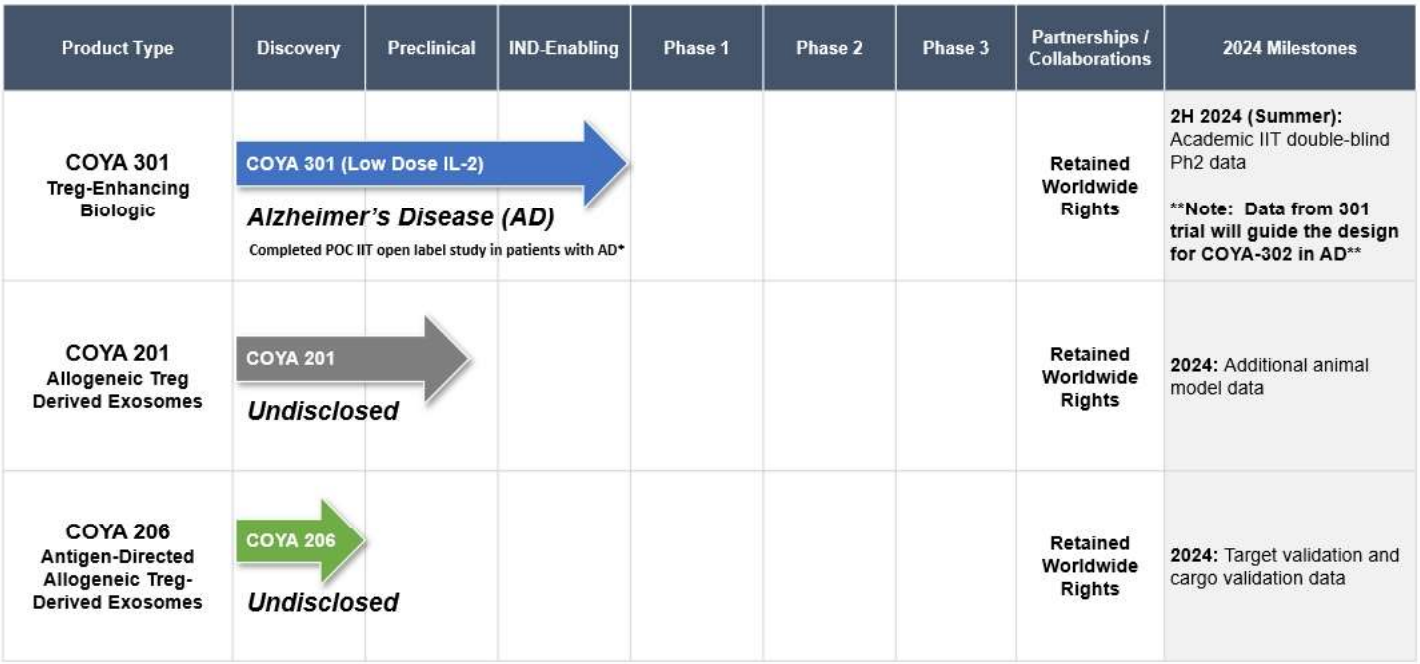
We intend to file an IND for COYA 302 for the treatment of FTD before the end of 2024. In addition, studies in animal models of PD are planned in 2024, and based on those studies, a subsequent IND filing is anticipated for the treatment of PD. We will await the results of the ongoing double-blind placebo-controlled trial being conducted by Dr. Appel of low dose IL-2, one of the key components of COYA 302, prior to determining our development plan for COYA 302 in AD patients.

Our Pipeline

The core of our approach and strategy is to leverage our Treg-modifying potential therapeutic modalities to advance the standard of care for neurodegenerative and autoimmune diseases. Building on our initial findings from our autologous Treg cell therapy modality, our goal is to offer patients therapies that improve outcomes of neurodegenerative, autoimmune, and metabolic diseases.

Product Type	Discovery	Preclinical	IND-Enabling	Phase 1	Phase 2	Phase 3	Partnerships / Collaborations	2024 Milestones
COYA 302 Treg-Enhancing / T Effector & Macrophage Depleting Biologics	COYA 302 (Low Dose IL-2 + CTLA4-Ig) → *Amyotrophic Lateral Sclerosis (ALS)* — Completed POC IIT open label study in patients with ALS*						Licensing Transaction on 12/6/23: Dr. Reddy's Laboratories	**1H 2024:** IND filing and Ph2 initiation upon IND acceptance **1H 2024:** PoC Peer-Reviewed publication **1H 2024:** Biomarker data publication
COYA 302 Treg-Enhancing / T Effector & Macrophage Depleting Biologics	COYA 302 (Low Dose IL-2 + CTLA4-Ig) → *Frontotemporal Dementia (FTD)*						Retained Worldwide Rights	**2H 2024:** IND filing and Ph2 initiation upon IND acceptance
COYA 302 Treg-Enhancing / T Effector & Macrophage Depleting Biologics	COYA 302 (Low Dose IL-2 + CTLA4-Ig) → *Alzheimer's Disease (AD)*						Retained Worldwide Rights	**2H 2024 (Summer)**: Academic IIT double-blind Ph2 data of Low dose Il-2 alone in AD
COYA 302 Treg-Enhancing / T Effector & Macrophage Depleting Biologics	COYA 302 (Low Dose IL-2 + CTLA4-Ig) → *Parkinson's Disease (PD)*						Retained Worldwide Rights	**1H/2H 2024:** Animal data **2025:** IND filing and Ph1/2 initiation upon IND acceptance

POC- Proof of Concept; IIT- Investigator Initiated Trial
* Conducted using commercially available products



Our Strategy

Our strategy is to discover, develop, manufacture, and commercialize proprietary medicinal products that enhance the function of Tregs. We intend for our product candidates to address unmet medical needs, principally in neurodegenerative, autoimmune, and metabolic diseases. We believe we can differentiate ourselves from other Treg companies by combining our understanding of Treg cell biology and the diseases where Treg cellular dysfunction is considered a likely driver of pathology with our three distinct potential therapeutic modalities: (i) Treg-enhancing biologics, (ii) Treg-derived exosomes, and (iii) autologous Treg cell therapy. Key elements of the Company's strategy include:

1. **Advance the development of COYA 302 (A Pipeline within a Product).** Our goal is to advance COYA 302, a biologic combination product candidate that aims to suppress inflammation via administration of a fusion protein (CTLA4-Ig) in conjunction with COYA 301, a biologic that aims to enhance Treg function. We believe this combination has synergistic impacts in enhancing Treg function. We aim to develop this combination in ALS and other neurodegenerative diseases including FTD, PD, and AD, and perhaps, in time, autoimmune diseases.

2. **COYA 301 as the backbone for combination therapies.** Our goal is to utilize COYA 301 our low dose IL-2 as the backbone in combination with other appropriate mechanisms, including CTLA4-Ig (COYA 302), and possibly GM-CSF, and other potential combinations to address various diseases.

3. **Leverage in-licensed technology to advance our Treg exosome therapies.** We expect to begin developing the next generation of our Treg exosome therapies ("COYA 206") utilizing technology we have in-licensed from Carnegie Mellon University which we believe may enable Treg exosomes to be homed to proteins of interest while delivering select payload into targeted cells. We believe COYA 206 provides a material advantage to our Treg-derived exosome potential therapeutic modality by allowing targeting of these exosomes to proteins of interest. There are diseases that may be driven by certain proteins and the ability to home in on these proteins may make COYA 206 more selective to that condition. Obtaining preclinical data illustrating this targeted approach is an important initiative for us.

4. **Actively pursue partnering opportunities for COYA 301 and COYA 302**. We consider the proof-of-concept data for COYA 302 and COYA 301 as encouragement to continue our development of these potential therapeutics, but also as encouragement to evaluate the merits of COYA 301 in combination with other potential therapeutic agents. We believe that business development opportunities may leverage COYA 301 as a backbone therapy in combination with other product candidates. We also believe that COYA 302 may be of interest to certain pharmaceutical companies that wish to expand their pipelines in ALS and other conditions that are driven by Treg cellular dysfunction. We intend to selectively consider partnering transactions for COYA 302.

5. **Expand pipeline by identifying and developing additional product candidates and identifying additional target indications.** We intend to develop other biologics and biologic combinations intended to ameliorate inflammation and lack of self-tolerance that characterize certain neurodegenerative, and autoimmune diseases.

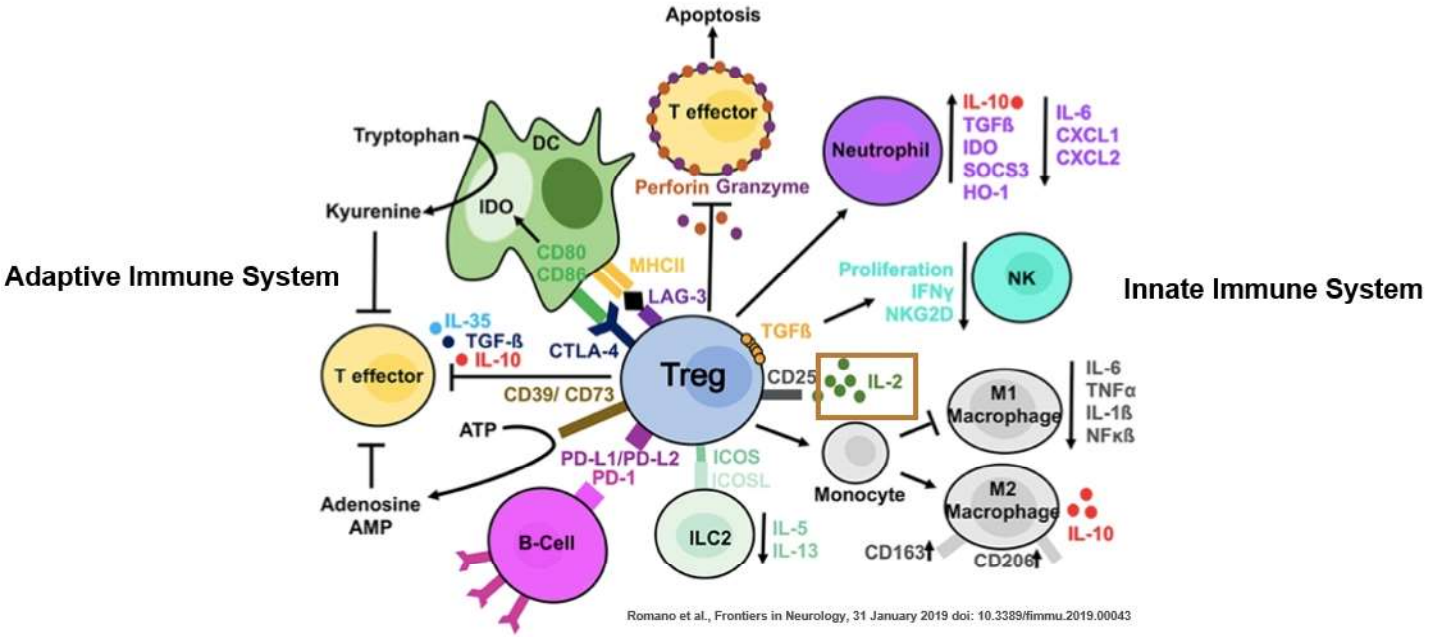
6. **Selectively enter new discovery relationships with premier research institutions and commercial partners.** We expect to have ongoing discussion with third-party pharmaceutical companies about their interest in partnering with us for the ongoing development and commercialization of certain of our development programs.

Regulatory T cells (Tregs)

In 1995, a subpopulation of suppressor T cells was identified that expressed CD4 and was named regulatory T cells (Tregs). CD4 is found on the surface of certain cells and plays a key role in maintaining homeostasis, a state of balance among all the body systems needed for the body to survive and function correctly, in the immune system. CD4+ T cells are commonly divided into two distinct lineages: Treg cells and conventional T helper (Th) cells (Pro-Inflammatory Cells).

Conventional Th cells are crucial in shaping the immune response, whether it is protection against a pathogen, a cytotoxic attack on tumor cells, or an unwanted response to self-antigens in the context of autoimmunity. Th cells control the adaptive immune system. The adaptive immune system includes the effectors cells of the cellular immune responses, the T lymphocytes, which mature in the thymus, and antibody-producing cells, the B lymphocytes, which arise in the bone marrow. Th cells control the adaptive immune system by activating, in an antigen-specific fashion, other effector cells such as CD8+ cytotoxic T cells (which are important for immune defense against intracellular pathogens), B cells (that are responsible for producing antibodies), and macrophages (*white blood cells that stimulate the action of other immune system cells*). By functioning in an antigen-specific fashion, the Th cell is capable of stimulating an immune response.

Tregs main function is the suppression and termination of pro-inflammatory immune responses. Tregs suppress both innate and adaptive immune reactions detrimental to the host, downregulate pro- inflammatory cytokine (*a type of protein that is made by certain immune and non-immune cells and has an effect on the immune system*) production, and can suppress the activation/expansion of CD4+CD25- effector T lymphocytes (Teffs). Immune homeostasis is reached when there is a balance between the number of functional Tregs and pro-inflammatory T cells. See the below figure for a visual representation:



Tregs are important anti-inflammatory immune cells involved in homeostasis. Tregs act on multiple immune cells to down-regulate the release of pro-inflammatory cytokines.

The Significant Role of Tregs in Neurodegenerative, Autoimmune, and Metabolic Diseases

Dysfunctional Tregs underlie many diseases, and this cellular dysfunction is driven by the chronic inflammatory environment and high levels of oxidative stress commonly observed in numerous diseases. Additionally, the degree of Treg dysfunction is associated

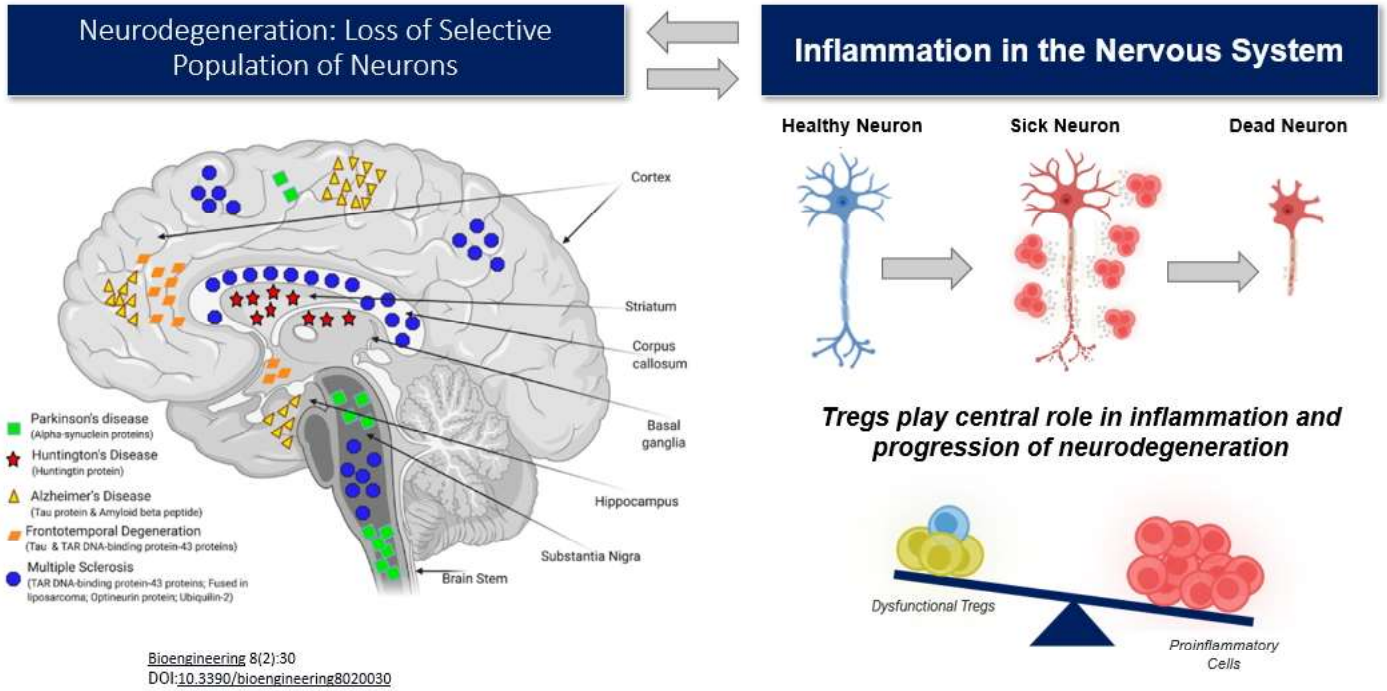
with the severity and progression of serious and life-threatening conditions, for which we believe new and effective therapies are urgently needed.

Since the discovery of Tregs in 1995, we have continued the development and research of Tregs by leveraging the scientific discoveries of Dr. Stanley Appel and his research team at Houston Methodist Hospital ("Methodist") in Houston, Texas. We have entered into an exclusive Patent and Know How License Agreement with Methodist, and we continue to work with them in support of their research through an exclusive Sponsored Research Agreement.

Recent scientific evidence from Dr. Appel demonstrates that dysregulation of the immune system negatively impacts the severity and progression of neurodegenerative conditions. We believe Dr. Appel's work demonstrates the role of Treg dysfunction in serious conditions such as ALS, AD, and FTD.

In particular, Dr. Appel discovered that Tregs are both reduced in numbers and function in these patients suffering from neurodegenerative diseases, and more marked reduction could be associated with more rapid disease progression. In addition, scientific evidence indicates an association between Treg dysfunction and the pathophysiology of certain autoimmune and metabolic conditions.

An increased ratio of pro-inflammatory T cells to functional Tregs leads to a disrupted immune homeostasis. See the below figure for a visual representation:



When Tregs become dysfunctional, a cytokine-mediated inflammatory state can arise leading to neurodegenerative, autoimmune, and metabolic diseases.

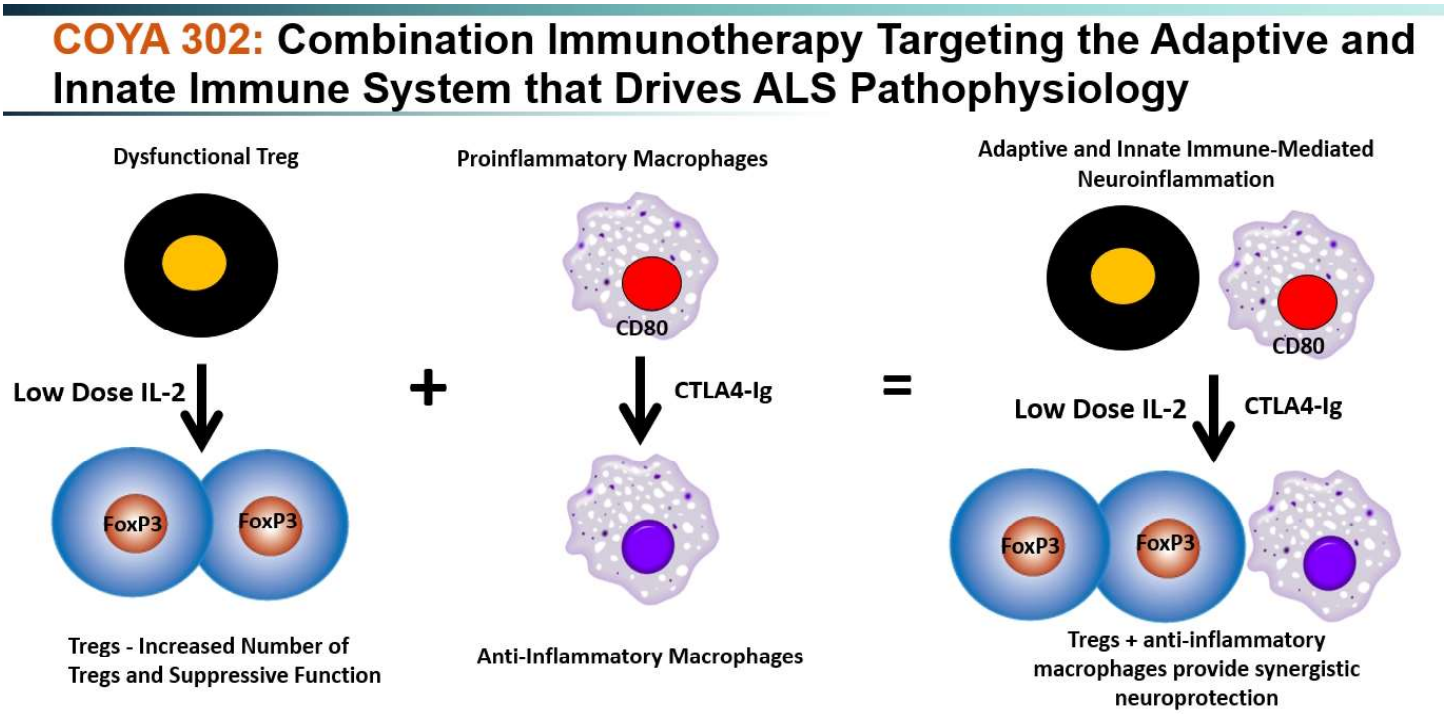
Our Biologics Potential Therapeutic Modality (the 300 Series)

Our growing expertise and clinical experience decoding Treg biology and the critical role of Tregs in the pathophysiology of neurodegenerative, autoimmune, and metabolic diseases, provide the basis for the research and development of innovative biologics and biologic combinations intended to enhance Treg function *in vivo* for the treatment of diseases of high unmet medical need.

COYA 302

COYA 302, is a biologic combination for subcutaneous administration intended to enhance Treg function while depleting T effector function and activated macrophages. COYA 302 is a combination of COYA 301 (low-dose IL-2) and the fusion protein CTL4-Ig. These two mechanisms may be additive or synergistic in suppressing inflammation. We believe the immunomodulatory fusion protein selectively inhibits the activation of pro-inflammatory effector T cells and macrophages, downregulating the secretion of pro-inflammatory cytokines, while COYA 301 enhances and expands Tregs *in vivo*. The combination of these two approaches is intended

to further shift the balance in favor of anti-inflammatory Tregs to pro-inflammatory cells *in vivo*. See the below figure for a visual representation:



Development Status

We are conducting CMC activities and IND-enabling toxicology studies to support the filing of an IND and the initiation of an industry-sponsored clinical trial of COYA 302 for the treatment of ALS. We expect to begin a Phase 2 clinical trial in ALS in the first half of 2024 which will evaluate the safety, pharmacokinetics, biological activity, and efficacy of COYA 302.

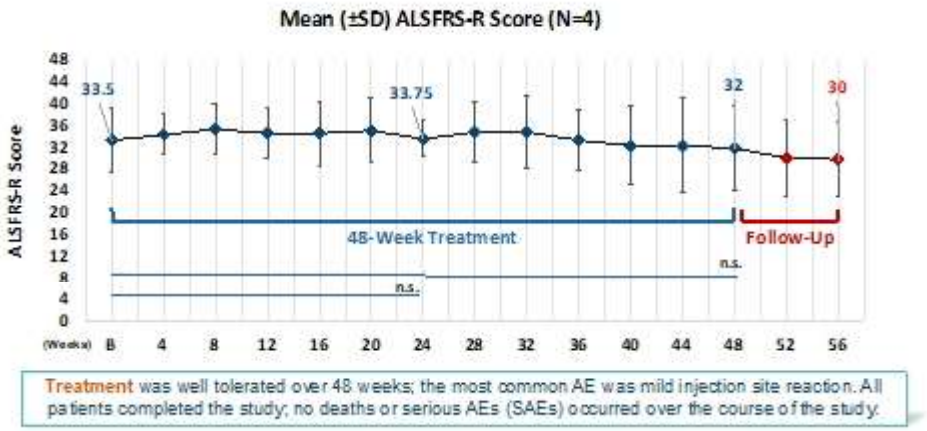
In vitro assays conducted by Dr. Appel and his team at Houston Methodist Hospital (using commercially available products) showed that *ex vivo* expanded human Tregs exhibited greater suppression of T responder ("Tresp") proliferation after exposure to the fusion protein component of COYA 302. In a separate assay, the addition of the fusion protein to *ex vivo* expanded human Tregs showed incremental suppression in the production of IL-6 by M1 proinflammatory macrophages.

Following the *in vitro* testing, a POC study in support of COYA 302 was conducted. This was an open label study conducted in 4 ALS patients, which evaluated the safety and tolerability, function of regulatory T-cells, biomarkers, and preliminary efficacy (as measured by the ALSFRS-R scale) utilizing as the treatment commercially available IL-2 and abatacept. Study data showed no decline or minimal decline at 24 and 48 weeks respectively after initiation of treatment and appeared to be well tolerated in all study patients as no serious adverse events were reported. Twenty-four weeks is an important timepoint as this is the period that ALS studies are usually benchmarked to measure differences in the ALSFRS-R scale for a treatment versus placebo. Based on this POC data, we intend to design a well-powered and well-controlled study to demonstrate the safety and efficacy of COYA 302 (COYA 301 or low dose IL-2, plus an abatacept proposed biosimilar, licensed from Dr. Reddy's Laboratories, or DRL_AB) in patients with ALS and are preparing for an IND submission to the FDA in the first half of 2024. We intend to initiate a Phase 2 trial after the acceptance of our IND application by the FDA.

The results of this POC study in four patients with amyotrophic lateral sclerosis (ALS) were presented by Dr. Appel on March 21, 2023, at a Company webcast and at the 2023 Muscle Dystrophy Association (MDA) Clinical & Scientific Conference in Dallas, Texas. Study assessments included functional status, as measured by the Revised ALS Functional Rating Scale (ALSFRS-R), regulatory T cell (Treg) suppressive function and numbers, serum biomarkers, and safety and tolerability. Study patients were treated with COYA 302 for 48 weeks (treatment phase) and were followed for additional 8 weeks after completion of the treatment phase (follow-up period). The ALSFRS-R scoring range is 0 to 48, with higher scores representing a better functional status.

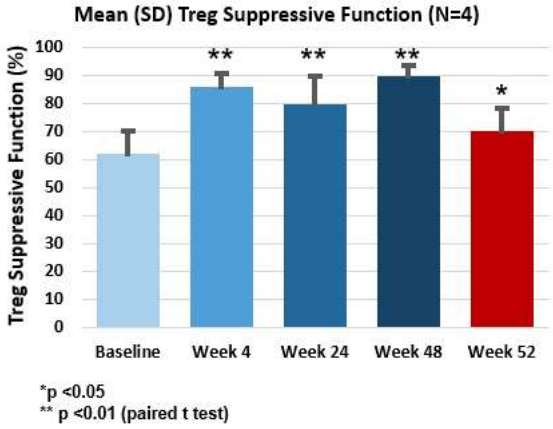
Study data showed no decline or minimal decline at 24 and 48 weeks, respectively, after initiation of treatment in this group of patients that were experiencing a mean decline of -1.1 points/month in their ALSFRS-R score prior to initiation of treatment with COYA 302. The mean (±SD) ALSFRS-R scores at week 24 (33.75 ±3.3) and week 48 (32 ±7.8) after initiation of treatment were not statistically different compared to the ALSFRS-R score at baseline (33.5 ±5.9), indicating clinically meaningful amelioration in the progression of the disease.

POC Study COYA 302: ALS Progression Over 24 and 48 Weeks

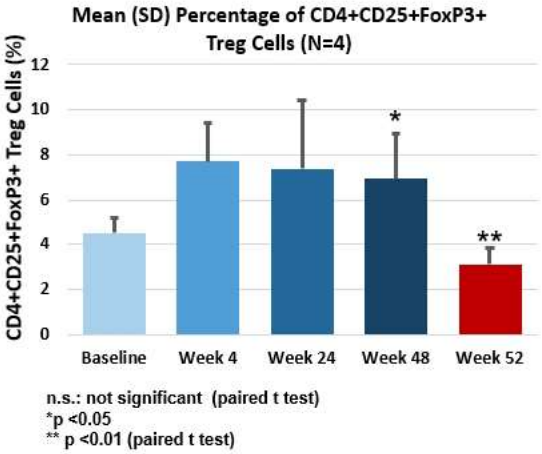


In addition, the POC Study showed enhanced Treg suppressive function at 24 weeks and 48 weeks. Treg suppressive function, expressed as percentage of inhibition of proinflammatory T cell proliferation, showed a statistically significant increase over the course of the treatment period and was significantly reduced at the end of the 8-week post-treatment follow-up period. Treg suppressive function at 24 weeks (79.9±9.6) and 48 weeks (89.5±4.1) were significantly higher compared to baseline (62.1±8.1) ($p<0.01$), suggesting enhanced and durable Treg suppressive function over the course of treatment. In contrast, Treg suppressive function (mean ±SD) was significantly decreased at the end of the 8-week follow-up period compared to end-of-treatment at week 48 (70.3±8.1 vs. 89.5±4.1, $p<0.05$). The study also evaluated serum biomarkers of inflammation, oxidative stress, and lipid peroxides. The available data up to 16 weeks after initiation of treatment suggest a decrease of these biomarker levels, which is consistent with the observed enhancement of Treg function. The evaluation of the full biomarker data is ongoing.

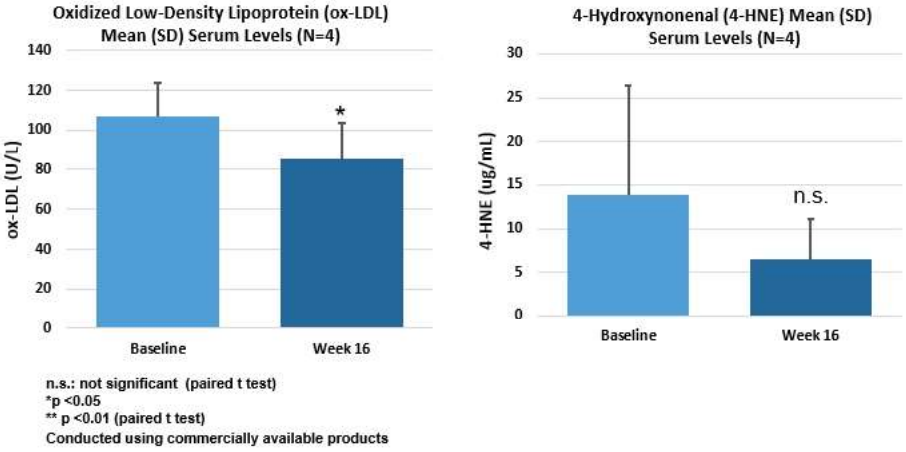
POC Study COYA 302: Increased Treg Suppressive Function *In Vivo*



POC Study COYA 302: Increased Treg Number *In Vivo*

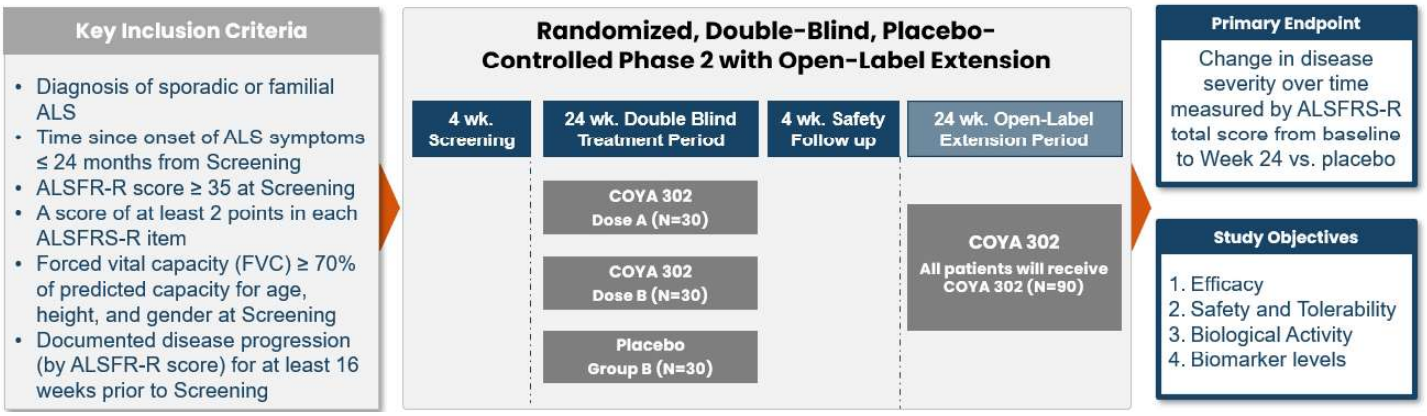


POC Study COYA 302: Lowered Lipid Peroxide Biomarkers (interim data)



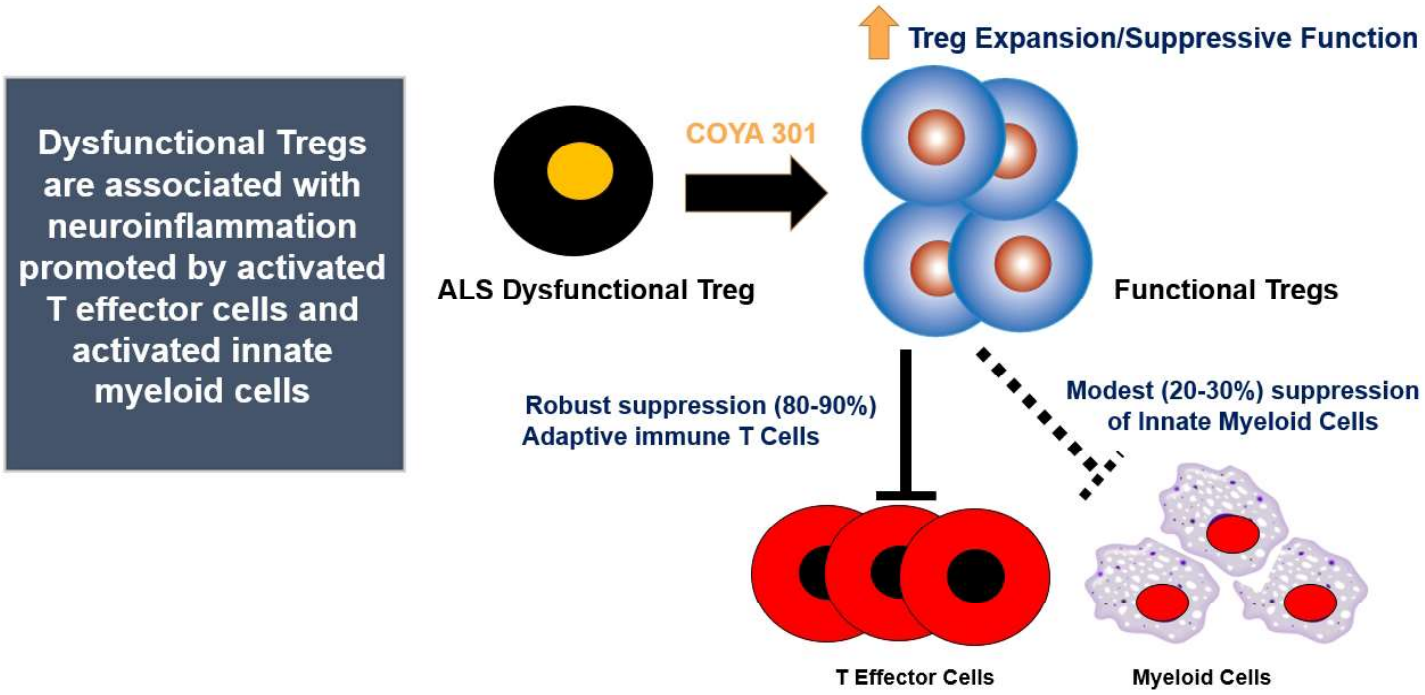
From the clinical safety perspective, the treatment used in the POC Study appeared to be well tolerated over the 48-week treatment period. The most common adverse event was mild injection-site reactions. No patient discontinued the study, and no deaths or other serious adverse events were reported.

We are planning to submit our IND application in the first half of 2024, with a Phase 2 trial expected to begin soon thereafter. A preliminary overview of our prospective Phase 2 Study of COYA 302 in ALS is shown in the figure below. The final trial design is subject to change pending acceptance of our IND application by FDA:



COYA 301

COYA 301, our low-dose interleukin 2 (IL-2) product candidate, is a biologic for subcutaneous administration intended to enhance Treg function and expand Treg numbers *in vivo.* We believe an increased ratio of functional Tregs shifts the balance *in vivo* in favor of anti-inflammatory Tregs to pro-inflammatory cells. See the below figure for a visual representation:



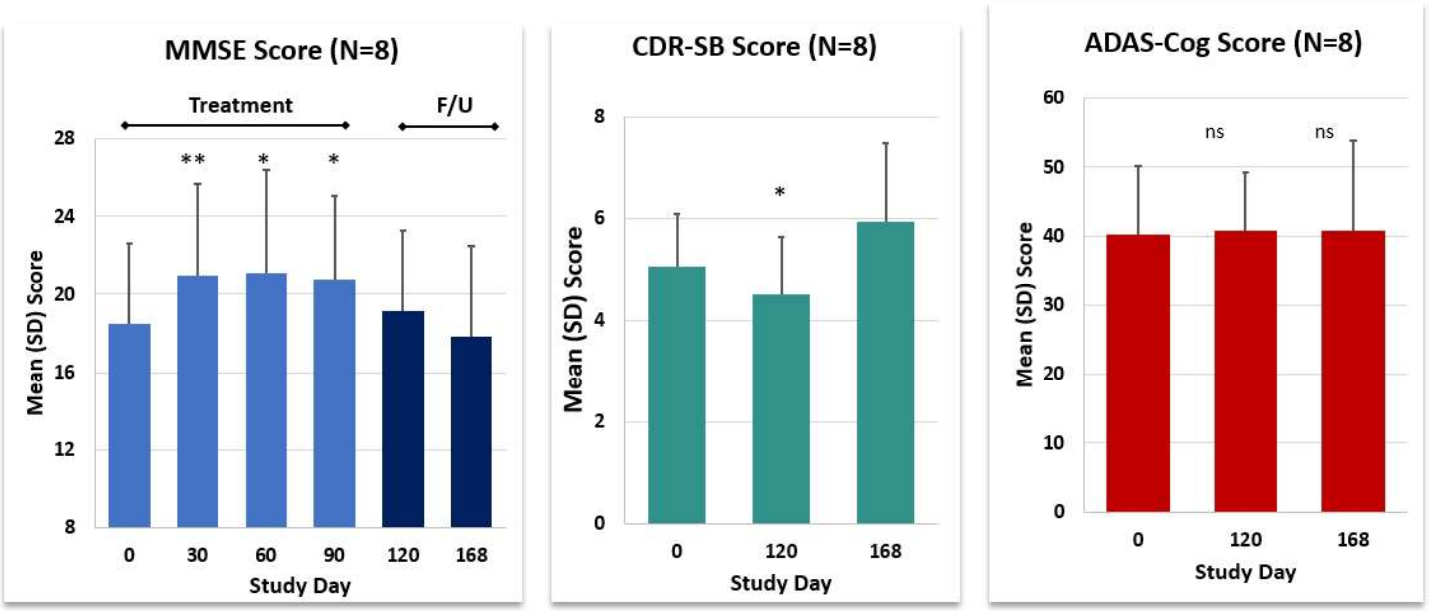
We are developing biologics and biologic combinations intended to ameliorate the inflammation and lack of self-tolerance that characterize certain neurodegenerative and autoimmune diseases, by increasing Treg suppressive and immunomodulatory functions.

COYA 301's subcutaneous administration allows patients to be dosed in their homes, which we believe provides convenience and pharmacoeconomic advantages over existing products requiring administration in a hospital setting.

Development Status

In the first half of 2023, we announced results from a POC study in support of COYA 301. This open label study was conducted in 8 patients with AD, and evaluated the safety and tolerability, biological activity, blood biomarkers, and preliminary efficacy of a treatment consisting of commercially available IL-2. Study data found that (i) cognitive function, as measured by 3 validated tools, either improved or did not decline, (ii) Treg function was significantly enhanced, (iii) pro-inflammatory blood cytokines and chemokines were significantly reduced with evidence of reduced neuroinflammation in the brain and (iv) the POC treatment appeared to be well tolerated, and no serious adverse events were reported.

Investigator Initiated Study of LD IL-2 in Alzheimer's Disease (AD)



*p<0.05, **p<0.01 ns: not significant

MMSE: Mini-Mental State Examination, ADAS-Cog: Alzheimer's Disease Assessment Scale-Cognitive Subscale
CDR-SB: Clinical Dementia Rating scale – Sum of Boxes

Conducted using commercially available product

Currently, an ongoing academic, Phase 2, double-blind, randomized trial (funded by the Gates Foundation and the Alzheimer's Association) for use of low dose IL-2 in mild to moderate AD patients is underway at Houston Methodist and we anticipate reporting top line data in Q3 2024. The study is now fully enrolled. A total of 38 patients were randomly assigned to receive subcutaneous LD IL-2 at two different dosing regimens, or matching placebo, over 21 weeks. The first patient cohort was randomized to receive LD IL-2 for 5 consecutive days every 4 weeks and the second cohort was randomized to receive LD IL-2 for 5 consecutive days every 2 weeks.

This Phase 2 study will evaluate the safety and tolerability, biological activity, blood and cerebrospinal fluid biomarkers, neuroimaging, and changes in cognitive function of LD IL-2 compared to placebo at pre-specified timepoints over the course of the 21-week treatment period and at 9 weeks after the last dose of study treatment.

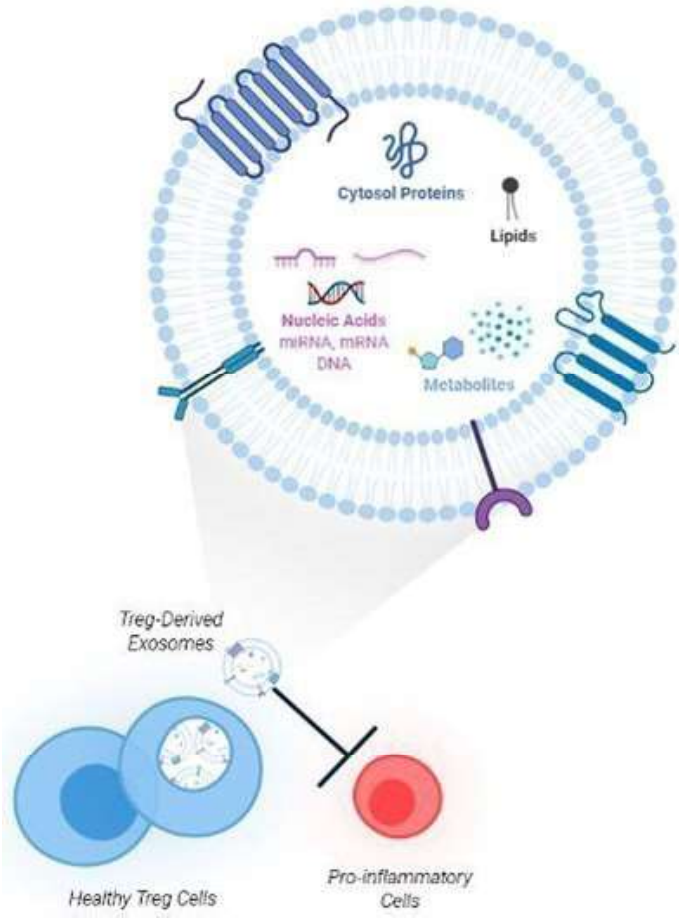
We intend to explore partnerships with other pharmaceutical and biotechnology companies that own strategic compounds that could potentially be suitable candidates for safe and effective new combination therapies with COYA 301.

Our Treg-Derived Exosomes Potential Therapeutic Modality (the 200 Series)

We are developing a Treg-derived exosome potential therapeutic modality consisting of both allogeneic Treg-derived exosomes and antigen derived Treg-directed exosomes that we believe may have unique advantages due to their nanosized (having dimensions limited to nanometers) and non-cell characteristics and to the potential for customization. Treg-derived exosomes are manufactured following the expansion and conversion of Tregs. The Treg exosomes are nanovesicles, tiny sacs released by cells that carry chemical messages between cells, produced by the Tregs and released to the bloodstream and different tissues to communicate with other cells, including pro-inflammatory T and B cells. Treg exosomes contain different types of cargo, such as proteins, lipids, and nucleic acids, and have suppressive contact-mediated receptors and proteins that are typically present on the parent Tregs, allowing them to efficiently modulate the immune and inflammatory responses.

We have filed intellectual property claims on the contents of the exosomes, namely the micro RNAs that are reproducibly represented from batch to batch. Many of these micro RNAs confer anti-inflammatory functionality as a mechanism of action and we believe may explain the exosomes' immunomodulatory function. The exosome field is an emerging and new area at present and understanding the functional aspects of the exosomes is an important but evolving regulatory aspect. We have filed intellectual property claims for compositions of matter that teach the reproducible micro RNA contents. To date, no patents have been issued.

We have developed technology to collect large volumes of Treg exosomes from the tissue culture media that is utilized in the Treg conversion and expansion process. One of the potential limitations of anti-inflammatory Treg cells is that they could be susceptible to the noxious, pro-inflammatory environment observed in some serious and progressive conditions, with the possibility of being converted to a dysfunctional Treg phenotype. Because Treg exosomes are not cells and are end-stage differentiated, they cannot be phenotypically changed, which is the shifting from a type of cell to another type of cell, by the inflammatory environment. In addition, Treg exosomes' very small size (between 30-200 nm) makes them able to readily reach sites of inflammation and cross biological barriers in the body, including the blood-brain barrier. See the below image for a visual representation of a Treg exosome.



We believe our data demonstrates the anti-inflammatory activity of Treg exosomes in *in vitro* assays and *in vivo* animal models of acute inflammation and ALS, following intravenous and intranasal administration. Further, we believe our research demonstrates that Treg exosomes exhibit greater anti-inflammatory potency than mesenchymal exosomes, as demonstrated in research recently published in the journal *Frontiers of Immunology*. Mesenchymal exosomes are extracellular vesicles that are derived from mesenchymal stem cells which are a heterogeneous population of cells that are isolated from various tissues, including bone marrow, adipose tissue, umbilical cords, and even urine.

We believe these Treg exosomes may provide an extensive arsenal of suppressive signaling components and anti-inflammatory mediators that are potentially able to suppress pro-inflammatory cascades in the body, including the brain.

While we maintain internal preclinical research and development activities in exosomes generally, we are simultaneously investigating alternative exosome technologies developed by academic institutions or commercial enterprises which we may be able to access, through external partnerships, licensing, and/or strategic collaborations.

COYA 201

Our allogeneic Treg exosome product candidate, COYA 201, is being developed following Treg conversion and expansion from healthy donors. We believe the manufacturing process under GMP conditions to date has shown consistent batch-to-batch comparability and adequate long-term stability. In addition, we believe the proprietary manufacturing and cryopreservation processes are highly efficient and will be able to supply a 12-month treatment for five patients from a single manufacturing run.

We believe that our Treg exosome modality for allogeneic use may allow targeting multiple indications in the neurodegenerative, autoimmune, and metabolic therapeutic categories.

In evaluations of our Treg exosome product in a preclinical lupus nephritis model in mice, COYA 201 was administered at different dose levels and was well tolerated, and no fatalities were observed at the administered dose of $1x10^{10}$ exosomes (low dosage level). However, as part of this dose-escalation study, as a result of toxicity when administered in extremely high doses ($1x10^{11}$ exosomes, or ten times the low dosage level) administered twice weekly, death in six animals (out of a total of 12) was observed. Dose escalation studies are standard in the early development of new treatments and the assessment of the "maximum tolerated dose" and identification of the dose that produces lethality in 50% of animals, are also common studies in early preclinical development. The primary endpoint of this study was proteinuria (amount of protein in urine) to assess renal function. The primary endpoint was not met. Currently, the side effect profile of our product candidates in humans is unknown. We continue to evaluate different potential indications to advance the development of COYA 201 into clinical studies. Following the completion of the preclinical studies in different animal models of disease, we will evaluate the data to potentially conduct further preclinical studies and to select a potential clinical indication for human studies.

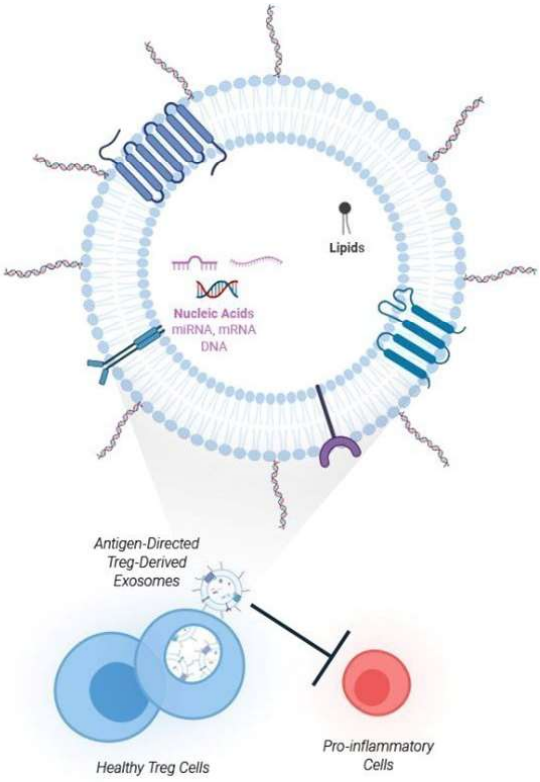
We conducted a preclinical study in a well-established animal model of systemic scleroderma, intended to evaluate the biological activity and potential efficacy of COYA 201 administered intravenously and intranasally. This study involved a bleomycin induced systemic scleroderma mouse model. The overall study design involved 15 animals/group, in 4 groups- vehicle, low dose exosome, high dose exosome, and saline. The endpoints measured included skin punch weight, skin histopathology, and lung histopathology. We are currently evaluating the results from this initial animal study and will use the data to guide the next steps for this development program.

COYA 201 has been tested in an in vitro humanized model of hepatic inflammation and fibrosis. We have conducted an initial preclinical study in a human liver microtissue model designed for the study of mechanisms of induction of liver inflammation and fibrosis and *in vitro* screening of drug efficacy. The model includes all the critical liver cells and inducers needed to recapitulate the inflamed liver disease state and serves as a powerful model for drug discovery and development. This cellular liver model involves co-culture of primary human hepatocytes, Kupffer cells, liver endothelial cells, and stellate cells and was evaluated across multiple groups, vehicle control, low dose exosomes, high dose exosomes, and saline solution. The primary objective of this initial study was to evaluate the biological activity of COYA 201 by assessing inflammation, measured by the levels of released pro-inflammatory cytokines, and fibrosis, measured by the release of procollagen by the hepatic cells. Following the establishment of the liver microtissues, the system was fed with high sugar, high insulin, and free fatty acids for 10 days. Samples for assessment of cytokines were collected on Day 5 of the study, and samples for assessment of procollagen were collected on Days 7 and 10. We observed a significant decrease ($p < 0.05$) in the secretion of pro-inflammatory cytokines, including interleukin 8 (IL-8), tumor necrosis factor alpha (TNFα), and macrophage inflammatory protein 1 alpha (MIP-1α), compared to the untreated controls. We also observed a significant increase ($p < 0.0001$) in the secretion of the anti-inflammatory cytokine interleukin 10 (IL-10), compared to the untreated control. In addition, we observed a mild decrease in procollagen that did not reach statistical significance, when compared to controls. The study met its primary objective by demonstrating that COYA 201 was biologically active in this model. Results from this study will guide the next steps in the early development of this program.

COYA 206

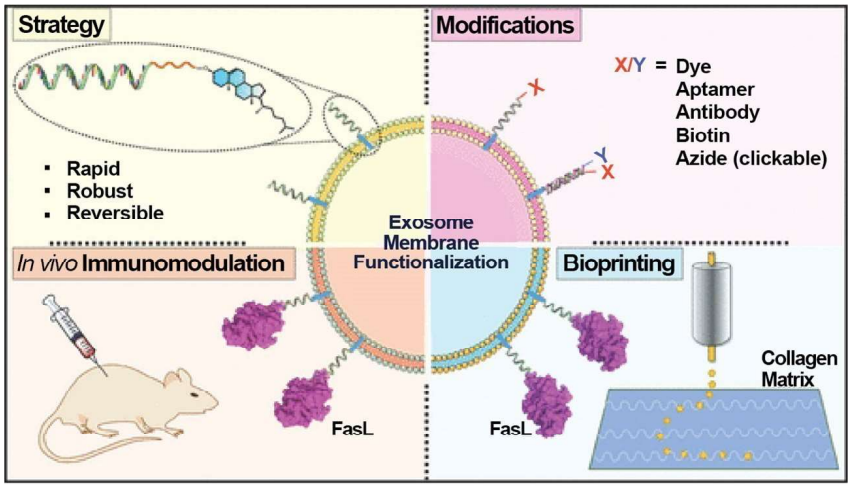
As part of our Treg exosome development programs, we are developing our next generation of antigen directed Treg-derived exosome product candidates. In September of 2023 we licensed the exclusive, worldwide rights of a proprietary Exosome Engineering Technology from Carnegie Mellon University with potential applications across multiple indications, including neurodegeneration, autoimmune, and oncology. (the "Carnegie Mellon License Agreement").

The Carnegie Mellon License Agreement involves the intellectual property rights to the research, development, and manufacturing of exosome-polymer hybrids ("EPHs"), a tether-based exosome functionalization strategy that enables Treg exosomes to be homed to proteins of interest, while delivering select payloads into targeted cells. See the below image for a visual representation of a tethering exosome.



Functionalized exosomes with an immunomodulatory protein, FasL, have demonstrated their biological activity both *in vitro* and *in vivo*. FasL-functionalized exosomes, when bioprinted on a collagen matrix, allows spatial induction of cell death in tumor cells and, when injected in mice, suppresses proliferation of pro-inflammatory T cells.

Schematic Representation of Functionalized Targeted Treg Exosomes



Yerneni, *et al., ACS Nano* 2019

We believe this proprietary technology sets the foundation to produce targeted Treg exosome potential therapeutics that are directed to epitopes, the part of an antigen molecule to which an antibody attaches itself, and proteins of interest, while delivering growth factors, drugs or other cargo, representing an innovative technology that could be advantageous relative to other Treg directed potential therapeutic modalities.

We are working on the characterization of the EPHs and are planning to do target validation following completion of this work to select product candidates and indications for future development.

Our Autologous Regulatory T Cells (Tregs) Potential Therapeutic Modality (the 100 Series)

COYA 101

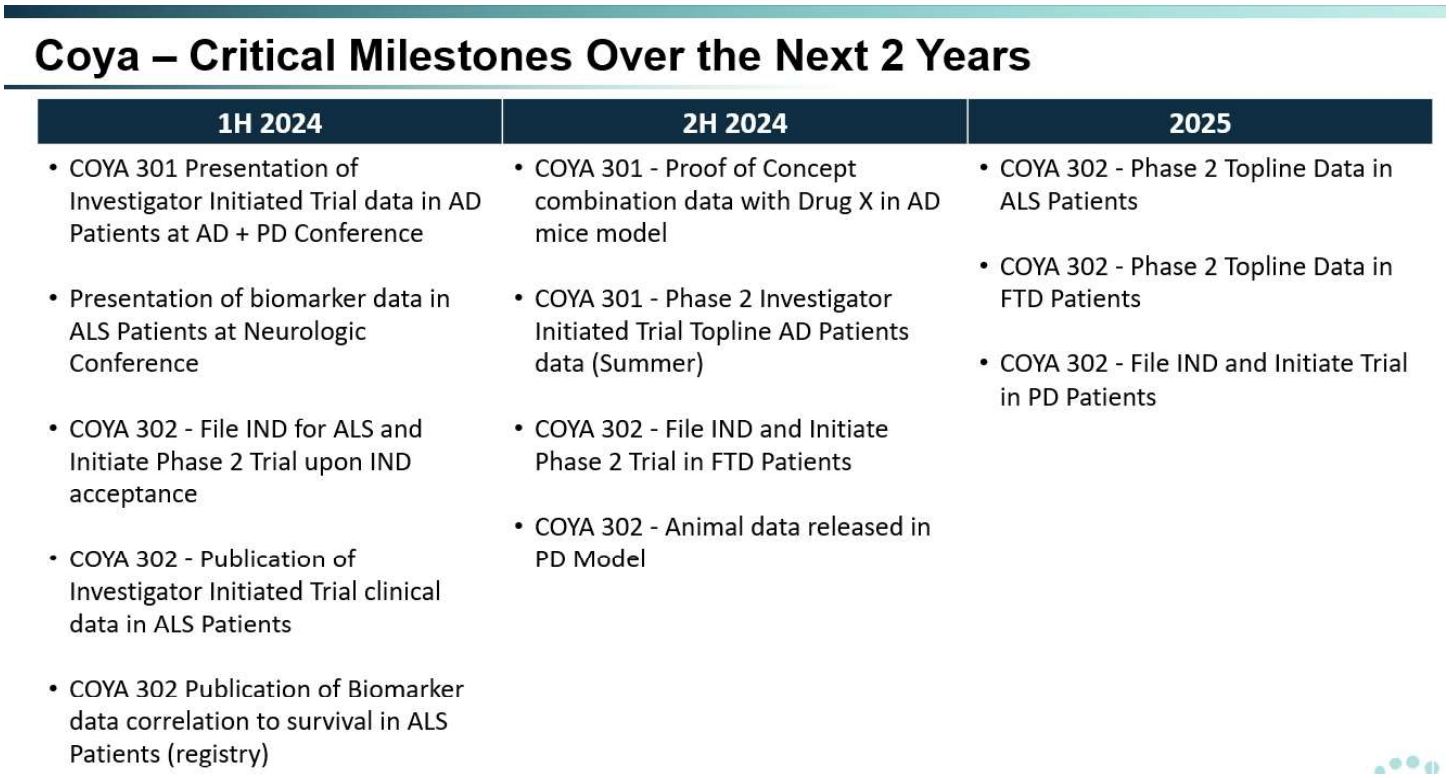
Our autologous Treg cell therapy product candidate COYA 101 has completed Phase 1 and Phase 2a studies and we believe the data from these trials provide us the information needed to design a well-powered and well-controlled confirmatory clinical study to evaluate the safety and efficacy of COYA 101 for the treatment of ALS.

After completion of the two investigator-initiated clinical studies, we had a Type B meeting (pre-IND) with CBER/FDA, and the FDA provided written responses on November 5, 2021. The main objective of the pre-IND meeting was to gather all necessary FDA feedback as early as possible to be able to address the FDA's requirements in the industry-sponsored IND submission. In its responses, the FDA provided clear guidance for the GMP manufacturing of COYA 101 for a well-controlled industry-sponsored study, and also provided insight for design of the clinical protocol for the next clinical study.

We currently believe that we are best served by utilizing our available cash to advance COYA 301, COYA 302, COYA 201 and COYA 206 candidates.

Key Milestones

We will continue to conduct research and development activities for our various product candidates and indications over the course of 2024-2025. Our anticipated developmental milestones are provided below:



The dates reflected in the foregoing are estimates only, and there can be no assurances that the events included will be completed on the anticipated timeline presented, or at all. Further, there can be no assurance that we will be successful in the development of any of our current product candidates or any other product candidate we may develop in the future, or that any of our current product candidates, or any other product candidate we may develop in the future, will receive FDA approval for any indication.

Competition

We believe that our investigational and proprietary biologic combination therapy, COYA 302, with a dual immunomodulatory mechanism of action represents a next generation approach that has competitive advantages over monotherapy approaches that target a single pathway to treating inflammatory disorders, which are driven by complex and multi-factorial pathways. COYA 302 is intended

to, *in-vivo*, enhance the anti-inflammatory function of regulatory T cells (Tregs) and suppress the inflammation produced by activated monocytes and macrophages. COYA 302 is comprised of COYA 301 (proprietary low dose interleukin-2 (LD IL-2)) and CTLA4-Ig and is being developed for subcutaneous administration for the treatment of patients with ALS, FTD, AD and PD. These mechanisms may have additive or synergistic effects. We believe that COYA 301 is ideally situated to serve as a backbone drug in combination with other biologics that synergistically modulate the immune system and represent novel approaches to treating inflammatory disorders.

We believe the ability of our product candidates to enhance Treg function *ex vivo* (Treg cell therapy and Treg exosomes) and *in vivo* (biologics), potentially resulting in amelioration of the chronic and progressive inflammatory environment that underlies certain serious diseases, represents a meaningful competitive advantage and may benefit us in our goal of successfully developing novel and highly effective treatments for neurodegenerative, autoimmune, and metabolic diseases. We believe our Treg exosomes are significantly more potent in suppressing inflammation than mesenchymal cell derived exosomes. Moreover, we are developing technology in conjunction with Carnegie Mellon University to target Treg exosomes to proteins of interest while loading with cargo of interest, requiring no genetic manipulation, while CAR Treg approaches require genetic manipulation. Moreover, Treg exosomes are end stage differentiated and cannot be converted in-vivo to a dysfunctional state, unlike cells. Our Treg cell therapy is a polyclonal product that requires no genetic manipulation. Moreover, we have developed bioreactors to shorten the time to obtain the final product (within 10-12 days). Finally, we have developed the ability to cryopreserve Treg cells and rethaw while maintaining full functional potency, allowing for chronic dosing from one patient manufacturing run.

However, the pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We will continue to face competition from various global pharmaceutical, biotechnology, specialty pharmaceutical and generic drug companies that engage in drug development activities.

Many of our competitors have similar products that focus on the same diseases and conditions that our current and future pipeline product candidates address and may address in the future. Many of our competitors have greater financial flexibility to deploy capital in certain areas as well as more commercial and other resources, marketing and manufacturing organizations, and larger research and development staff. As a result, these companies may be able to pursue strategies or approvals that we are not able to finance or otherwise pursue and may receive FDA, or other applicable regulatory approvals more efficiently or rapidly than us. Also, our competitors may have more experience in marketing and selling their products post-approval and gaining market acceptance more quickly.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our product candidates could become less competitive if our competitors are able to license or acquire technology that is more effective or less costly and thereby offer an improved or a cheaper alternative to our product candidates.

Competitor companies developing Biologic approaches to enhancing Tregs, leveraging IL-2 formulations, include: Amgen (AMGN) (IL-2 mutein for GVHD and autoimmune diseases), Nektar Therapeutics (NKTR) (Pegylated IL-2 for autoimmune diseases), Merck (MRK) (IL-2 mutein for autoimmune diseases), Xencor (XNCR) (IL-2 Fc Fusion Protein for autoimmune diseases), Selecta Biosciences (SELB) (recombinant IL-2 + ImmTOR for autoimmune diseases), Cue Biopharma (CUE) (IL-2 bispecific for GVHD and autoimmune diseases), and Moderna (MRNA) (LNP encapsulated mRNA based therapeutic encoding IL-2 for autoimmune diseases), and ILTOO Pharma (low dose IL-2 formulation).

Competitor companies developing Treg based cellular therapeutics include: Abata Therapeutics (CAR Treg for autoimmune diseases), Sonoma Biotherapeutics (CAR Treg for autoimmune diseases), Sangamo Therapeutics (SGMO) (CAR Treg for Renal Disease, IBD), TRex Bio (Treg cell therapy for Immunology/Inflammation), Mozart Therapeutics (CD8 Treg cell modulators for Celiac Disease/IBD), GentiBio (Treg cell therapy generated from T-effector cells for T1 Diabetes), Kyverna Therapeutics (Autologous and Allogeneic cell therapies for autoimmune diseases), Cellenkos (Allogeneic umbilical cord blood Tregs for multiple conditions), AZ Therapies (Allogeneic CAR Tregs for CNS Diseases), and Quell Therapeutics (Autologous CAR Tregs for liver transplantation, T1 Diabetes and ALS).

To our knowledge, there exists no other Treg-derived exosome competitor. However, there exists other cell derived exosome competitors including: Evox Therapeutics (Mesenchymal Derived Exosomes), Capricor Therapeutics (Cardiosphere Derived Exosomes), and Exopharm (Platelet Derived Exosomes), and Rion (Platelet Derived Exosomes).

We expect any product candidates that we develop and commercialize will compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidate portfolio in our target commercial markets.

Government Regulation

The 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, post-approval monitoring and post-approval reporting of drugs, including biologics. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and biologics and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations and other federal, state and local statutes and regulations. In the case of biologics, the section of the FDCA that governs the approval of drugs via New Drug Applications ("NDAs") does not apply to the approval of biologics. Rather, biologics, such as gene therapy products, are approved for marketing under provisions of the Public Health Service Act ("PHSA") via a Biologics License Application ("BLA"). However, the application process and requirements for approval of BLAs are very similar to those for NDAs. 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. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or after approval, may subject an applicant to administrative or judicial sanctions.. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, withdrawal of approvals, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before our product candidates are approved for potential therapeutic indications and may be marketed in the U.S. generally involves the following:

- completion of extensive non-clinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA, to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the U.S.

Preclinical Studies and Clinical Trials for Biologics

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as in vitro and animal studies to assess safety and in some cases to establish the rationale for potential therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research patients will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND

sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trial are minimized and are reasonable related to the 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. The FDA, the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including clinical trials results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor can submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate potential therapeutic indications to support BLAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- ***Phase* I—**Phase I clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- ***Phase II*—**Phase II clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- ***Phase III*—**Phase III clinical trials typically involve administration of the investigational product 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 and physician labeling.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended potential therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human volunteers and any clinically important increase in the severity or rate of a serious suspected adverse reaction over that listed in the investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional non-clinical studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and 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 manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity 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.

U.S. Marketing Approval for Biologics

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. A BLA must contain proof of the drug's safety and efficacy. The marketing application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a drug may be marketed in the U.S.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews a BLA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, program to ensure that the benefits of the drug outweigh its risks. The REMS program could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which 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 typically will 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 requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase IV clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and making the product available in the U.S. for the disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same potential therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different potential therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same potential therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same potential therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective 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.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients earlier than under standard FDA development and review procedures.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below.

In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase I, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under Priority Review, the FDA must review an application in six months compared to ten months for a standard review.
Additionally, products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which 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.

Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for Accelerated Approval, that all advertising and promotional materials that are

intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.
Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

U.S. Post-Approval Requirements for Drugs and Biologics

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an BLA. For example, the FDA may require post-market testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. 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;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or withdrawal of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and issuance of corrective information.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade

Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Healthcare Reform

In March 2010, Congress passed the Affordable Care Act, or the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional policy reforms. The ACA, for example, contains provisions that subject products to potential competition by lower-cost products and may reduce the profitability of products through increased rebates for drugs reimbursed by Medicaid programs; address a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increase the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; establish annual fees and taxes on manufacturers of certain branded prescription drugs; and create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 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.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA. The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, in June 2021, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Congress has continually explored legislation intended to address the cost of prescription drugs. Notably, the major committees of jurisdiction in the Senate (Finance Committee, Health, Education, Labor and Pensions Committee, and Judiciary Committee), regularly evaluate and hold hearings on legislation intended to address various elements of the prescription drug supply chain and prescription drug pricing. Proposals include a significant overhaul of the Medicare Part D benefit design efforts to cap the increase in drug prices, create drug price transparency, curb anti-competitive behavior, and efforts to allow the Secretary of the Department of Health and Human Services to negotiate drug prices with prescription drug manufacturers. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates. The former Trump administration took several regulatory steps and proposed numerous prescription drug cost control measures. Similarly, the Biden administration has identified promoting competition and lowering drug prices as a priority.

These initiatives recently culminated in the enactment of the Inflation Reduction Act ("IRA"), in August 2022, which, among other things, will allow the U.S. Department of Health and Human Services ("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, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including restrictions or prohibitions on certain marketing practices, reporting of

specified categories of remuneration provided to health care practitioners, and reporting and justification of price increases greater than a specified level. In some cases, states have designed programs to encourage importation from other countries and bulk purchasing, though the federal government has not yet approved any such plans. 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 pharmaceuticals and other healthcare products and services, which could result in reduced demand for our product candidates.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additionally, we may face competition in the United States for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act, or MMA, contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. The final rule became effective November 30, 2020. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. Individual states in the U.S. have also been increasingly 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.

From time to time, legislation is drafted, introduced, and passed in Congress that could significantly change the statutory provisions governing the sale, marketing, coverage, and reimbursement of products regulated by CMS or other government agencies. In addition to new legislation, CMS regulations and policies are often revised or interpreted by the agency in ways significantly affecting our business and our products.

Other Healthcare Laws and Regulations

If we obtain regulatory approval of our products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing strategies. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or paying remuneration (a term interpreted broadly to include anything of value, including, for example, gifts, discounts and credits), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. Violations of the federal Anti-Kickback Statute can result in significant civil monetary and criminal penalties, per kickback plus three times the amount of remuneration and a prison term per violation. Further, violation of the federal Anti-Kickback Statute can also form the basis for False Claims Act liability (discussed below). 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. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only government programs.

Additionally, the civil False Claims Act (the "FCA") prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in very significant monetary penalties, for each false claim and treble the amount of the government's damages. Manufacturers can be held liable under the FCA

even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal government continues to use the FCA, and the accompanying threat of significant liability, in its investigations and prosecutions of pharmaceutical and biotechnology companies throughout the U.S. Such investigations and prosecutions frequently involve, for example, the alleged promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with the FCA and other applicable fraud and abuse laws.

We may be subject to the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Federal government price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs.

The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, includes a fraud and abuse provision referred to as the HIPAA All-Payor Fraud Law, 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.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, including the final omnibus rule published on January 25, 2013, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions. Many states also have 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.

We may also be subject to federal transparency laws, including the federal Physician Payment Sunshine Act, which was part of the ACA and requires manufacturers of certain drugs and biologics, among others, to track and disclose payments and other transfers of value they make to U.S. physicians and teaching hospitals, as well as physician ownership and investment interests in the manufacturer. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. This information is subsequently made publicly available in a searchable format on a CMS website. Failure to disclose required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and/or other healthcare providers.

As noted above, analogous state laws and regulations, such as, state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. There are also state and local laws that require the registration of pharmaceutical sales representatives.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to

resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource consuming and can divert a company's attention from the business.

Government Regulation of Drugs Outside of the United States

To market any product outside of the U.S., we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our products. For instance, in the United Kingdom and the European Economic Area, or the EEA (comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure*—If pursuing marketing authorization of a product candidate for a potential therapeutic indication under the centralized procedure, following the opinion of the European Medicines Agency's Committee for Medicinal Products for Human Use, or, CHMP, the European Commission issues a single marketing authorization valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the European Medicines Agency, or EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, is a significant potential therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of potential therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.

- *National authorization procedures*—There are also two other possible routes to authorize products for potential therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure.

- *Decentralized procedure*—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- *Mutual recognition procedure*—In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country.

- Following authorization through either procedure, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In the EEA, new products for potential therapeutic indications that are authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new potential therapeutic

indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

The criteria for designating an "orphan medicinal product" in the EEA are similar in principle to those in the U.S. In the EEA 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 EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. 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 potential therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. The ten-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 (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

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

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member State in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific trial site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the "Common Technical Document") with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (the "Clinical Trials Regulation") was adopted. It is expected that the new Clinical Trials Regulation will apply following confirmation of full functionality of the Clinical Trials Information System, or CTIS, the centralized European Union portal and database for clinical trials foreseen by the regulation, through an independent audit. The regulation becomes applicable six months after the European Commission publishes notice of this confirmation. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

The collection and use of personal health data in the European Union, previously governed by the provisions of the Data Protection Directive, is now governed by the General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any clinical trial activities in EU members states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data patients residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out

of the European Union to the U.S. or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Should we utilize third-party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Environmental Regulation

We are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions, product stewardship and end-of-life handling or disposition of products, and environmental protection, including those governing the generation, storage, handling, use, transportation and disposal of hazardous or potentially hazardous materials. Some of these laws and regulations require us to obtain licenses or permits to conduct our operations. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. Although the costs to comply with applicable laws and regulations, including requirements in the U.S. and the European Union relating to the restriction of use of hazardous substances in products, have not been material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an BLA plus the time between the submission date of an BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") significantly changed the regulatory environment for biologics.

The BPCIA includes, among other provisions:

- A 12-year exclusivity period from the date of first licensure, or BLA approval, of the reference product, during which approval of a 351(k) application referencing that product may not be made effective;
- A four-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted; and
- An exclusivity period for certain biological products that have been approved through the 351(k) pathway as interchangeable biosimilars.

The BPCIA also establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHSA.

The BPCIA also created an abbreviated approval pathway for biological products shown to be highly similar 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.
The BPCIA is complex and its interpretation and implementation by the FDA are still somewhat unpredictable. 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 effect, implementation, and meaning of the BPCIA is subject to uncertainty.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to a BLA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act ("BPCA") provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Intellectual Property and Protection

As of March 8, 2024, our patent estate derived from our relationship with The Houston Methodist Hospital includes one U.S. non-provisional patent application, six foreign patent applications, and five pending Patent Cooperation Treaty ("PCT") applications, each co-owned with or in-licensed from The Houston Methodist Hospital. These patent applications are directed to our Treg and exosome compositions and methods of use, methods of Treg and exosome manufacture, and methods of in vivo Treg expansion via combination therapies, among other things. If any patents issue from or claim priority to these patent applications, the patents are expected to expire in 2040 and 2042, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. All of our Houston Methodist Hospital patents have composition and method claims, with the exception of a biomarker patent, which has only method claims.

In addition, our patent estate derived from our relationship with ARScience Biotherapeutics, Inc. (described below) includes one published patent application and one provision patent application. The patents, if granted, are expected to expire in 2041 and 2043, respectively, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The ARScience Biotherapeutics, Inc. patents have composition, method, and utility claims.

In addition, our patent estate derived from our relationship with Dr Reddy's Laboratories includes one published patent application. This patent, if granted, is expected to expire in 2039, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Dr. Reddy's patent has composition, method, and utility claims.

In addition, our patent estate derived from our relationship with the University of Nebraska includes two provisional patent applications. These patents, if granted, are expected to expire in 2044, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The University of Nebraska patents have use claims.

Finally, our patent estate derived from our relationship with Carnegie Mellon includes one pending patent application. The patent, if granted, would be expected to expire in 2043, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Carnegie Mellon patent has method claims.

Material Contracts

Development and License Agreement with Dr. Reddy's Laboratories

On December 5, 2023, we entered into a Development and License Agreement (the "DRL Development Agreement") with Dr. Reddy's Laboratories Ltd. ("DRL") and its affiliate, Dr. Reddy's Laboratories SA (collectively, "Dr. Reddy's"), pursuant to which, among other things, we granted to Dr. Reddy's an exclusive, royalty-bearing right and license to commercialize COYA 302 solely for use in patients with amyotrophic lateral sclerosis ("ALS") in the United States, Canada, the European Union and the United Kingdom (collectively, the "New Territories"). We previously granted Dr. Reddy's Laboratories Ltd. an exclusive license to obtain regulatory approval and commercialize COYA 302 for ALS and certain other indications in all other countries (other than the New Territories, Japan, Mexico, and in each country in South America), pursuant to the License and Supply Agreement entered with Dr. Reddy's Laboratories Ltd., effective as of April 1, 2023.

Upon execution of the DRL Development Agreement, Dr. Reddy's paid a non-refundable upfront payment of $7.5 million. Under the terms of the DRL Development Agreement, Dr. Reddy's will make development funding payments to us for development of COYA 302 as follows: (i) $4.2 million upon FDA acceptance of an Investigational New Drug ("IND") application for COYA 302 for the treatment of ALS and (ii) an additional $4.2 million payment upon the dosing of the first patient in the first phase 2 clinical trial for COYA 302 for the treatment of ALS in the United States. We anticipate that the IND filing will be made in the first half of 2024. The DRL Development Agreement also calls for up to an aggregate of $40.0 million in development milestones and up to an aggregate of $677.25 million in sales milestones, relating to the New Territories, should all such development and sales milestones be achieved. We will also be owed royalties by Dr. Reddy's on Net Sales (as defined in the DRL Development Agreement) of COYA 302 in the low to mid-teens (prior to paying royalties due pursuant to previously disclosed license agreements related to COYA 302). We will have the responsibility for the clinical development of COYA 302 and for seeking regulatory approval in the United States for COYA 302 in ALS.

The foregoing summary of the DRL Development Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the DRL Development Agreement, which is filed as an exhibit to this Annual Report on Form 10-K for the year ended December 31, 2023.

Dr. Reddy's License and Supply Agreement

In March 2023, we entered into an exclusive License and Supply Agreement (the "DRL Supply Agreement") with DRL. The DRL Supply Agreement became effective on April 1, 2023. Pursuant to the terms of the DRL Supply Agreement, we will in-license DRL's proposed abatacept biosimilar for use in the development of our combination product for neurodegenerative diseases COYA 302. COYA 302 is a dual biologic intended to suppress neuroinflammation via multiple immunomodulatory pathways, for the treatment of neurodegenerative conditions. The DRL Supply Agreement also provides for the license of our low dose IL-2 ("COYA 301") to DRL to permit the commercialization by DRL of COYA 302 in territories not otherwise granted us. In consideration for the license, we paid a non-refundable upfront fee of $0.4 million. We will pay to DRL up to an aggregate of approximately $2.9 million of pre-approval regulatory milestone payments for the first indication in the Field (as defined in the DRL Supply Agreement), of which an aggregate of $0.2 million has been paid to date, and an additional approximately $20.0 million if all other development, regulatory approval and sales milestones are incurred under the DRL Supply Agreement. We will also pay to DRL a low-six figure milestone payment per additional

indication. Further, pursuant to the DRL Supply Agreement, we will pay to DRL single-digit royalties on Net Sales (as defined in the DRL Supply Agreement).

ARScience License Agreement

In August 2022, we entered into a License Agreement (the "ARS License Agreement") with ARScience Biotherapeutics, Inc. ("ARS") pursuant to which ARS granted to us an option to acquire an exclusive, royalty-bearing license for two patents regarding certain formulations of IL-2, with the right to grant sublicenses through multiple tiers under these patents (the "ARS Option").

Under the ARS License Agreement, we may owe tiered payments to ARS based on our achievement of certain developmental milestones. Under the ARS License Agreement, we will pay an aggregate of $13.3 million in developmental milestone payments for the first Combination Product (as defined in the ARS License Agreement) in a new indication. We will then pay an aggregate of $11.6 million in developmental milestone payments for each Combination Product in each subsequent new indication. Further, for the first Mono Product (as defined In the ARS License Agreement) we will pay an aggregate of $11.8 million in developmental milestone payments. We will then pay an aggregate of $5.9 million in developmental milestone payments for each Mono Product in each subsequent new indication, and an aggregate of $5.9 million if all developmental milestones are achieved for each new indication. We will also owe royalties on net sales of licensed products ranging from low to mid-single digit percentages. In the event we sublicenses our rights under the ARS License Agreement, we will owe royalties on sublicense income within the range of 10% to 20%.

Houston Methodist Agreements

In September 2022, we entered into an Amended and Restated Patent Know How and License Agreement, effective as of October 2020 (the "Methodist License Agreement"), with The Methodist Hospital ("Methodist") to make, sell and sublicense products and services using the intellectual property and know-how of Methodist. As part of the Methodist License Agreement, we will pay Methodist a four-figure license maintenance fee annually until the first sale of licensed product occurs. The term of the Methodist License Agreement is effective until no intellectual property patent rights remain, unless terminated sooner by (1) bankruptcy or insolvency, (2) the failure by us to monetize the intellectual property within five years of the date of the agreement (further discussed below), (3) due to breach of contract, or (4) at our election for any or no reason.

In addition to the equity issuance and reimbursement of patent related expenses, the Methodist License requires us to make payments of up to $0.4 million per product candidate in aggregate upon the achievement of specific development and regulatory milestone events by such licensed product. We are also required to pay Methodist, on a licensed product-by-licensed product and country-by-country basis, tiered royalties (subject to customary reductions) equal to high-single digit to low-double digit percentages of annual worldwide net sales of such licensed product during a defined royalty term. We are also required to pay a low single digit percentage for certain licensed services. Commencing on January 1, 2025, the minimum amount which will be owed by us once commercialization occurs is $0.1 million, annually.

The Methodist License Agreement provides that in the event we sublicense products and services covered by the Methodist License Agreement, then royalties owed to Houston Methodist would be computed as a percentage of payments received by us from the sublicensee. In addition, the termination provisions provide that Houston Methodist may only terminate the Methodist License Agreement, among other things, in the event that after five years we are not "Actively Attempting to Develop or Commercialize," as such terms are defined in the Methodist License Agreement.

Sponsored Research Agreement with Houston Methodist Research Institute

In February 2021, we entered into a one-year Sponsored Research Agreement ("SRA") with Houston Methodist Research Institute ("HMRI"), a Texas nonprofit corporation and an affiliate of Methodist, which can be extended or renewed by mutual agreement. Under the SRA, we agreed to fund up to $1.5 million in research in the area of neurodegenerative diseases performed by HRMI. In return, we will gain expanded access to data methods and know-how per the SRA, and, if the research produces intellectual property, we will have all first rights to the intellectual property. On May 4, 2023,we executed the SRA with HMRI, in which we agreed to fund $0.5 million through May 2024. We incurred $0.3 million and $1.6 million in research and development expenses under the SRA during the years ended December 31, 2023 and 2022, respectively.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included or incorporated by reference in this Annual Report on Form 10-K. The risks described below are material risks currently known, expected or reasonably foreseeable by us. However, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition. If any of these risks actually materialize, our business, prospects, financial condition and results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Summary of Risks Associated with our Business

Our business and an investment in our Company is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this summary. Some of these risks include:

- We are a clinical-stage biopharmaceutical company with no product(s) approved for commercial sale.
- We rely on our license agreements to provide certain intellectual property rights relating to autologous regulatory Treg technology. If the license is terminated, we could lose the use of rights material to the development of our product candidates.
- If we are unable to receive non-dilutive funding in the form of a government grant, or through a partnership with an established pharmaceutical company, then we may not be able to advance COYA 101 into a Phase 2b clinical trial.
- We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future, and we may not generate sufficient revenue to achieve or maintain profitability.
- We will need to raise significant additional capital, which may not be available to us on acceptable terms, or at all. If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened.
- If we issue additional securities in the future, including issuances of shares of common stock upon exercise of our outstanding options and warrants, our existing stockholders will be diluted and our stock price may be negatively affected.
- Our business may be materially adversely affected by public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic).
- We may encounter substantial delays in our planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- We do not currently own, lease or operate a principal laboratory, research and development or manufacturing facility of our own. We currently collaborate with various research institutions to perform these activities, including The Methodist Hospital in Houston, Texas. Establishing our own facilities would result in significant additional expense and may result in potential delays in testing and production.
- Any clinical trials that are planned or are conducted on our product candidates may fail. Clinical trials are lengthy, complex and extremely expensive processes with uncertain outcomes and results and frequent failures.
- Our dependence on third parties to manufacture our product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired.
- Our business is subject to, and may be affected by, extensive and costly government regulation.
- We may not obtain approval for our products and any product for which we obtain required regulatory marketing authorization could be subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.
- Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.
- We face competition from companies that have greater resources than we do, and we may not be able to effectively compete against these companies.
- Global events, including political instability, natural disasters, events of terrorism and wars, including the war between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China; and the conflict between Hamas and Israel may negatively impact our business.
- If others claim we are infringing on the intellectual property rights of third parties, we may be subject to costly and time-consuming litigation.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a clinical-stage biotechnology company with limited resources, have a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a clinical-stage biotechnology company that commenced operations in 2020. In addition, we have no products approved for commercial sale and therefore all sources of capital have been obtained solely through financing.

Pharmaceutical development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have completed a Phase 2a clinical trial for just one of our product candidates, and have not obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Given the highly uncertain nature of drug development, we may never complete clinical trials beyond Phase 2 for any of our product candidates or initiate clinical trials for any of our product candidates, obtain marketing approval for any product candidates, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage pharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business, operating results and financial condition will suffer.

We have incurred significant losses since our inception and we expect to incur significant losses for the foreseeable future, and we will require sufficient additional funding to finance our operations, which may not be available.

Since our inception in 2020, we have incurred significant operating losses. Our net loss was $8.0 million for the year ended December 31, 2023, and our accumulated deficit as of December 31, 2023 was $25.9 million. We expect to continue to incur increasing operating losses for the foreseeable future as we continue to develop our product candidates. In addition, we anticipate that our expenses will increase substantially if, and as, we:

- advance the development of COYA 301 and COYA 302;
- advance additional product candidates to clinical trials, including COYA 201 and COYA 206;
- seek to discover and develop additional product candidates;
- establish and validate our own clinical- and commercial-scale current good manufacturing practices, or cGMP, facilities;
- submit a BLA or marketing authorization application ("MAA") for COYA 301 or seek marketing approvals for any of our other product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- incur additional costs associated with operating as a public company; and
- increase our employee headcount and related expenses to support these activities.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We continue to incur significant research and development and other expenses related to ongoing operations and the development of our product candidates, including COYA 301, COYA 302, COYA 201, and COYA 206. All of our product candidates will require substantial additional development time, capital and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We do not anticipate generating revenues from product sales unless and until such time as our product candidates may be approved by FDA or other applicable regulatory authorities, and we are able to successfully market and sell a product candidate. Our ability to generate revenues from product sales depends on our, or potential future collaborators, success in:

- completing clinical development of our product candidates;
- seeking and obtaining regulatory approvals for product candidates for which we successfully complete clinical trials, if any;
- launching and commercializing product candidates, by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;

- qualifying for adequate coverage and reimbursement by government and third-party payors for our product candidates;
- establishing, maintaining and enhancing a sustainable, scalable, reproducible and transferable manufacturing process for our cell therapy product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate products and services, in both amount and quality, to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as a viable treatment option;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, know-how, and trademarks;
- avoiding and defending against third-party interference or infringement claims; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our current expectations if we are required by the FDA or other global regulatory authorities to perform clinical trials and other preclinical studies in addition to those that we currently anticipate.

Even if we are able to generate revenues from the sale of any approved products, we may not become profitable or be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease the value of our Company and impair our ability to raise capital, thereby limiting our research and development programs and efforts to expand our business or continue our operations.

We will need to raise additional capital and if we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened.

We believe that our existing cash, together with interest thereon, will be sufficient to fund our operations into 2026. We intend to use our existing cash to, among other uses, advance our pipeline product candidates through preclinical and clinical development. Developing pharmaceutical products and conducting preclinical studies and clinical trials is expensive. We will need to raise significant additional capital to do so. Market volatility resulting from of the ongoing conflict between Russia and Ukraine, and Hamas' attack against Israel and the ensuing conflict, generally rising prices, increasing interest rates, effects of the COVID-19 pandemic or other factors could adversely impact our ability to access capital as and when needed. We have no commitments for any additional financing, and will likely be required to raise such financing through the sale of additional equity securities or debt, which, in the case of equity securities, may occur at prices lower than the price of our common stock and warrants. These financings could result in substantial dilution to the holders of our common stock and warrants or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we issue debt, we may need to dedicate a substantial portion of our operating cash flow to paying principal and interest on such debt and we may need to comply with operating restrictions, such as limitations on incurring additional debt, which could impair our ability to acquire, sell or license intellectual property rights which could impede our ability to conduct our business. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

Our present and future capital requirements will be significant and will depend on many factors, including:

- the progress and results of our development efforts for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments;
- the degree and rate of market acceptance of our product candidates;
- costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;
- the extent to which we acquire or in-license other products and technologies;

- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and
- legal, accounting, insurance and other professional and business-related costs.

We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

As a public company, we are obligated to develop and maintain proper and effective controls over financial reporting. If we fail to maintain proper and effective internal controls over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our securities.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our annual report on Form 10-K for that fiscal year. Our management, including our principal executive officer and principal financial officer, does not expect that our internal control over financial reporting will prevent all error and all fraud. We continue to operate with a small staff for financial reporting. Though the process and design of our internal controls over financial reporting have not been altered, the small number of staff involved in financial reporting may limit our ability to properly segregate internal control procedures which could result in deficiencies or material weaknesses in our internal controls in the future. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal control over financial reporting in the future. A material weakness in our internal control over financial reporting would require management to consider our internal control over financial reporting as ineffective. If our internal control over financial reporting is not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

Any acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

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

In addition, if we engage in acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses or acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our growth or limit access to technology or drugs that may be important to the development of our business.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. Our ability to successfully commercialize our existing product candidates depends on our ability to successfully obtain regulatory approvals, among other factors. Thus, we may not generate meaningful revenue until after we have successfully begun and completed clinical development and received regulatory approval for the commercial sale of a product candidate. We may never complete clinical development or receive regulatory approval for the commercial sale of a product candidate and thus may never generate revenue from product sales.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when, if ever, we will be able to generate any meaningful revenue or achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations, and cause a decline in the value of our securities, all or any of which may adversely affect our viability.

Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we may prioritize development of certain product candidates over others. We may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our programs, we may focus our programs on specific diseases and disease pathways and decide which product candidates to prioritize and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or potential therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. We may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. If we make incorrect determinations regarding the viability or market potential of any or all of our programs or product candidates or misread trends in the pharmaceutical industry, in particular, for neurodegenerative diseases, our business, prospects, financial condition and results of operations could be materially adversely affected.

We face risks related to public health epidemics and pandemics, including COVID-19, which could significantly disrupt our preclinical studies and clinical trials.

We are subject to risks associated with public health crises, such as pandemics and epidemics, which may have a material adverse effect on our business. Global health outbreaks, such as COVID-19, have and may continue to adversely affect our employees,

disrupt our business operations and practices, as well those of our customers, partners, vendors and suppliers. Public health measures by government authorities such as travel bans, social-distancing, lockdown measures, vaccination requirements may cause us to incur additional costs, limit our operations, modify our business practices, diminish employee productivity or disrupt our supply chain, which may have a material adverse effect on our business. To the extent a public health crisis will impact our business, financial condition and results of operations depends on factors outside of our control, including severity, duration and the measures to contain the health outbreak..

Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.

Recent disruptions to the global economy since 2020 have impeded global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these disruptions in lead times and increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we have undertaken or may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain will not have a material adverse effect on our business, financial condition and results of operations.

Furthermore, inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

Unfavorable global economic conditions and adverse developments with respect to financial institutions and associated liquidity risk could adversely affect our business, financial condition and stock price.

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

Adverse global conditions, including economic uncertainty, may negatively impact our financial results.

Global conditions, dislocations in the financial markets, any negative financial impacts affecting United States corporations operating on a global basis as a result of tax reform or changes to existing trade agreements or tax conventions, or inflation, could adversely impact our business in a number of ways, including longer sales cycles, lower prices for our products, reduced licensing renewals, customer disruption or foreign currency fluctuations.

In addition, the global macroeconomic environment could be negatively affected by public health emergencies, pandemic or other epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine and the resulting prolonged conflict and other political tensions, Hamas' attack against Israel and the ensuing conflict, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

Changes in U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was signed into law to address the COVID-19 crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) net operating loss rules, (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Internal Revenue Code of 1986, as amended, or the Code.

On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the "Tax Cuts and Jobs Act" (the "TCJA"), which also significantly changed the U.S. federal income taxation of U.S. corporations. TCJA remains unclear in many respects and has been, and may continue to be, subject to amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, or the IRS, any of which could lessen or increase certain adverse impacts of TCJA. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

While some of these U.S. federal income tax changes may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going-forward basis. We continue to work with our tax advisors and auditors to determine the full impact TCJA and the CARES Act will have on us. We urge our investors to consult with their legal and tax advisors with respect to both TCJA and the CARES Act and the potential tax consequences of investing in our securities.

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

We have incurred significant losses since our inception and we expect to continue to incur significant losses for the foreseeable future. Under the Internal Revenue Code of 1986, or the Code, a corporation is generally allowed a deduction for net operating losses ("NOLs"), carried over from a prior taxable year. Any NOLs generated after 2017 have no expiration.

Net operating loss and tax credit carry-forwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and are subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code. Based upon our analysis, we have determined that such an ownership change has occurred and a Section 382 limitation has been applied in the current year to limit the amount of tax attributes utilized.

Risks Related to Development, Regulatory Approval and Commercialization

Our business depends upon the success of our** potential **therapeutic modalities and product candidates.

Our success depends on our ability to utilize our three Treg-modifying potential therapeutic modalities (the "Treg Modalities") and to obtain regulatory approval for our product candidates, to generate other product candidates derived from our Treg Modalities, and to then commercialize our other product candidates for one or more indications. Our Treg Modalities and our product candidates have not been approved and may never become commercialized. All of our product candidates developed from our Treg Platforms will require significant additional clinical and non-clinical development, review and approval by the FDA or other applicable regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. If any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, such problems could impact or halt the development plans for our other product candidates because all of our product candidates are based on the same core Treg engineering technology.

Utilizing Treg cells represents a novel approach to the treatment of neurodegenerative and auto immune diseases, and we must overcome significant challenges in order to develop, commercialize and manufacture our product candidates.

We have concentrated our research and development efforts on utilizing Treg cells as an immunotherapy. To date, the FDA has approved only a small number of cell-based therapies for commercialization. We are not aware of any Treg therapy approved by any regulatory authority for commercial use. The processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our product candidates. Because our Treg Modalities are novel, and cell-based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like our Treg product candidates. This novelty may lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications if and when submitted, increase our development costs and delay or prevent commercialization of

our products. Additionally, advancing novel therapies for neurodegenerative and auto immune diseases creates significant challenges for us, including:

- educating medical personnel regarding the potential side-effect profile of our cells and, as the clinical program progresses, on observed side effects with the therapy;
- training a sufficient number of medical personnel on how to properly administer the clinical trials;
- enrolling sufficient numbers of patients in clinical trials;
- developing a reliable, safe and effective means of genetically modifying our cells;
- manufacturing our cells on a large scale and in a cost-effective manner;
- sourcing starting material suitable for clinical and commercial manufacturing; and
- establishing sales and marketing capabilities, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products.

We must be able to overcome these challenges in order for us to develop, commercialize and manufacture COYA 301, COYA 302, COYA 201, COYA 206 and COYA 101 and any of our other product candidates.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control.

Clinical trials are expensive, time consuming and subject to substantial uncertainty. Failure can occur at any time during the clinical trial process, due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA, or other applicable regulatory authorities may suspend or terminate clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. The FDA, or other applicable regulatory authorities may also require us to conduct additional testing, preclinical studies or clinical trials due to negative or inconclusive results or other reasons, fail to approve the raw materials, manufacturing processes or facilities of third-party manufacturers upon which we rely, find deficiencies in the manufacturing processes or facilities upon which we rely, and change their approval policies or regulations or their prior guidance to us during clinical development in a manner rendering our clinical data insufficient for approval. In addition, data collected from clinical trials may not be sufficient to support the submission of a Biologics License Application ("BLA") or other applicable regulatory filing. We cannot guarantee that any clinical trials that we may plan or initiate will be conducted as planned or completed on schedule, if at all.

A failure of one or more of our clinical trials could occur at any stage. Events that may prevent successful initiation, timely completion, or positive outcomes of our clinical development include, but are not limited to:

- delays in obtaining regulatory approval to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- our ability to recruit sufficient patients for our clinical trials in a timely manner or at all;
- delays in achieving a sufficient number of clinical trial sites or obtaining the required institutional review board, or IRB, approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by us or by the FDA or other regulatory agencies based on emerging data;
- clinical sites deviating from trial protocol or dropping out of a trial;
- suspension or termination of a clinical trial by the IRBs of the institutions in which such trials are being conducted or by the Data Safety Monitoring Board, or DSMB (where applicable);
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching a consensus with regulatory agencies on the design or implementation of our clinical trials;
- changes in regulatory requirements or guidance that may require us to amend or submit new clinical protocols, or such requirements may not be as we anticipate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- insufficient or inadequate quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;

- failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, or additional administrative burdens associated with foreign regulatory schemes; or
- failure of ourselves or any third-party manufacturers, contractors or suppliers to comply with regulatory requirements, maintain adequate quality controls, or be able to provide sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates.

If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions. If we experience delays in the initiation, enrollment or completion of any preclinical study or clinical trial of our product candidates, or if any preclinical studies or clinical trials of our product candidates are canceled, the commercial prospects of our product candidates may be materially adversely affected, and our ability to generate product revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs and slow down our product candidate development and approval process.

There is no assurance that we will develop our product candidates successfully or be able to obtain regulatory approval for them.

We cannot guarantee that any of our product candidates will be safe and effective, or will be approved for commercialization, on a timely basis or at all. Although certain of our employees have prior experience with clinical trials, regulatory approvals and cGMP manufacturing, we have not previously completed any clinical trials or submitted a BLA to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. The FDA, and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. For further details about such reasons, see "-*Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control*." Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize any of our products and materially adversely affect our business, financial condition, results of operations and growth prospects.

Furthermore, because our product candidates are based on similar technology as COYA 301, if our clinical trials of COYA 301 encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for our other product candidates in our pipeline could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We currently collaborate with various research institutions to perform the research and development activities needed to develop our product candidates, and if we ever choose to or need to find alternative research institutions, we may not be able to do so at all or, if we are able to do so, it may be costly and may cause significant delays in the development and commercialization of our product candidates.

We do not currently own, lease or operate a principal laboratory, research and development or manufacturing facility of our own. Currently, we collaborate with various research institutions to perform research and development for our products, including The Methodist Hospital located in Houston, Texas. Establishing our own facilities would result in significant additional expense and may result in potential delays in testing and production. Building and operating our own production facilities would require substantial additional funds and other resources, of which there can be no assurance that we will be able to obtain. In addition, there can be no assurances that we would be able to enter into any arrangement with third parties to manufacture our product, if any, on acceptable terms or at all. The commercial success of products outside the United States will also be dependent on the successful completion of arrangements with future partners, licensees or distributors in each territory. There can be no assurance that we will be successful in continuing to contract with research institutions to perform research and development for our products, that we would be able to establish our own facilities should we choose to or find it necessary to do so, that we would be successful in establishing additional collaborative arrangements or that, if established, such future partners will be successful in commercializing our products.

Positive results from early studies of our product candidates are not necessarily predictive of the results of later studies and any future clinical trials of our product candidates. If we cannot show positive results or replicate any positive results from our earlier studies of our product candidates in our later studies and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. For example, preclinical models do not adequately represent the clinical setting, and thus cannot predict clinical activity nor all potential risks, and may not provide adequate guidance as to appropriate dose or administration regimen of a given therapy. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Interim data from clinical trials that we may conduct 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. Preliminary 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 announced. Negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates.

Any positive results from studies of our product candidates may not necessarily be predictive of the results from later studies and clinical trials. Similarly, even if we are able to complete our planned studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such studies and clinical trials of our product candidates may not be replicated in subsequent studies or clinical trial results.

Many companies in the pharmaceutical industry have suffered significant setbacks in mid and late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, findings made while clinical trials were underway, or safety or efficacy observations made in studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in studies and clinical trials nonetheless failed to obtain regulatory approval.

We may encounter substantial delays in our planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Our planned clinical trials are expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND or, in the case of the European Medicines Agency (the "EMA"), a clinical trial application (a "CTA"), will result in the FDA or EMA allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("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;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required IRB approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including, but not limited to, after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments in trials conducted by competitors that raise FDA or EMA concerns about risk to patients broadly; or if the FDA or EMA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays or difficulties resulting from the COVID-19 pandemic;
- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices, requirements, or applicable EMA or other regulatory guidelines in other countries;
- occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete future clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA 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 product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. If we are unable to design, conduct and complete our planned clinical trials successfully, our product candidates will not be able to receive regulatory approval.

In order to obtain FDA approval for any of our product candidates, we must submit to the FDA a new drug application with substantial evidence that demonstrates that the product candidate is both safe and effective in humans for its intended use. This demonstration will require significant research, preclinical studies and clinical trials.

Clinical trials are time-consuming, expensive and difficult to design and implement, in part because they are subject to rigorous requirements and the outcomes are inherently uncertain. Clinical testing may take many years to complete, and failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. If we receive authorization to conduct our planned clinical trials, we could encounter problems that could halt our planned clinical trials or require us to repeat such clinical trials. If patients participating in our planned clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we or the FDA believe that patients are being exposed to unacceptable health risks, such clinical trials may have to be suspended or terminated. Suspension, termination or the need to repeat a clinical trial can occur at any stage.

The clinical trial success of each of our product candidates depends in part on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. There is a lack of consensus regarding standardized processes for assessing clinical outcomes based on clinician-rated scales. Accordingly, the scores from our clinical trials may not be reliable, useful or acceptable to the FDA or other regulatory agencies.

Changes in standards related to clinical trial design could have a material adverse effect on our ability to design and conduct clinical trials as planned. For example, we expect to conduct clinical trials comparing our product candidates to both placebo and other approved drugs, but regulatory authorities may not allow us to compare our product candidates to a placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct such a planned clinical trial could increase. The FDA may disagree with our trial design and our interpretation of data from our planned clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our planned clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims or removal of certain warnings that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, which could have a material adverse effect on the labeling, distribution or promotion of a drug product.

Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing and commercialization of our product candidates and significantly increase our overall costs of drug development.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease that the product

candidate is intended to treat and who meet other eligibility criteria. The rates of patient enrollment, a significant component in the timing of clinical trials, are affected by many factors, including:

- our ability to open clinical trial sites;
- the size and nature of the patient population;
- the design and eligibility criteria of the clinical trial;
- the proximity of subjects to clinical sites;
- the patient referral practices of physicians;
- changing medical practice patterns or guidelines related to the indications we are investigating;
- competing clinical trials or approved therapies which present an attractive alternative to patients and their physicians;
- perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- our ability to obtain and maintain patient consents due to various reasons, including but not limited to, patients unwillingness to participate due to the ongoing COVID-19 pandemic;
- the risk that enrolled subjects will drop out or die before completion of the trial;
- patients failing to complete a clinical trial or returning for post-treatment follow-up; and
- our ability to manufacture the requisite materials for a patient and clinical trial.

In addition, we need to compete with many ongoing clinical trials to recruit patients into our expected clinical trials. Our clinical trials may also compete with other clinical trials for product candidates that are in a similar cellular immunotherapy area as our product candidates, and this competition could 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 may 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 site. If we are unable to enroll a sufficient number of patients in our clinical trials in a timely manner, our completion clinical trials may be delayed or may not be achieved, which would prevent us from commercializing our product candidates.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

In order to obtain FDA or other regulatory authority approval to market a new biological product we must demonstrate proof of safety, purity and potency, and efficacy in humans. To meet these requirements we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical 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 to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, because standards for pre-clinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre-IND proposal, the FDA may not accept the IND submission as presented, in which case patient enrollment would be placed on partial or complete hold and treatment of enrolled patients could be discontinued while the product candidate is re-evaluated. Even if clinical trials do begin for our preclinical programs, our clinical trials or development efforts may not be successful.

If any of our product candidates, or any competing product candidates, demonstrate serious adverse events, including the development of severe or fatal cytokine release syndrome, neurotoxicity or graft-versus-host disease, we may be required to halt or delay further clinical development.

Undesirable side effects that may be caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

In a pilot initial study of COYA 201, our Treg exosome product candidate, in a preclinical lupus nephritis model in mice, COYA 201 was administered at different dose levels and appeared to be well tolerated at the administered dose of $1x10^{10}$ exosomes (the low dosage level). However, we observed fatalities as a result of toxicity when COYA 201 was administered in extremely high doses ($1x10^{11}$ exosomes, or ten times the low dosage level), administered twice weekly. We do not know if these findings will translate into humans, for whom we expect to require significantly lower dosage levels. Though there were fatalities at the highest dosage administered (6 deaths out of a total of 12 animals), COYA 201 appeared to be well tolerated at the administered dose of $1x10^{10}$ exosomes. Dose escalation studies are standard in the early development of new treatments and the identification of the "maximum tolerated dose" and the "LD50", the dose that produces lethality in 50% of animals, are common studies in early preclinical development. As such, there can be no guarantee that any toxicity, or other adverse events observed in this model, will not occur in human subjects during clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects and/or unexpected characteristics. We continue to evaluate different potential indications to advance the development of COYA 201 into clinical studies.

Following the completion of the preclinical studies in different animal models of disease, we will evaluate the data to potentially conduct further preclinical studies and to select a potential clinical indication for human studies.

There can be no assurance that patients will not experience cytokine release syndrome, or CRS, neurotoxicity, graft-versus-host disease, or GVHD or other serious adverse events. Severe adverse events associated with COYA 301 may also develop. Such adverse events may cause delays in completion of our clinical programs. If unacceptable side effects arise in the development of our product candidates such that there is no longer a positive benefit risk, we, the FDA, the IRBs at the institutions in which our trials are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death.

Approval may be delayed or denied because we cannot satisfy FDA's Chemistry, Manufacturing and Control Requirements.

Formulation and manufacturing of biologic products such as ours is complex and expensive. Our BLAs must include information about the chemistry and physical characteristics of our products, and we must demonstrate that we have a reliable process for manufacturing the products in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP") requirements. The manufacturing process must consistently produce quality batches of the biologic, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we are unable to successfully complete any of these complex steps, approval of our biologic may be delayed or denied.

We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving such designations, and even if received, they may not benefit the development and regulatory approval process.

We may seek various designations by the regulatory authorities such as Regenerative Medicine Advanced Therapy Designation, or RMAT, Breakthrough Therapy Designation, Fast Track Designation, or PRIority MEdicine, or PRIME, from regulatory authorities, for any product candidate that we develop. A product candidate may receive RMAT designation from the FDA if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such condition. A breakthrough therapy is defined by the FDA as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation by the FDA. PRIME is a voluntary scheme launched by the EMA to strengthen support for the development of medicines

that target an unmet medical need through enhanced interaction and early dialogue with developers of promising medicines in order to optimize development plans and speed up evaluation to help such medicines reach patients earlier.

Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. The FDA and the EMA, as applicable, have broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for one or more of these designations, we cannot assure you that the applicable regulatory authority would decide to grant it. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures, as applicable. The FDA or EMA, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from any source.

We may seek Orphan Drug Designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

We have received Orphan Drug Designation for our COYA 101 product candidate for the active moiety or the principal molecular structural features. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation may entitle a party to financial incentives such as grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation may entitle a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for our product candidates, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, 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. Moreover, 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 if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. 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. While we may seek Orphan Drug Designation for applicable indications for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our Treg Modalities. We are seeking to do so through our internal research programs, and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are

ultimately identified. In addition, targets for different neurodegenerative and auto immune diseases may require changes to our cell manufacturing platform, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology modality used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may choose to cease development if we determine that clinical results do not show promise;
- product candidates we develop may nevertheless be covered by third-party patents or other exclusive rights;
- a product candidate may 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; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of neurodegenerative or auto immune disease, and we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a potential therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

If third parties that we rely on to conduct clinical trials do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as contract research organization, or CROs, to conduct or otherwise support clinical trials for our product candidates. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including Good Clinical Practice, or GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the competent authorities of the European Union member states, and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, we plan to rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with

outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If we fail to compete effectively with academic institutions and other biotechnology companies that are developing similar or alternatives to cellular immunotherapy product candidates, our business will be materially adversely affected.

The development and commercialization of new cellular immunotherapy products is highly competitive. We face competition from existing and future competitors with respect to each of our product candidates currently in development, and will face competition with respect to other product candidates that we may seek to develop or commercialize in the future. In addition, numerous academic institutions are conducting preclinical and clinical research in these areas, as well as with other white blood cell types including NK-T cells and gamma-delta T cells. It is also possible that new competitors, including those developing similar or alternatives to cellular immunotherapy product candidates, may emerge and acquire significant market share. Such competitors may have an advantage over us due to their greater size, resources or institutional experience, or may develop product candidates that are safer, more effective, more widely accepted, more cost-effective or enable higher patient quality of life than ours. More established biopharmaceutical companies may also develop and commercialize their product candidates at a faster rate, which could render our product candidates obsolete or non-competitive before they are fully developed or commercialized. If we are not able to compete effectively against our existing and potential competitors, our business, financial condition, results of operations and growth prospects may be materially adversely affected.

If any of our product candidates are approved for marketing and commercialization and we have not developed or secured third- party marketing, sales and distribution capabilities, we will be unable to successfully commercialize such products and may not be able to generate product revenue.

We currently have no sales, marketing or distribution organizational experience or capabilities. We will need to develop internal sales, marketing and distribution capabilities to commercialize any product candidate that gains FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into partnerships 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 to market products or decide to co-promote products with partners, 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 product 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, if any, either on our own or through third parties, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

If we are not able to establish pharmaceutical or biotechnology collaborations on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may seek to collaborate

with pharmaceutical and biotechnology companies to develop and commercialize such product candidates. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

If we enter into collaborations with third parties to develop or commercialize our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

If we enter into future collaboration with third parties, we could face the following risks:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

If conflicts arise between our collaborators and us, our collaborators may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Our collaborators may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Our product candidates could be subject to regulatory limitations following approval, if and when such approval is granted.

Following approval of a product candidate, if any, we must comply with comprehensive government regulations regarding the manufacture, labeling, marketing, distribution and promotion of biologic products. We must comply with the FDA's regulations, which prohibit promoting off-label uses. We may not be able to obtain the labeling claims necessary or desirable to successfully commercialize our product candidates in development.

The FDA and foreign regulatory authorities could impose significant restrictions on the use of an approved product including potentially restricting its use to limited clinical centers as well as through the product label, and on advertising, promotional and distribution activities associated with such approved product. The FDA or a foreign regulatory authority could also condition their approval on the performance of post-approval clinical trials, patient monitoring or testing, which could be time-consuming and expensive. If the results of such post-marketing trials are not satisfactory, the FDA or such foreign regulatory authority could withdraw marketing authorization or may condition continued marketing on commitments from us or our partners that may be expensive and/or time-consuming to fulfill.

In addition, if we or others identify side-effects after any of our products are on the market, if manufacturing problems occur subsequent to regulatory approval, or if we, our manufacturers or our partners fail to comply with regulatory requirements, including those mentioned above, we or our partners could be subject to the following:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned clinical trials;
- restrictions on such products manufacturing processes;
- changes to the product label;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- Untitled or Warning Letters from the FDA;
- withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; or
- imposition of civil or criminal penalties.

Any one or a combination of these penalties could prevent us from achieving or maintaining market acceptance of the affected product, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating any revenue or profit from the sale of such product and could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, third-party payors may impose limitations on centers and personnel that may administer our products, including but not limited to requiring third-party accreditation to be obtained before the use of our products is reimbursed in such a center, which could materially adversely affect our potential commercial success and lead to slower market acceptance.

The commercial success of any of our product candidates will depend upon such product candidate's degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Our product candidates may not be commercially successful. Even if requisite approvals are obtained from the FDA in the United States and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance by physicians, patients and healthcare payors of cell therapy products in general, and our product candidates in particular, as medically necessary, cost-effective and safe. Physicians, patients, healthcare payors and others in the medical community may not accept any product that we commercialize. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of cell therapy products and, in particular, our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA;
- the willingness of physicians to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements imposed by the FDA or other regulatory authorities, including any limitations or warnings contained in a product approved labeling;
- relative convenience and ease of administration;

- the timing of market introduction of competitive products;
- adverse publicity concerning our product candidates or favorable publicity about competing products and treatments;
- sufficient third-party payor coverage, any limitations in terms of center or personnel training requirement imposed by third parties and adequate reimbursement;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a Risk Evaluation and Mitigation Strategy, or REMS;
- the effectiveness of our sales, marketing and distribution efforts; and
- potential product liability claims.

Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after such product is launched. Our product candidates may not achieve broad market acceptance.

Furthermore, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. 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.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market such products and to generate product revenue.

We expect the cost of administration of our product candidates to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our products, if approved, will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor could depend upon several factors, including the third-party payor's determination that use of a product is (i) a covered benefit under its health plan, (ii) safe, effective and medically necessary, (iii) appropriate for the specific patient, (iv) cost-effective and (v) neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved drug products. In the United States, third-party payors, including government payors such as Medicare and Medicaid, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. Medicare and Medicaid are increasingly used as models for the development of private payors' and government payors' coverage and reimbursement policies. Currently, few cell therapy products have been approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services (the "CMS"), the agency responsible for administering Medicare. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, since there is a limited body of established protocols and precedents for these types of drug products. Moreover, reimbursement agencies in the European Union may be more conservative than CMS. For example, several immunotherapy drugs have been approved for reimbursement in the United States, whereas they have not been approved for reimbursement in certain European Union member states. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Outside the United States, international operations vary significantly by country and are subject to extensive government price controls and other market regulations, and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries could place pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It can also take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products, but monitor and control Company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our

products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs could limit coverage and the level of reimbursement for our product candidates. Payors are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and Actual Acquisition Cost.

The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. Furthermore, most third-party payors currently require additional accreditation for approved cell therapy drugs, which limits the centers that can administer the drugs, and similar limitations may also be imposed on the product candidates that we are developing. We expect to experience pricing pressures in connection with the sale of our product candidates, if any, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and on prescription drugs and surgical procedures in particular, has become intense. As a result, increasingly high barriers to entry are developing for new drug products such as ours.

Healthcare reform initiatives and other administrative and legislative proposals may harm our business.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

Specifically, there have been proposals in the United States to control the cost of drug treatments, patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. We believe that coverage and reimbursement for new therapies will be increasingly restricted. Recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Furthermore, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs could restrict the amount that we are able to charge for our drug products, which could render our product candidates, if approved, commercially unviable and materially adversely affect our ability to raise additional capital on acceptable terms.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any BLAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our BLAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any BLA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our BLAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

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

Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, 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.

If we market approved products outside the United States, we expect that we will be subject to additional risks in commercialization, including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, and other public health crises, illnesses, epidemics or pandemics, such as the potential impact of the COVID-19 outbreak

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Any of the foregoing difficulties, if encountered, could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our business operations and relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to penalties.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, the Health Insurance Portability and Accountability Act, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, the U.S. Physician Payments Sunshine Act and its implementing regulations, U.S. state laws and regulations, including, state anti-kickback and false claims laws, laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, laws requiring the registration of pharmaceutical sales representatives, laws governing the privacy and security of health information in certain circumstances, and similar healthcare laws and regulations in other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will also involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and

imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Any of the foregoing could significantly harm our business, financial condition, results of operations and growth prospects.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 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;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted, or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer's Medicaid rebate liability;
- 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, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- expansion of the entities eligible for discounts under the Public Health Service program; and a licensure framework for follow on biologic products.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. This includes enactment of the TCJA (as defined below), which, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. On September 9, 2021, the Biden Administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The United States Department of Health and Human Services ("HHS") plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act (the "IRA") in August 2022, which will, among other things, allow the HHS to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services ("CMS") reimburses under Medicare Part B and Part D, although only

high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price 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. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. 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.

Individual states in the United States have also become 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Risks Related to Our Employees, Managing Our Growth and Our Operations

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

As of March 1, 2024, we had eight full-time employees. We will need to continue to expand our managerial, operational, quality, manufacturing, finance, sales and other resources in order to manage our operations and clinical trials, continue our development activities and eventually commercialize our product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- discover new product candidates, develop the process and analytical methods for IND-enabling studies and FDA submissions, complete the required IND-enabling studies for each, and receive approval from the FDA and other regulatory authorities to initiate clinical trials for such product candidates;
- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- complete the technology transfer to and qualification of our cGMP manufacturing CDMO partner and process; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

If we are unable to attract skilled employees, increase the size of our organization or manage our future growth effectively, it will impair our ability to execute our business strategy and our business, financial condition, results of operations and growth prospects will be materially adversely affected.

If we fail to attract and retain senior management and clinical and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our chief executive officer, as well as other members of our senior management team. We are currently under contract with or have a business relationships with certain members of our senior management and clinical and key scientific personnel, and the loss of services of any of these individuals, whether due to termination of contract, illness, death, or for any other reason, would likely have an adverse consequence on our business, including, but not limited to potentially delaying or preventing the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our future product candidates.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable

terms, or at all. If we are unable to hire and retain the qualified personnel we need to operate our business, our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials will face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Any such outcomes could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Although we maintain product liability insurance coverage that also covers our clinical trials, such insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

In addition, although we are dependent on certain key personnel, we do not have any key man life insurance policies on any such individuals. Therefore, if any of our chief executive officer or other executive officers die or become disabled, we will not receive any compensation to assist with such individual's absence. The loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal.

We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry

biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore materially adversely affect our business, financial condition, results of operations and growth prospects.

Computer system interruptions, cyber-attacks or security breaches could significantly disrupt our product development programs and our ability to operate our business.

Our computer systems, as well as those of various third parties on which we rely, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any significant system failure, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidate could be delayed.

Furthermore, federal, state and international laws and regulations, such as the European Union's General Data Protection Regulation, or the GDPR, which took effect in May 2018, and the California Consumer Protection Act, which took effect on January 1, 2020, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail or if our privacy practices do not meet the requirements of such laws. Other states are considering similar laws that could impact our use of research data with respect to individuals in those states. There are extensive documentation obligations and transparency requirements, which may impose significant costs on us. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

Risks Related to Manufacturing

Our manufacturing process is complex and we may encounter difficulties in production, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.

Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with the collection of starting material from the donor, shipping such material to the manufacturing site, shipping the final product back to the clinical trial recipient, preparing the product for administration, infusing the patient with the product, manufacturing issues or different product characteristics resulting from the differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth and variability in product characteristics.

Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If, for any reason in our clinical studies, we lose the starting material for a manufactured product for one of our clinical trial patients at any point in the process, the manufacturing process for that patient would need to be restarted, or could result in such patient no longer participating in our clinical trial. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We will be required to maintain a chain of identity with respect to materials as they move from the donor to the manufacturing facility, through the manufacturing process and back to the clinical trial recipient. Maintaining a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product or regulatory action, including withdrawal of our products from the market, if licensed. Any failure in the foregoing processes could render a batch of product unusable, could affect the regulatory approval of such product candidate, could cause us to incur fines or penalties or could harm our reputation and that of our product candidates.

We may make changes to our manufacturing process for various reasons, such as to control costs, achieve scale, decrease processing time, increase manufacturing success rate or for other reasons. Changes to our process made during the course of clinical development could require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. Other changes to our manufacturing process made before or after

commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

We rely on third parties to manufacture our product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate cGMP facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We outsource all manufacturing of our product candidates and products to third parties until we can complete a cGMP facility that will allow us to supply the product candidates needed for our early-stage clinical trials. We compete with other companies for access to cGMP facilities and cannot assure continued access.

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. If these third-party manufacturers are unable to, or do not, scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

While we have entered into supply relationships with third-party manufacturers for supplies of certain of our product candidates for purpose of preclinical testing, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any product candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with sufficient third-party manufacturers, reliance on third-party manufacturers entails risks, including:

- reliance on the third-party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third-party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. The failure of our third-party manufacturers to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. If the third parties that we engage to supply any materials or to manufacture any products for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of the COVID-19 pandemic and the actions undertaken by governments and private enterprises to contain COVID-19, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

For COYA 201, we rely on Terumo BCT to manufacture the Terumo Bioreactors to generate the appropriate number of expanded Treg cells. Since the Treg exosomes are generated from these expanded Treg cells, the bioreactor is a required component of the process. Most of the reagents used in the process can be sourced from multiple manufacturers. In addition, COYA 201 requires a tangential flow filtration technology sourced from Repligen. Furthermore, COYA 201 requires a Nanosight technology sourced from Malvern. With respect to COYA 206, we will rely on multiple manufacturers of materials and equipment that are utilized in the manufacturing of COYA 206. For example, to image the exosomes we will rely on Malvern, to measure the size of the exosomes we will rely on Izon, for western blotting we will rely on ThermoFisher, for mass spectrometry we will rely on Applied Biosystems, and for DNA tethering materials we will rely on multiple manufacturers. For COYA 301, we have licensed the biologic cytokine from ARScience Biotherapeutics, Inc. and will rely on its manufacturing of the subject cytokine. For COYA 302, which involves COYA 301 plus a fusion protein, we have entered into the DRL License Agreement with DRL whereby will in-license DRL's proposed Abatacept biosimilar to be used in the development and commercialization of COYA 302 in the United States, Canada, Mexico, South America, the European Union, the United Kingdom, and Japan.

Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates. Any alternative vendor would also need to be qualified through a New Drug Application ("NDA") supplement and may need to undergo an FDA inspection before the supplement can be approved, which could result in further delay, including delays related to additional clinical trials.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredients ("APIs") on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our product candidates, and clinical trials of future potential product candidates, may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

We are dependent on third parties to store our Treg cells and other products and any damage or loss would cause delays in replacement, and our business could suffer.

The Treg cells and other products are stored in freezers at third-party biorepositories and will also be stored in our freezers at our production facility. If these materials are damaged at these facilities, including by the loss or malfunction of these freezers or our back-up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement Treg cells and exosomes, viral vector, and master and working cell banks of the engineered K562 cells, which would impact clinical supply and delay our patients' treatments. If we are unable to establish replacement materials, we could incur significant additional expenses and liability to patients whose treatment is delayed, and our business could suffer.

We have not yet developed a validated methodology for freezing and thawing large quantities of Treg cells, which we believe will be required for the storage and distribution of our Treg product candidates.

We have not yet demonstrated that Treg cells, which can be frozen and thawed in smaller quantities, can also be frozen and thawed in large quantities without damage, in a cost-efficient manner and without degradation over time. We may encounter difficulties not only in developing freezing and thawing methodologies for large scale use, but also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze Treg cells for shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing our production facility, will be limited. Even if we are able to successfully freeze and thaw Treg cells in large quantities, we will still need to develop a cost-effective and reliable distribution and logistics network, which we may be unable to accomplish.

Furthermore, we have not yet demonstrated long-term stability of cryopreserved Treg cells and therefore do not know if we will be able to store the cryopreserved cells for extended periods of time. If we are unable to demonstrate long-term stability, we will need to reduce the manufacturing batch size to ensure that the material we produce will be used before it expires. In that case, the scaling of our production processes will not deliver the efficiencies we expect, and the cost per dose of our product candidates will be substantially higher.

For these and other reasons, we have not yet established the long-term stability of our cryopreserved Treg Cells and we may not be able to commercialize Treg cells on a large scale or in a cost-effective manner. If such product is found to be instable, we would be required to conduct more frequent manufacturing runs, which could cause us to incur significant additional expenses.

Risks Related to Our Intellectual Property

If our license agreement with The Methodist Hospital is terminated, we could lose our rights to key components enabling our Treg Modalities.

Key components of the technology utilized in our Treg Modalities have been in-licensed pursuant to an Amended and Restated Patent and Know How License Agreement, (the "Methodist License Agreement"), between us and The Methodist Hospital located in Houston, Texas (the "Methodist"). Pursuant to the Methodist License Agreement, Methodist granted to us an exclusive, worldwide, royalty-bearing, sublicensable license under specified patents and patent applications related to Treg technology in the field of therapeutics. Pursuant to the Methodist License Agreement, we are also required to pay Methodist, on a licensed product-by-licensed product and country-by-country basis, royalties (subject to customary reductions) ranging from 1% to 10% of annual worldwide net sales of such licensed product. The applicable royalty percentage increases as Licensed Products are used to treat from only one to more than three indications and if a given licensed product utilizes only Treg cell therapy or is a combination of both Treg cell therapy and exosomes. Therefore, the lowest tier is paid when there is only a single indication being addressed with a single product. There is only

one low double-digit tier with such tier bearing only on combination products where there are three or more indications being served. We are also required to pay a low single digit percentage for certain licensed services. We are required to pay mid-teens royalties on sublicense revenue.

The term of the Methodist License Agreement extends until expiration of the last of the patent rights licensed to us by the Licensor, which is currently expected to occur in approximately 2039. The Licensor may terminate the Methodist License Agreement or convert it into a non-exclusive license upon the occurrence or non-occurrence of certain events subject to the terms and conditions therein, such as (i) not "Actively Attempting to Develop or Commercialize" (as defined in the Methodist License Agreement) for a continuous period of 6 months anytime beginning October 2, 2025, (ii) breach of obligation to make timely payments or reports by us, (iii) an uncured material breach by us, (iv) the cessation of our business or our insolvency, liquidation or receivership. If the Licensor terminates or narrows the Methodist License Agreement, we could lose the use of intellectual property rights that may be material or necessary to the development or production of our product candidates, which could impede or prevent our successful commercialization of such product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects.

Furthermore, our Methodist License Agreement with the Licensor is field-specific and has been granted to us in the field of therapeutics. This Methodist License Agreement permits Licensor to practice the licensed rights, and to allow non-profit academic third parties to practice the licensed rights for certain academic purposes. As such, certain patents in a patent family that is licensed to us by the Licensor have been licensed to at least one other third party. Although these patents should not be overlapping with our licensed patents, there is a risk that inadvertent overlap may occur, and thus resources may have to be expended to resolve any such overlap and to prevent other licensees from practicing under our licensed patents rights. If any of the foregoing were to occur, it could delay our development and commercialization of our product candidates, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our development and commercialization rights to our current and future product candidates and technology are subject, in part, to the terms and conditions of licenses granted to us by others.

Our patent portfolio consists of pending patent applications licensed from third parties, jointly owned with third parties and assigned solely to us based on our ongoing development activities. We are reliant upon certain of these rights and proprietary technology from third parties for the engineering and development of our current and future product candidates. However, these and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we choose to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

We also engage in collaborations with scientists at academic and non-profit institutions to access technologies and materials that are not otherwise available to us. Although the agreements that govern these collaborations may include an option to negotiate an exclusive license to the institution's rights in any inventions that are created in the course of these collaborations, we may not be able to come to a final agreement for an exclusive license with an institution.

Such licenses and other contracts may be the subject of disagreements with the grantors and/or various third parties regarding the interpretation of such licenses and contracts. The resolution of any such disagreements that may arise could affect the scope of our rights to the relevant technology, or affect financial or other obligations under the relevant agreement, either of which could inhibit our ability to utilize the underlying technology in a cost-effective manner to develop and commercialize our product candidates, which in turn could have materially adversely affect our business, financial condition, results of operations and growth prospects.

Under certain circumstances such as a material breach of terms, our licensors could terminate our license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with our best interests. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be impaired. Additionally, we may be required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in-license from them.

Furthermore, our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership 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 harm our competitive position, and our business.

Duration of patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and the expiration of our patents may subject us to increased competition.

As of the date of this Annual Report on Form 10-K, our patent estate derived from our relationship with The Houston Methodist Hospital included one U.S. non-provisional patent application, five foreign patent applications, and six pending Patent Cooperation Treaty ("PCT") applications, each co-owned with or in-licensed from The Houston Methodist Hospital. These patent applications are directed to our Treg and exosome compositions and methods of use, methods of Treg and exosome manufacture, and methods of in vivo Treg expansion via combination therapies, among other things.

We have filed intellectual property claims on the contents of the exosomes, namely the micro RNAs that are reproducibly represented from batch to batch. Many of these micro RNAs confer anti-inflammatory functionality as a mechanism of action and may explain the exosomes immunomodulatory function. The exosome field is an emerging and new area at present and understanding the functional aspects of the exosomes is an important but evolving regulatory aspect. We have filed intellectual property claims for compositions of matter that teach the reproducible micro RNA contents. To date, no patents have been issued.

If any patents issue from or claim priority to these patent applications, the patents are expected to expire in 2040 and 2042, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, our patent estate derived from our relationship with ARScience Biotherapeutics, Inc. (described below) included one published patent application and one provision patent application. The patents are expected to expire in 2041 and 2043, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. All of our Houston Methodist Hospital patents have composition and method claims, with the exception of a biomarker patent, which has only method claims. The ARScience Biotherapeutics, Inc. patents have composition, method, and utility claims. Our patent estate derived from our relationship with Dr Reddy's Laboratories includes one published patent application This patent, if granted, is expected to expire in 2039, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Dr. Reddy's patent has composition, method, and utility claims. our patent estate derived from our relationship with the University of Nebraska includes two provisional patent applications. These patents, if granted, are expected to expire in 2044, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The University of Nebraska patents have use claims. Finally, our patent estate derived from our relationship with Carnegie Mellon included one pending patent application. The patents, if granted, would is expected to expire in 2043, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Carnegie Mellon patent has method claims.

We can provide no assurance that we will be able to file or receive additional patent protection for our product candidates.

Patent expiration dates may be shortened or lengthened by a number of factors, including terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Our patent protection could also be reduced or eliminated for noncompliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies. In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights.

Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent; provided that the patent is not enforceable for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims directed to the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, we could be exposed to liability to the applicable patent owner. If we or our licensors fail to maintain the patents and patent applications covering our product candidates and technologies, we may not be able

to prevent a competitor from marketing products that are the same as or similar to our product candidates. Further, others commercializing products similar or identical to ours, and our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, which could increase competition for our product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects.

If any patent protection we obtain is not sufficiently robust, our competitors could develop and commercialize products and technology similar or identical to ours.

The market for cell therapy is highly competitive and subject to rapid technological change. Our success depends, in large part, on our ability to maintain a competitive position in the development and protection of technologies and products for use in these fields and to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business. If we are unable to protect our intellectual property, our competitive position could be materially adversely affected, as third parties may be able to make, use or sell products and technologies that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred. This, in turn, would materially adversely affect our ability to compete in the market.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates or effectively prevent others from commercializing competitive technologies and product candidates.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Claim scope in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Even after issuance, our owned and in-licensed patents may be subject to challenge, which if successful could require us to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the use of the underlying technology, which could materially adversely affect our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, even after issuance, may be challenged in the courts or patent offices in the United States and abroad. Third-party challenges may result in a loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to prevent others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and product candidates.

Even if our patents are determined to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which could materially adversely affect our ability to develop, manufacture and market our product candidates.

There are many patents issued or applied for in the biotechnology industry, and we may not be aware of patents or patent applications held by others that relate to our business. We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and elsewhere that is relevant to or necessary for the development and commercialization of our product candidates in any jurisdiction.

For example, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or

made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications directed to our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to patents directed to such technologies. If third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter recited by the patent claims of our applications.

Furthermore, after issuance, the scope of patent claims remains subject to construction as 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, and we may incorrectly determine that our product candidates 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. Our determination of the expiration date of any patent in the United States or elsewhere that we consider relevant may also be incorrect, which. If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We may also be forced to attempt to redesign our product candidates in a manner that no longer infringes 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 the development and commercialization of our product candidates.

Claims brought against us for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, would be costly and time-consuming and could prevent or delay us from successfully developing or commercializing our product candidates.

Our success depends in part on our ability to develop, manufacture and market our technology and use our technology without infringing the proprietary rights of third parties. As the relevant product industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated. As a result, our technology and any future products that we commercialize could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our product candidates.

We may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Accordingly, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether any such claims that we are infringing patents or other intellectual property rights have merit, such claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend.

Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our product candidates while we develop non-infringing substitutes, or may result in significant settlement costs. Litigation can involve substantial damages for infringement (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), and the court could prohibit us from selling or require us to take a license from a third party, which the third party is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees, milestone fees, or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use, or sale.

We may not be able to effectively monitor unauthorized use of our intellectual property and enforce our intellectual property rights against infringement, and may incur substantial costs as a result of bringing litigation or other proceedings relating to our intellectual property rights.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products for potential infringement of our rights. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully monitor unauthorized use of our intellectual property could result in competitors offering products that incorporate our product or service features, which could in turn reduce demand for our products.

We may also, from time to time, seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property.

If we choose to enforce our patent rights against a party, that party could counterclaim that our patent is invalid and/or unenforceable. The defendant may challenge our patents through proceedings before the Patent Trial and Appeal Board, or PTAB, including *inter partes* and post-grant review. Proceedings to challenge patents are also available internationally, including, for example, opposition proceedings and nullity actions. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability and PTAB challenges are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion 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. Third parties may also raise similar claims before the PTAB, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our product candidates.

In addition, such lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. Litigation is inherently unpredictable, and there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. Furthermore, 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. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights.

There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could materially adversely affect the value of our common stock and warrants. Finally, any uncertainties resulting from the initiation and continuation of any litigation could materially adversely affect our ability to raise the funds necessary to continue our operations.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We have a number of international patents and patent applications, and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. However, filing, prosecuting and defending patents relating to our product candidates, including all of our in-licensed patent rights, in all countries throughout the world would be prohibitively expensive. We must ultimately seek patent protection on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Furthermore, the protection offered by intellectual property rights in certain countries outside of the United States may be less extensive than those in the United States. Consequently, we may not be able to prevent third parties from utilizing proprietary technology in all countries outside of the United States, even if we pursue and obtain issued patents in particular foreign jurisdictions, or from selling or importing products made using our proprietary technology in and into the United States or other jurisdictions. Such products may compete with our products, and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing. If such competing products arise in jurisdictions where we are unable to exercise intellectual property rights to combat them, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

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

The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. For example, in recent years the U.S. Supreme Court modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Those changes may materially adversely affect our patent rights and our ability to obtain issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Under the Leahy-Smith America Invents Act, or the America Invents Act, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on 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 weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects.

We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors.

While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self-executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be materially diminished.

Trade secrets are difficult to protect. We rely on trade secrets to protect our proprietary information and technologies, especially where we do not believe patent protection is appropriate or obtainable, or where such patents would be difficult to enforce. We rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators and other advisors to protect our trade secrets and other proprietary information. We cannot guarantee that we have entered into such agreements with each party that may have had access to our proprietary information or technologies, or that such agreements, even if in place, will not be circumvented. These agreements may not effectively prevent disclosure of proprietary information or technology and may not provide an adequate remedy in the event of unauthorized disclosure of such information or technology. In addition, others may independently discover our trade secrets and proprietary information, in which case we may have no right to prevent them from using such trade secrets or proprietary information to compete with us. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business, financial condition, results of operations and growth prospects.

Risks Related to Our Securities

If we sell securities in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock, warrants or other securities convertible into our common stock, at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any of our securities sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders and holders of our warrants could experience additional dilution and, as a result, our stock price may decline.

Our directors, executive officers and principal stockholders have substantial control over us and could delay or prevent a change of corporate control.

Our directors, executive officers, and 5% stockholders beneficially own approximately 30.6% of the voting power of our outstanding common stock. As a result, such entities and individuals will have the ability, acting together, to significantly influence the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our Certificate of Incorporation and Bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. Certain of these individuals also have significant control over our business, policies and affairs as officers or directors of our Company. Therefore, you should not invest in reliance on your ability to have any control over our Company.

The market price for our common stock may be volatile, and your investment in our securities could decline in value.

The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours without product revenues and earnings, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or disapproval of our product candidates or other product-related actions;
- developments involving our discovery efforts and clinical trials;
- developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;
- developments involving our efforts to commercialize our products, including developments impacting the timing of commercialization;
- announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general;
- public concerns as to the safety or efficacy of our product candidates or our competitors' products;
- changes in government regulation of the pharmaceutical or medical industry;
- changes in the reimbursement policies of third party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- developments involving corporate collaborators, if any;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

Certain companies with public floats comparable to our public float have experienced extreme volatility that was seemingly unrelated to the underlying performance of the respective company. We may experience similar volatility, which may make it difficult for prospective investors to assess the value of our common stock.

In addition to the risks addressed above in "- The market price for our common stock may be volatile, and your investment in our securities could decline in value," our common stock may be subject to extreme volatility that is seemingly unrelated to the underlying performance of our business. Recently, companies with comparable public floats have experienced instances of extreme stock price run-ups followed by rapid price declines, and such stock price volatility was seemingly unrelated to the respective company's underlying performance. Although the specific cause of such volatility is unclear, our public float may amplify the impact the actions taken by a few stockholders have on the price of our stock, which may cause our stock price to deviate, potentially significantly, from a price that better reflects the underlying performance of our business. Should our common stock experience run-ups and declines that are seemingly unrelated to our actual or expected operating performance and financial condition or prospects, prospective investors may have difficulty assessing the rapidly changing value of our common stock. In addition, investors of our securities may experience losses, which may be material, if the price of our common stock declines or if such investors purchase shares of our common stock prior to any price decline.

The warrants from our initial public offering are speculative in nature and may not have any value do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.

The warrants issued in our initial public offering do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price during a fixed period of time. The holders of the warrants may exercise their right to acquire common stock and pay an exercise price of $7.50 per share of common stock. The warrants became exercisable beginning on the closing of our initial public offering and will expire on the second anniversary of the date of issuance.

Until the holder of a warrant acquires shares of our common stock upon exercise of a warrant, the warrant will not provide the holder with any rights as a common stockholder, such as voting rights or the right to receive dividends. Upon exercise of a warrant, a holder will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date of the warrant.

The warrants issued in our initial public offering may not have any value.

The market value of the warrants issued in our initial public offering, if any, is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their imputed offering price. There can also be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants and, consequently, whether it will ever be profitable for holders of the warrants to exercise them.

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

As a public company, and particularly after we no longer qualify as an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, once we no longer qualify as an emerging growth company, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

We qualify as an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These provisions include, but are not limited to: being permitted to have only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations disclosure; an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act; not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements 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. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We intend to take advantage of the exemptions discussed above. As a result, the information we provide will be different than the information that is available with respect to other public companies. In this Annual Report on Form 10-K, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our securities less attractive if we rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and the market price of our common stock may be more volatile.

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year following the fifth anniversary of the completion of our initial public offering, (ii) the first fiscal year after our annual gross revenue exceeds $1.235 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700.0 million as of the end of the second quarter of that fiscal year.

We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

The administrator of our amended and restated 2021 Equity Incentive Plan (the "Amended and Restated Equity Plan") is authorized to exercise its discretion to effect the* repricing *of stock options and stock appreciation rights and there may be adverse consequences to our business if the administrator of the Amended and Restated Equity Plan exercises such discretion.

Pursuant to our Amended and Restated Equity Plan, we are authorized to grant equity awards, including stock options and stock appreciation rights, to our employees, directors and consultants. The administrator of the Amended and Restated Equity Plan (which is our compensation committee) is authorized to exercise its discretion to reduce the exercise price of stock options or stock appreciation rights or effect the repricing of such awards. Although we do not anticipate needing to exercise this discretion in the near term, or at all, if the administrator of the Amended and Restated Equity Plan were to exercise such discretion without seeking prior stockholder approval, certain proxy advisory firms or institutional investors may be unsupportive of such actions and publicly criticize our compensation practices, and proxy advisory firms may recommend an "against" or "withhold" vote for members of our compensation committee. In addition, if we are required to hold an advisory vote on named executive officer compensation (known as the "say-on-pay" vote) at the time of, or subsequent to, any such repricing, it is likely that proxy advisory firms would issue an "against" recommendation on our say on pay vote and institutional investors may not be supportive of our say-on-pay vote. If proxy advisory firms or institutional investors are successful in aligning their views with our broader stockholder base and we are required to make changes to the composition of our board and its committees, or if we need to make material changes to our compensation and corporate governance practices, our business might be disrupted and our stock price might be negatively impacted. Even if we are able to successfully rationalize the exercise of such discretionary power, defending against any "against" or "withhold" recommendation for members of our compensation committee, any "against" recommendation on our say on pay vote or public criticism could be distracting to management, and responding to such positions from such firms or investors, even if remedied, can be costly and time-consuming.

In addition, if the administrator of the Amended and Restated Equity Plan does determine to reprice stock options or stock appreciation rights, even absent negative reactions from proxy advisory firms and institutional investors, management attention may be diverted and we could incur significant costs, including accounting and administrative costs and attorneys' fees. We may also be required to recognize incremental compensation expense as such result of a repricing. These actions could cause our stock price to decrease and experience periods of increased volatility.

The rights of the holders of our securities may be impaired by the potential issuance of preferred stock.

Our amended and restated certificate of incorporation (the "Amended Charter") contains provisions that gives our board of directors the ability to designate and issue preferred stock in one or more series. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the relative voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could have the effect of discouraging, delaying or preventing a change of control of us. The possible

impact on takeover attempts could adversely affect the price of our securities. Although we have no present intention to designate any series, or issue any shares, of preferred stock, we may do so in the future.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently do not have research coverage by securities industry and financial analysts. We may not receive any research coverage by equity research analysts. Equity research analysts may elect not to initiate or to continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we obtain research coverage by such securities or industry analysts, if one or more of the analysts who cover us downgrade our stock, our stock price may decline significantly. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our organizational documents and Delaware law might discourage or delay attempts to acquire us that you might consider favorable.

Our Amended Charter, Amended and Restated Bylaws (the "Amended Bylaws") and Delaware law contain provisions that could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions:

- classifying our board into three classes;
- authorizing "blank check" preferred stock, which would be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors and officers;
- limiting the ability of our stockholders to call and bring business before special meetings;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and
- providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents certain stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our amended and restated certificate of incorporation, 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.

Our Amended Charter provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders and federal district courts will be the sole and exclusive forum for Securities Act claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our Amended Charter provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or to our stockholders; (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law (the "DGCL"), the Amended Charter or the Amended Bylaws or as to which the DGCL confers exclusive jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim governed by the internal affairs doctrine of the law of the State of Delaware, provided that the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction. Our Amended Charter further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts are the sole and exclusive forum for the resolution of any complaint asserting a right under the Securities Act, subject to a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. We note that investors cannot waive compliance with the federal

securities laws and the rules and regulations thereunder. The choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Further, the choice of forum provisions may result in increased costs for a stockholder to bring a claim. Alternatively, if a court were to find the choice of forum provisions contained in our Amended Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Provisions in our organizational documents regarding exculpation and indemnification of our directors and officers may result in substantial expenditures by us and may discourage lawsuits against our directors and officers.

Our Amended Charter and Amended Bylaws, to the maximum extent permissible under Delaware law, eliminates the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty. These provisions may discourage us, or our stockholders through derivative litigation, from bringing a lawsuit against any of our current or former directors or officers for any breaches of their fiduciary duties, even if such legal actions, if successful, might benefit us or our stockholders. In addition, our Amended Charter and Amended Bylaws provides that we will, to the fullest extent permitted by Delaware law, indemnify our directors and officers for costs or damages incurred by them in connection with any threatened, pending, or completed action, suit, or proceeding brought against them by reason of their positions as directors and officers. We also entered into indemnification agreements with each of our directors and executive officers. See "Certain Relationships and Related Party Transactions - Agreements with Directors and Officers - Indemnification Agreements." Although we expect to purchase directors' and officers' insurance, these indemnification obligations could result in our incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers.

We ratified certain actions pursuant to Section 204 of the Delaware General Corporation Law and filed Certificates of Validation with the Secretary of State of the State of Delaware.

As of February 1 and 2, 2022 respectively, our Board and our stockholders, ratified certain actions (the "2020 Ratifications") pursuant to Section 204 ("§204") of the Delaware General Corporation Law (the "DGCL"), which allows a Delaware corporation to ratify a defective corporate act retroactive to the date the corporate act was originally taken. The Ratification was adopted in order to correct certain failures of authorization with respect to the (i) merger of Nicoya Health, Inc. with and into the Company as of December 22, 2020 (the "Merger"), and (ii) amendment and restatement of the Corporation's certificate of incorporation filed with the Secretary of State of the State of Delaware (the "Secretary of State") on December 22, 2020 (the "A&R Charter") (collectively, the "2020 Corporate Acts") and thereby remove any uncertainty and confirm the valid issuance of (a) 1,887,453 shares of putative common stock of the Company to the former stockholders of Nicoya Health, Inc. pursuant to the Merger effective December 22, 2020, and (b) 7,361,744 shares of putative Series A preferred stock to the investors participating in that certain Series A Financing effective on December 22, 2020 (collectively, the "2020 Issuances").

Consequently, in accordance with §204, our Board ratified the 2020 Corporate Acts and the 2020 Issuances, and approved the submission to (i) the stockholders of the Company for ratification and approval of each of the 2020 Corporate Acts and the 2020 Issuances; and (ii) upon receiving stockholder ratification and approval, the Secretary of State of the State of Delaware of a Certificate of Validation regarding the Merger, and a separate Certificate of Validation regarding the A&R Charter. Our stockholders ratified the 2020 Corporate Acts and the 2020 Issuances on February 2, 2022.

Similarly, on February 16, 2022, our Board ratified certain actions (the "2021 Ratifications") pursuant to §204 in order to correct certain failures of authorization with respect to the (i) appointment and removal of certain members of our Board that occurred between March 30, 2021 and June 6, 2021 (the "Director Designations"); (ii) approval of our 2021 Equity Incentive Plan on February 5, 2021 (the "Equity Plan Adoption"); and (iii) certain option grants under the 2021 Equity Incentive Plan on April 10, 2021, May 17, 2021 and June 7, 2021 that resulted in the issuance of options exercisable for up to an aggregate of 45,650 putative shares of common stock at an exercise price of $1.09 per share (the "Option Grants"), and thereby remove any uncertainty regarding the composition of our Board as well as confirm the valid issuance of the Option Grants.

Consequently, in accordance with §204, our Board ratified the Director Designations, the Equity Plan Adoption and the Option Grants, and approved the submission to the stockholders of the Company for ratification and approval of each of the Director Designations and the Equity Plan Adoption, which our stockholders ratified on February 24, 2022.

Although we believe we have fully complied with the procedures and requirements of §204, there can be no assurance that (i) claims that the 2020 Corporate Acts, the 2020 Issuances, the Director Designations, the Equity Plan Adoption, and/or the Option Grants or putative stock ratified in connection with the 2020 Issuances and/or the Option Grants are void or voidable due to the identified failure of authorization, or (ii) claims that the Delaware Court of Chancery should declare in its discretion that the ratification pursuant to §204 not be effective or be effective only on certain conditions or other claims related thereto, will not be asserted, and, if asserted, that any such claims will not be successful. Under §204, these claims must be brought within 120 days from (A) the filing of the applicable

Certificate of Validation in the case of 2020 Corporate Acts and 2020 Issuances; (B) the date the stockholders ratify the Director Designations and Equity Plan Adoption in the case of the Director Designations and Equity Plan Adoption; and (C) the date the Board approved the 2021 Ratifications in the case of the Option Grants. If any of the ratifications pursuant to §204 were not effective, then the 2020 Corporate Acts, the 2020 Issuances, the Director Designations, the Equity Plan Adoption, and the Option Grants, as applicable, would be invalid and, as applicable, we could have liability to holders of the common stock and/or the Series A preferred stock corresponding to the 2020 Issuances and the grantees under the Option Grants, as applicable, including being subject to monetary damages and rescission rights.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have certain processes for assessing, identifying and managing cybersecurity risks, which are built into our overall information technology function and are designed to help protect our information assets and operations from internal and external cyber threats, and protect employee, collaborator and patient information from unauthorized access or attack, as well as secure our networks and systems. Such processes include physical, procedural and technical safeguards and routine review of our policies and procedures to identify risks and refine our practices. We consider the internal risk oversight programs of third-party service providers before engaging them in order to help protect us from any related vulnerabilities.

We do not believe that there are currently any known risks from cybersecurity threats that have affected, or are reasonably likely to materially affect, us or our business strategy, results of operations or financial condition.

Governance; Board Oversight

The Audit Committee of our Board provides direct oversight over cybersecurity risk, and provides updates to the Board of Directors regarding such oversight, when and if appropriate. Management provides periodic updates to the Audit Committee regarding cybersecurity matters including significant new cybersecurity threats or incidents, when and if appropriate.

We use technology-based tools that are designed to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

Item 2. Properties.

We currently conduct business operations from our virtual headquarters in Houston, Texas. We have intentions to move into a physical corporate headquarters sometime in the near future.

Item 3. Legal Proceedings.

From time to time, we may be involved in claims that arise during the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

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

Market Information

Our common stock trades on Nasdaq under the symbol “COYA.”

Holders

As of March 1, 2024, there were approximately 76 holders of record of our common stock. This number does not include beneficial owners whose shares are held in street name. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Dividends

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends if any, on the common stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Recent Sales of Unregistered Securities

In April 2022, we issued $10.5 million principal amount of convertible promissory notes, which bore interest at an annual rate of 6.0%, paid in kind, and had a maturity date of June 30, 2024 (the “2022 Promissory Notes”). The notes automatically converted into shares of common stock in connection with the closing of our initial public offering on January 3, 2023.

The foregoing transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. We believe this transaction was exempt from registration under the Securities Act in reliance on Section 4(a)(2), and/or Rule 506 of Regulation D promulgated thereunder, as a transaction by an issuer not involving any public offering.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and operating results together with our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of the Annual Report on Form 10-K captioned "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical-stage biotechnology company focused on developing proprietary new therapies to enhance the function of Tregs. Tregs are a subpopulation of T-lymphocytes consisting of CD4+CD25high hFOXP3+ cells that suppress inflammatory responses. Tregs were first discovered in 1995 by Dr. Shimon Sakaguchi and since their discovery, multiple lines of research have contributed to elucidate Treg biology and its role in health and disease. Tregs and their transcription factors have been shown to be essential to maintaining cellular homeostasis by regulating autoimmune and inflammatory responses and maintaining self-tolerance in mammals. Dysfunctional Tregs underlie numerous disease states, and this cellular dysfunction is driven by the chronic inflammatory environment and high levels of oxidative stress commonly observed in certain diseases. Further, the degree of Treg dysfunction is correlated with the severity and progression of serious and life-threatening conditions. These and other recent advances in the understanding of Treg biology, have made this subset of T-lymphocytes an important potential therapeutic target, which we believe may provide new treatments for serious diseases.

We have built a diversified product candidate pipeline that includes both ex vivo and in vivo approaches intended to restore the suppressive and immunomodulatory functions of Tregs. Our product candidate pipeline is based on our three distinct potential therapeutic modalities: Treg-enhancing biologics, Treg-derived exosomes, and autologous Treg cell therapy. "Autologous" means the treatment of a patient with human cells derived from the patient itself, whereas "Allogeneic" means the treatment of a patient with human cells derived from a donor other than the patient, where such donor is genetically non-identical. Our core focus is developing these therapies to target Treg dysfunction, which has been identified to be an important pathophysiological component of neurodegenerative, autoimmune, and metabolic diseases, where new and effective therapies are urgently needed.

Our lead assets are our Treg-enhancing biologics, which have been developed from key learnings established in our early work and discoveries of our autologous Treg cell therapy asset. Our autologous Treg cell therapy program has completed a Phase 1 and Phase 2a studies in amyotrophic lateral sclerosis, or ALS. We believe the clinical data from these initial studies served as an important confirmation of the underlying immunomodulatory properties of Tregs and their potential therapeutic benefits. These studies have also significantly expanded our own foundational knowledge of the biological activity of Tregs and key biomarkers of disease progression and drug effect, which we believe will be critical for the design of our future clinical and preclinical studies, the selection of future targeted diseases and the overall advancement of our development pipeline. We believe our findings have also established mechanistic benefits of combination biologics to address Treg dysfunction as well as highlighted important advantages of scalability and cost.

COYA 302, our lead asset, is the combination of our proprietary low dose interleukin-2 (COYA 301, or LD IL-2) and the immunomodulatory drug CTLA4-Ig, and we believe this combination has the potential to provide a sustained and durable effect on our first series of indications (neurodegenerative disorders) through targeting of multiple pathways. Our research and clinical efforts have led us to believe that combination biologics using our LD IL-2 as a backbone modality could be the best way to treat neurodegenerative conditions that are inherently driven by a complexity of pathways. We believe COYA 302 represents the most clinically advanced of what we hope will be a family of combination therapies that all feature our LD IL-2. Moreover, given its growing list of indications, we can now refer to COYA 302 as a "Pipeline in a Product."

Our operations have consisted of developing our clinical and preclinical product candidates and we have devoted substantially all of our resources to developing product and technology rights, conducting research and development, organizing and staffing our company, business planning and raising capital. We have funded our operations primarily through private convertible preferred stock offerings, a convertible debt financing, the public offering of our securities that closed in January 2023, and a private placement offering. Our net losses were $8.0 million and $12.2 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $25.9 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product

manufacturing, marketing, sales and distribution. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our product candidates;
- initiate nonclinical studies and clinical trials for any additional product candidates that we may pursue;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- acquire or in-license other product candidates and technologies;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions. The financial statements included elsewhere in this Annual Report on Form 10-K have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business and do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Product Developments

During the first half of 2023, our combination product for neurodegenerative diseases, or COYA 302, and our low dose IL-2, or COYA 301, showed positive results in a proof of concept, or POC, open label study in amyotrophic lateral sclerosis, or ALS, patients and in Alzheimer's Disease, or AD, patients, respectively. Both POC studies were conducted with commercially available products as investigator-initiated trials.

The POC study in support of COYA 302, an open label study conducted in 4 ALS patients, evaluated the safety and tolerability, function of regulatory T-cells, biomarkers, and preliminary efficacy (as measured by the ALSFRS-R scale) utilizing commercially available IL-2 and abatacept. Study data showed no decline or minimal decline at 24 and 48 weeks respectively after initiation of treatment and appeared to be well tolerated in all study patients as no serious adverse events were reported. Twenty-four weeks is an important timepoint as this is the period that ALS studies are usually benchmarked to measure differences in the ALSFRS-R scale for a treatment versus placebo. Based on this POC data, we intend to design a well-powered and well-controlled study to demonstrate the safety and efficacy of COYA 302 (COYA 301 or low dose IL-2, plus an abatacept proposed biosimilar, or DRL_AB, licensed from Dr. Reddy's Laboratories Ltd., or DRL) in patients with ALS. We are now preparing for an IND filing with the FDA in the first half of 2024. We intend to initiate a Phase 2 trial after the acceptance of our IND application by the FDA.

The POC study in support of COYA 301, an open label study conducted in 8 patients with AD, evaluated the safety and tolerability, biological activity, blood biomarkers, and preliminary efficacy of commercially available IL-2. Study data found that (i) cognitive function, as measured by 3 validated tools, either improved or did not decline, (ii) Treg function was significantly enhanced, (iii) pro-inflammatory blood cytokines and chemokines were significantly reduced with evidence of reduced neuroinflammation in the brain and (iv) the study treatment appeared to be well tolerated as no serious adverse events were reported. Currently, an ongoing academic Phase 2 double-blind, placebo-controlled, randomized trial for use of low dose IL-2 in mild to moderate AD patients is underway at Houston Methodist and we anticipate reporting top line data in the summer of 2024. On October 9, 2023, we announced that this study was fully enrolled with 38 patients. The study will evaluate the safety and tolerability, biological activity, blood and cerebrospinal fluid biomarkers, neuroimaging, and changes in cognitive function of LD IL-2 compared to placebo at pre-specified timepoints over the course of the 21-week treatment period and at 9 weeks after the last dose of study treatment.

Financings

On December 5, 2023, we entered into a Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of 4,370,382 shares of our common stock, or the 2023 Private Placement. The 2023 Private Placement resulted in gross proceeds of approximately $26.5 million, at a price of $6.06 per share of common stock, before deducting placement agent commissions and other offering expenses. In connection with the 2023 Private Placement, we issued to the placement agents and our financial advisor warrants to purchase up to an aggregate of 319,004 shares of common stock with an exercise price of $7.58 per share. These warrants have a term of four years from issuance, and will be exercisable beginning six months from the closing of the 2023 Private Placement.

On January 3, 2023, we closed our initial public offering, or IPO, of 3,050,000 shares of our common stock and accompanying warrants to purchase up to 1,525,000 shares of common stock. The warrants were offered and sold at the rate of one warrant for every two shares of common stock purchased in the offering, with each full warrant having an exercise price of $7.50 per share. Each share of common stock and accompanying warrant were sold at a combined offering price of $5.00, for gross proceeds of approximately $15.3 million, before deducting underwriting discounts and offering expenses. We issued the underwriters an additional 213,500 warrants with an exercise price of $6.25 per warrant as additional consideration. We granted the underwriters a 30-day over-allotment option to purchase up to an additional 290,000 shares of common stock and/or warrants to purchase 145,000 shares of common stock at the IPO price, less the underwriting discount. On January 25, 2023, we sold an additional 237,804 shares of common stock and accompanying warrants to purchase up to 145,000 shares of common stock upon the underwriters' exercise in part of their over-allotment option for additional gross proceeds of approximately $1.1 million, before deducting underwriting discounts and offering expenses. Upon the sale of the over-allotment option, we issued the underwriters an additional 16,646 warrants with an exercise price of $6.25 per warrant. Our shares of common stock began trading on the Nasdaq Capital Market under the ticker symbol "COYA" on December 29, 2022.

Components of Results of Operations

Collaboration Revenue

To date, we have not recognized any revenue from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all. Collaboration revenue represents revenue from the Development and License Agreement, or DRL Development Agreement, pursuant to which we granted DRL, and its affiliate, Dr. Reddy's Laboratories SA, or collectively, Dr. Reddy's an exclusive, royalty-bearing right and license to commercialize COYA 302, solely for use in patients with ALS in the United States, Canada, the European Union and the United Kingdom, or collectively, the New Territories.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our potential therapeutic candidates. We expense research and development costs as incurred, including:

- Expenses incurred to conduct discovery-stage laboratory work and preclinical studies including supplies, reagents, chemicals as well as external costs of funding research performed by third parties including consultants, academic and other institutions and clinical research organizations, or CROs that conduct our preclinical and nonclinical studies;
- activities being performed under our sponsored research arrangement with Houston Methodist;
- personnel expenses, including salaries, benefits and stock-based compensation expense for our employees engaged in research and development functions;
- clinical trial expenses and related clinical expenses to obtain regulatory approval of our potential therapeutic candidates including costs of research performed by third parties, costs associated with CRO's that conduct our clinical trials, costs to operate, manage, and monitor investigative sites and clinical, regulatory, manufacturing and other professional services;
- clinical expenses incurred under agreements with contract manufacturing organizations, or CMOs, or incurred directly by us for manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- fees paid to consultants who assist with research and development activities;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

We classify and evaluate our research and development expenses in two dimensions: clinical and preclinical, and external and internal. We do not further classify or evaluate our internal research and development expenses by product candidate or by Series as these expenses primarily relate to compensation, materials and supplies, and other costs which are deployed across multiple potential therapeutic modalities, multiple product candidates, and multiple potential therapeutic areas under development.

Once a product candidate has received approval from the FDA of its IND application, we consider it a clinical product candidate. For each of our clinical product candidates, we report or will report external development costs and other external research and development costs attributable to such clinical product candidates. These external development costs include: fees paid to CROs, CMOs and research laboratories, process development, manufacturing and clinical development activities. Any internal research and development expenses associated with clinical product candidates are captioned as internal research and development costs as described in the paragraph above.

Until such time as a product candidate has received approval of its IND application, we consider it a preclinical product candidate. Each of our preclinical product candidates is being developed on one of our three potential therapeutic modalities: (1) Treg-enhancing biologics; (2) Treg-derived exosomes; and (3) autologous Treg cell therapy. The product candidates utilizing our Treg-enhancing biologics are collectively referred to as the "300 Series." The product candidates utilizing our Treg-derived exosomes are collectively referred to as the "200 Series." The product candidates utilizing our autologous Treg cell therapy are collectively referred to as the "100 Series." Currently, our 300 Series product candidates include COYA 301 and COYA 302, our 200 Series product candidates include COYA 201 and COYA 206, and our 100 Series product candidate is COYA 101. For our preclinical candidates we report external development costs and other external research and development costs collectively by Series. These external development costs include: fees paid to CROs, CMOs and research laboratories, process development, manufacturing and clinical development activities. Preclinical research and development activities often benefit more than one preclinical product candidate within a given Series and so disaggregating the data would neither be practicable or meaningful.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our clinical trials, including later-stage clinical trials, for current and future product candidates and prepare regulatory filings for our product candidates. In addition, we expect spending in 2024 to increase over 2023 spending levels and will be focused primarily on advancing COYA 301 and COYA 302. As described in the notes to financial statements contained elsewhere in this Annual Report on Form 10-K, under the terms of our license we may be required to make payments to Methodist if certain milestones are achieved. This could result in significant charges to research and development in the period such milestones become probable of being achieved.

In-Process Research and Development

Research and development costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility which includes manufacturing, clinical, intellectual property and/or regulatory success which has no alternative future use. The licenses purchased by us require substantial completion of research and development and regulatory and marketing approval efforts in order to reach technological feasibility. As such, and since our inception, the purchase price of licenses acquired is classified as acquired in-process research and development expenses in the statements of operations.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees and consultants in executive, finance and accounting, legal, operations support, information technology and human resource functions. General and administrative expense also includes corporate facility costs not otherwise included in research and development expense, including rent, utilities, depreciation and maintenance, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our general and administrative expense will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, legal support and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of the Nasdaq Capital Market and the Securities and Exchange Commission, or SEC, director and officer insurance, investor and public relations costs. If any of our current or future product candidates

obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Depreciation

Depreciation expense relates to the fixed assets which consist mainly of lab equipment. The lab equipment is depreciated over its estimated useful life of five years.

Change in Fair Value of Convertible Promissory Notes

Under the fair value election as prescribed by ASC 815, we recognize the qualifying change in fair value of our convertible promissory notes each reporting period until the notes are settled. Changes in fair value attributable to changes in instruments specific credit risk are recorded in other comprehensive income to the extent they are material.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest earned on our excess cash and federal tax credits.

Income Taxes

For tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017, or the TCJA, eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the U.S. and 15 years for research activities performed outside the U.S. pursuant to Section 174 of the Code. In addition, we recognized revenue in connection with the DRL Development Agreement and long-term deferred revenue was required to be recognized in 2023 for tax purposes. We have limitations on the utilization of net operating losses and tax credits under Sections 382 and 383 of the Code. These requirements temporarily increase our U.S. federal and state cash tax payments and reduces cash flows in 2023. Cash tax payments are expected to be funded from existing cash balances and cash flows from operations.

Results of Operations

For the Years Ended December 31, 2023 and 2022

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022:

	Years Ended December 31,		
	2023	2022	Change
Collaboration revenue	$ 6,002,206	$ -	$ 6,002,206
Operating expenses:			
Research and development	5,501,527	4,412,498	1,089,029
In-process research and development	543,186	525,000	18,186
General and administrative	7,833,481	4,847,080	2,986,401
Depreciation	27,361	27,361	-
Total operating expenses	13,905,555	9,811,939	4,093,616
Loss from operations	(7,903,349)	(9,811,939)	1,908,590
Other income:			
Change in fair value of convertible promissory notes	-	(2,496,510)	2,496,510
Other income, net	639,365	63,673	575,692
Pre-tax loss	(7,263,984)	(12,244,776)	4,980,792
Income tax expense	(723,852)	-	(723,852)
Net loss	$ (7,987,836)	$ (12,244,776)	$ 4,256,940

Collaboration Revenue

Collaboration revenue was $6.0 million for the year ended December 31, 2023, related to the DRL Development Agreement we entered into with Dr. Reddy's in December 2023. We had no such collaboration revenue in 2022.

Research and Development Expenses

Research and development expenses increased by $1.1 million from $4.4 million for the year ended December 31, 2022 to $5.5 million for the year ended December 31, 2023. The increase was due to a $2.2 million increase in our preclinical expenses, a $0.5 million increase in internal research and development expenses, partially offset by a $1.4 million decrease in costs attributable to our sponsored

research agreement with Houston Methodist Hospital, and a $0.3 million decrease in costs for our clinical product candidate. For our product candidates (COYA 101), we track our external research and development expenses on a candidate-by-candidate basis. For our preclinical product candidates, we track our external research and development expenses in aggregate by Series. External research and development expenses include fees paid to CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not further classify or evaluate our internal research and development expenses by product candidate or by Series as these expenses primarily relate to compensation, materials and supplies, and other costs which are deployed across multiple potential therapeutic modalities, multiple product candidates, and multiple potential therapeutic areas under development.

Research and development expenses disaggregated and classified by clinical and preclinical, and external and internal expenses are summarized in the table below:

	Years Ended December 31,	
	2023	2022
External costs:		
Clinical product candidates:		
COYA 101	$ -	$ 288,072
Preclinical product candidates:		
COYA 200 Series	7,684	882,945
COYA 300 Series	3,306,627	209,420
Sponsored research	256,571	1,635,712
Internal costs:		
Internal research and development expenses, including stock-based compensation	1,930,645	1,396,349
Total	$ 5,501,527	$ 4,412,498

In-Process Research and Development

Under the terms of our exclusive License and Supply Agreement, or DRL Agreement, with DRL, we paid license fees of $0.5 million which was expensed as in-process research and development expense during the year ended December 31, 2023. For the year ended December 31, 2022, we paid license fees of $0.5 million under the terms of our license agreement with ARScience Biotherapeutics, Inc., which were expensed as in-process research and development.

General and Administrative Expenses

General and administrative expenses increased by $3.0 million from $4.8 million for year ended December 31, 2022 to $7.8 million for the year ended December 31, 2023. The increase was primarily due to an increase in personnel related expenses due to increases in employee headcount and an increase in our professional fees and consulting fees as we expanded our operations to support our research and development efforts. We expect that our general and administrative fees will continue to increase as we operate as a public company.

Other income, net

Other income, net increased by $0.6 million from the year ended December 31, 2022 compared to the year ended December 31, 2023. The increase was due to interest and dividends earned on cash balances received from our IPO and the 2023 Private Placement.

Income tax expense

We recorded of $0.7 million income tax expense for the year ended December 31, 2023. We had no such income tax expense for the year ended December 31, 2022.

Liquidity and Capital Resources

Overview

Since our inception, we have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since our inception through December 31, 2023 we have funded our operations through the sale of convertible promissory notes and convertible preferred stock, our IPO, and the 2023 Private Placement. As of December 31, 2023 we had $32.6 million in cash and cash equivalents and had an accumulated deficit of $25.9 million. We expect our existing cash and cash equivalents, together with the $7.5 million non-refundable upfront payment, or DRL Upfront Payment, to enable us to fund our operating expenses and capital expenditure requirements

into 2026. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

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

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- expenses needed to attract and retain skilled personnel;
- costs associated with being a public company;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We need significant additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table shows a summary of our cash flows for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
	2023	**2022**
Cash used in operating activities	$ (11,188,811)	$ (7,239,354)
Cash used in investing activities	(543,186)	(525,000)
Cash provided by financing activities	38,425,063	9,357,878
Net increase in cash and cash equivalents	$ 26,693,066	$ 1,593,524

Operating Activities

During the year ended December 31, 2023, we used $11.2 million of cash in operating activities. Cash used in operating activities reflected our net loss of $8.0 million, offset by a $4.6 million net decrease in our operating assets and liabilities and noncash charges of $1.4 million, which primarily consisted of $0.9 million in stock-based compensation and other charges of $0.5 million in acquired in-process research and development costs. The primary use of cash was to fund our operations related to the development of our product candidates.

During the year ended December 31, 2022, we used $7.2 million of cash in operating activities. Cash used in operating activities reflected our net loss of $12.2 million, offset by a $0.8 million net decrease in our operating assets and liabilities and noncash charges of $4.3 million, which primarily consisted of $2.5 million in the change in fair value of the convertible promissory notes, $1.0 million of debt issuance costs, and $0.5 million in acquired in-processing research and development costs. The primary use of cash was to fund our operations related to the development of our product candidates.

Investing Activities

During each of the years ended December 31, 2023 and 2022, we used $0.5 million of cash for the purchase of in-process research and development.

Financing Activities

During the year ended December 31, 2023, financing activities provided $38.4 million of cash, which consisted of $24.1 million in proceeds from the 2023 Private Placement, net of offering costs, $14.3 million in proceeds from issuance of common stock in the IPO, net of offering costs, and $0.1 million in proceeds from the exercise of stock options.

During the year ended December 31, 2022, financing activities provided $9.4 million of cash, which consisted of $10.5 million from the issuance of our convertible promissory notes, partially offset by the payment of issuance costs of $1.0 million.

DRL Development Agreement

In December 2023, we entered into the DRL Development Agreement, with Dr. Reddy's, pursuant to which, among other things, the Company granted to Dr. Reddy's an exclusive, royalty-bearing right and license to commercialize COYA 302 solely for use in patients with ALS, in the United States, Canada, the European Union and the United Kingdom, or collectively, the New Territories. We previously granted DRL an exclusive license to obtain regulatory approval and commercialize COYA 302 for ALS and certain other indications in all other countries (other than the New Territories, Japan, Mexico, and in each country in South America), pursuant to the License and Supply Agreement entered between with DRL, or the DRL Supply Agreement, effective as of April 1, 2023. COYA 302 is comprised of two components, COYA 301 and DRL_AB. In accordance with the DRL Supply Agreement, we in-licensed DRL_AB for the development and commercialization of COYA 302. Further, under the DRL Development Agreement, Dr. Reddy’s is responsible for the development of DRL_AB. We will have the responsibility for the clinical development of COYA 302 and for seeking regulatory approval in the United States for COYA 302 in ALS.

The collaboration is managed by a joint steering committee, or JSC, which is comprised of representatives from both parties. Decisions of the JSC are made by consensus. If the JSC is unable to reach a consensus, and the parties’ executives are not able to resolve the dispute, then Dr. Reddy’s has final decision-making authority, subject to specified limitations (as set forth in the DRL Development Agreement).

Pursuant to the DRL Development Agreement, we are entitled to an up-front, nonrefundable payment of $7.5 million, which was received in January 2024. Additionally, we are entitled to receive (i) an additional $4.2 million upon FDA acceptance of an Investigational New Drug, or IND, application for COYA 302 for the treatment of ALS and (ii) an additional $4.2 million payment upon the dosing of the first patient in the first phase 2 clinical trial for COYA 302 for the treatment of ALS in the United States. We anticipate an IND filing will be made in the first half of 2024. The DRL Development Agreement also calls for up to an aggregate of $40.0 million in development milestones and up to an aggregate of $677.3 million in sales milestones, related to the New Territories, should all such development and sales milestones be achieved. We will also be owed royalties by Dr. Reddy's on Net Sales (as defined in the DRL Development Agreement) of COYA 302 in the low to mid-teens (prior to paying royalties due pursuant to previously disclosed license agreements related to COYA 302).

Both parties shall discuss in good faith and agree in writing on the terms of a commercial supply agreement for the purpose of supply of COYA 302 to Dr. Reddy's. No such agreement has been entered into at the time of the filing of this Annual Report on Form 10-K.

The DRL Development Agreement expires on a country-by-country basis upon expiration of Dr. Reddy's obligation to make royalty payments for Product in each territory. Dr. Reddy's has the right to terminate the agreement upon specified prior written notice to us. Additionally, either party may terminate the agreement in the event of an uncured material breach of the agreement by, or insolvency of, the other party. Either party may terminate the agreement in the event that the other party commences a legal action challenging the validity, enforceability or scope of any licensed patent rights.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Policies

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid/accrued research and development expenses and include fair value of the Company's convertible promissory notes (see Notes 3 and 8 to our financial statements found elsewhere in this Annual Report on Form 10-K), equity and related inputs, including discount for lack of marketability and volatility, used to estimate the fair value of the grant date fair value of stock options (see Note 9 to our financial statements found elsewhere in this Annual Report on Form 10-K). We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

Collaboration Revenues

Our revenues have been solely generated through our DRL Development Agreement, which falls under the scope of Accounting Standards Codification, or ASC, Topic 808, *Collaboration Arrangements*, or ASC 808, as both parties are active participants in the arrangement that are exposed to significant risks and rewards. While this arrangement is within the scope of ASC 808, we analogize to ASC 606, *Revenue from Contracts with Customers*, for some aspects of this arrangement, including delivery of a good or service (i.e. unit of account). Revenue recognized by analogizing ASC 606 is recorded as collaboration revenue on the statements of operations. The terms of the arrangement includes payments of the following: nonrefundable, up-front license fees; regulatory and commercial milestone payments and royalties on net sales of licensed products. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps at inception of the agreement or upon material modification of the agreement: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. We identified two performance obligations for purposes of recognizing revenue, (i) certain development activities to advance the Product through clinical development, or R&D Services, and (ii) granting DR. Reddy's an exclusive, royalty-bearing right and license to commercialize the Product, or the License. We allocated the transaction price to both performance obligations based on the estimated stand-alone selling prices at contract inception and we will reevaluate the transaction price and the total estimated costs expected to be incurred to satisfy the performance obligations and adjust deferred revenue at the end of each reporting period. Such changes will result in a change to the amount of collaboration revenue recognized and deferred revenue.

Significant estimates were used in the determination of the stand-alone selling prices. The stand-alone selling price of the License was based on a discounted cash flow approach and considered several factors including, but not limited to, discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential using an adjustment market approach. The stand-alone selling price of the R&D Services was estimated using the expected cost-plus margin approach.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue an expense for preclinical studies and clinical trial activities performed by our vendors based upon estimates of the proportion of work completed. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the prepaid/accrual accordingly. Nonrefundable advance payments for goods and services, including fees for clinical trial expenses, process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Stock-Based Compensation

We measure compensation expense for all stock-based awards based on the estimated fair value of the stock-based awards on the grant date. We use the Black-Scholes option pricing model to value our stock option awards. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We have not issued awards for which vesting is subject to a market or performance conditions.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which requires assumptions, including the fair value of our common stock prior to the IPO, volatility, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. Certain assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These subjective assumptions are estimated as follows:

Fair value of common stock— Historically, for all periods prior to our IPO, the fair value of the shares of common stock underlying our share-based awards was estimated on each grant date by our board of directors. To determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid. Since becoming a public company in 2022, we have used our stock price to determine fair value of our common stock.

Expected volatility—As a privately held company we did not have any trading history for our common stock; accordingly the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. As a public company will continue to use the average volatility for comparable publicly traded biotechnology companies until we have ample trading history of our own stock commensurate with the estimated expected term of our options.

Estimating the Fair Value of Convertible Promissory Notes

We have elected the fair value option for the accounting for our convertible promissory notes issued in 2022 and utilized an independent third-party valuation specialist to assist management in measuring the fair value. The fair value of the convertible promissory notes are determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present

value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various IPO, settlement, equity financing, corporate transaction and dissolution scenarios. Since the convertible promissory notes converted to common stock on January 3, 2023, we were able to utilize this information in the estimate of the fair value of the convertible promissory notes at December 31, 2022.

Commitments and contingencies, including license and sponsored research agreements

Patent Know How and License Agreement with The Methodist Hospital

In September 2022, we entered into Methodist License Agreement with Methodist to make, sell and sublicense products and services using the intellectual property and know-how of Methodist. As part of the Methodist License Agreement, we will pay Methodist a four-figure license maintenance fee annually until the first sale of licensed product occurs. The term of the Methodist License Agreement is effective until no intellectual property patent rights remain, unless terminated sooner by (1) bankruptcy or insolvency, (2) the failure by us to monetize the intellectual property within five years of the date of the agreement (further discussed below), (3) due to breach of contract, or (4) at our election for any or no reason.

In addition to the equity issuance and reimbursement of patent related expenses, we agreed to make contingent milestone payments to Methodist on a Licensed Product-by-Licensed Product or Licensed Service-by-Licensed Service basis upon the achievement of certain development, approval and sales milestones (i) related to the treatment of ALS totaling up to $0.3 million in the aggregate, and (ii) related to the treatment of each other indication (that is not ALS) totaling between $0.2 million and up to $0.4 million in the aggregate per indication. We are also required to pay Methodist, on a licensed product-by-licensed product and country-by-country basis, royalties (subject to customary reductions) equal to 1% to 10% of annual worldwide net sales of such licensed product during a defined royalty term. The applicable royalty percentage increases as Licensed Products are used to treat from one to more than three indications and if a given Licensed Product utilizes only T-reg cell therapy or is a combination of both T-reg cell therapy and exosomes. Therefore, the lowest tier is paid when there is only a single indication being addressed with a single product. The highest tier is paid only on combination products where there are three or more indications being served. We are also required to pay a low single digit percentage for certain licensed services. We are required to pay royalties at between 10% to 20% of sublicense revenue. Commencing on January 1, 2025, the minimum amount which will be owed by us once commercialization occurs is $0.1 million annually.

The Methodist License Agreement provides that in the event we sublicense products and services covered by the Methodist License Agreement, then royalties owed to Houston Methodist would be computed as a percentage of payments received by us from the sublicensee. In addition, the termination provisions provide that Houston Methodist may only terminate the Methodist License Agreement, among other things, in the event that after five years we are not "Actively Attempting to Develop or Commercialize," as such term is defined in the Methodist License Agreement.

Sponsored Research Agreement with Houston Methodist Research Institute

In February 2021, we executed the SRA with HMRI. Pursuant to the SRA, we agreed to fund $1.5 million in research in the area of neurodegenerative diseases through February 2022. We subsequently amended the SRA to extend the term through February 2025, which includes an annual funding commitment of $1.5 million per year. As of September 15, 2022, we provided notice to HMRI regarding termination of the SRA in expectation that a reduced yearly budget be negotiated post termination. On May 4, 2023, we executed the SRA with HMRI, in which we agreed to fund approximately $0.5 million through May 2024. We incurred $0.3 million and $1.6 million in research and development expenses under the SRA during the years ended December 31, 2023 and 2022, respectively.

ARScience License Agreement

In August 2022, we entered into the ARS License Agreement with ARS pursuant to which ARS granted us an option to, if we choose to exercise such option, to acquire an exclusive, royalty-bearing license for two patents regarding certain formulations of IL-2 (the product that serves as the basis for COYA 301), with the right to grant sublicenses through multiple tiers under these patents. In consideration for the ARS Option, we paid ARS a one-time, non-refundable, non-creditable option fee of $0.1 million.

On December 1, 2022, we exercised the ARS Option by written notice to ARS, or the Option Exercise Notice. Upon the delivery of the Option Exercise Notice (such date of delivery, the "Effective Date"), ARS automatically was deemed to have granted to us the licenses and all provisions of the ARS License Agreement and the ARS License Agreement became effective as of the Effective Date. Pursuant to the terms of the ARS License Agreement, we paid to ARS a mid-six-figure up-front fee.

In addition, we may also owe tiered payments to ARS based on our achievement of certain developmental milestones. Under the ARS License Agreement, we will pay an aggregate of $13.3 million in developmental milestone payments for the first Combination Product (as defined in the ARS License Agreement) in a new indication. We will then pay an aggregate of $11.6 million in developmental milestone payments for each Combination Product in each subsequent new indication. Further, for the first Mono Product (as defined in the ARS License Agreement), we will pay an aggregate of $11.8 million in developmental milestone payments. We will then pay an aggregate of $5.9 million in developmental milestone payments for each Mono Product in each subsequent new indication, and we will owe an aggregate of $5.9 million if all developmental milestones are achieved for each new indication. We will also owe royalties on net sales of licensed products ranging from low to mid-single digit percentages. In the event we sublicense our rights under the ARS License Agreement, we will owe royalties on sublicense income within the range of 10% to 20%. To date, the $0.1 million option fee and the mid-six-figure up-front fee (upon exercise of the ARS Option) are the only payments made to ARS under ARS License Agreement.

Dr. Reddy's License and Supply Agreement

In March 2023, we entered into the DRL Supply Agreement with DRL. The DRL Supply Agreement became effective on April 1, 2023. Pursuant to the terms of the DRL Supply Agreement, we will in-license DRL_AB to be used in the development and commercialization of COYA 302 in the U.S., Canada, Mexico, South America, the European Union, the United Kingdom, and Japan. In consideration for the license, we paid a one-time, non-refundable upfront fee of $0.4 million. We will pay to DRL up to an aggregate of approximately $2.9 million of pre-approval regulatory milestone payments for the first indication in the Field (as defined in the DRL Supply Agreement), of which an aggregate of $0.2 million has been paid to date, and an additional approximately $20.0 million if all other development, regulatory approval and sales milestones are incurred under the DRL Supply Agreement. We will also pay to DRL a low-six figure milestone payment per additional indication. Further, pursuant to the DRL Supply Agreement, we will pay to DRL single-digit royalties on Net Sales (as defined in the DRL Supply Agreement).

Recent Accounting Pronouncements

See Note 2 to our financial statements found elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our financial statements.

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

Not Applicable.

Item 8. Financial Statements and Supplementary Data.

The information required by this item appears in a separate section of this Annual Report on Form 10-K beginning on page F-1 and is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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 by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting were effective as of December 31, 2023.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fourth quarter ended December 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) None.

(b) During the fiscal quarter ended December 31, 2023, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(c) of Regulation S-K.

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

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023, and is incorporated herein by reference.

Item 11. EXECUTIVE COMPENSATION

Information required by this item is incorporated herein by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a)(1) Financial Statements

The financial statements and related notes, together with the report of Weaver and Tidwell, L.L.P. appear at pages F-1 through F-20 following the Exhibit List as required by "Part II—Item 8—Financial Statements and Supplementary Data" of this Form 10-K.

(a)(2) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(a)(3) Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibit Number	Description
2.1	Agreement and Plan of Merger by and among Coya Therapeutics, Inc. and Nicoya Health, Inc. dated December 22, 2020 (incorporated by reference to Exhibit 2.1 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2023).
3.2	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2023).
4.1	Form of Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
4.2#	First Amended Investors' Rights Agreement dated as of March 4, 2022, by and among Coya Therapeutics, Inc. and certain holders of its capital stock (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
4.3	Form of Underwriters' Warrant (incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 13, 2022).
4.4	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 5, 2022).
4.5	Form of Warrant Agency Agreement between Coya Therapeutics, Inc. and Computershare Limited (incorporated by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 13, 2022).
4.6	Form of Newbridge/Allele Warrant used in December 2023 Private Placement (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on December 6, 2023).
4.7*	Description of Securities of Coya Therapeutics, Inc.
10.1	The Amended and Restated Coya Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 13, 2022).
10.2†	Form of Indemnification Agreement to be entered into by Coya Therapeutics, Inc. with its Officers and Directors (incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.3†	Executive Employment Agreement, dated December 15, 2020, by and between Coya Therapeutics, Inc. and Howard Berman (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.4†#	Employment Agreement Addendum, dated April 1, 2022, by and between Coya Therapeutics, Inc. and Howard Berman (incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.5†	Executive Employment Agreement, dated March 14, 2022, by and between Coya Therapeutics, Inc. and David Snyder (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.6†	Amended and Restated Employment Agreement, dated July 11, 2023, between the Company and Dr. Fred Grossman (incorporated by reference to Exhibit 10.1 to the Form 8-K filed by the Company on July 14, 2023).
10.7#	Amended and Restated Patent Know How and License Agreement, effective as of October 6, 2020, by and between Coya Therapeutics, Inc. and The Methodist Hospital (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).

10.8#	Sponsored Research Agreement, dated February 3, 2021, by and between Coya Therapeutics, Inc. and The Methodist Hospital Research Institute d/b/a Houston Methodist Research Institute (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.9#	First Amendment to Sponsored Research Agreement, dated February 4, 2022, by and between Coya Therapeutics, Inc. and The Methodist Hospital Research Institute d/b/a Houston Methodist Research Institute (incorporated by reference to Exhibit 10.9 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.10#	Second Amendment to Sponsored Research Agreement, dated February 4, 2022, by and between Coya Therapeutics, Inc. and The Methodist Hospital Research Institute d/b/a Houston Methodist Research Institute (incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.11#	Material Transfer and Option Agreement, dated June 24, 2022, by and between Coya Therapeutics, Inc. and Carnegie Mellon University (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.12#	License Agreement by and between Coya Therapeutics, Inc. and ARScience Biotherapeutics, Inc., dated August 23, 2022 (incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.13	Series A Placement Agent Warrant (incorporated by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.14	Convertible Note Placement Agent Warrant (incorporated by reference to Exhibit 10.14 of the Company's Registration Statement on Form S-1 filed with the SEC on November 18, 2022).
10.15†	Form of Stock Option Grant Notice and Option Agreement (incorporated by reference to Exhibit 10.15 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 13, 2022).
10.16	Form of Securities Purchase Agreement December 2023 Private Placement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 6, 2023).
10.17#	License and Supply Agreement by and between Coya Therapeutics, Inc. and Dr. Reddy's Laboratories Ltd. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2023).
10.18*#	Development and License Agreement by and among Coya Therapeutics, Inc., Dr. Reddy's Laboratories SA, and Dr. Reddy's Laboratories Ltd., dated December 5, 2023.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
97.1*	Clawback Policy.
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

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* Filed herewith.
** Furnished herewith.
† Management contract or compensatory plan or arrangement.
# Certain identified information has been excluded from this exhibit (indicated by asterisks) because it is both not material and the type of information that the Company treats as private or confidential, in accordance with the rules of the SEC.

Item 16. Form 10-K Summary
None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Coya Therapeutics, Inc.

Date: March 19, 2024 By: /s/ Howard Berman
Name: Howard Berman
Title: Chief Executive Officer

Date: March 19, 2024 By: /s/ David Snyder
Name: David Snyder
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Howard Berman **Howard Berman**	Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2024
/s/ David Snyder **David Snyder**	Chief Financial Officer (Principal Financial and Accounting Officer) Chief Operating Officer	March 19, 2024
/s/ Ann Lee **Ann Lee**	Director	March 19, 2024
/s/ Anabella Villalobos **Anabella Villalobos**	Director	March 19, 2024
/s/ Hideki Garren **Hideki Garren**	Director	March 19, 2024
/s/ Dov Goldstein **Dov Goldstein**	Director	March 19, 2024
/s/ Dieter Weinand **Dieter Weinand**	Director	March 19, 2024
/s/ Wilbur L. Ross **Wilbur Ross**	Director	March 19, 2024

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Coya Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Coya Therapeutics, Inc. ("the Company") as of December 31, 2023 and 2022, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 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 December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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 audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/ s / Weaver and Tidwell, L.L.P.

We have served as the Company's auditor since 2021.

Austin, Texas
March 19, 2024

COYA THERAPEUTICS, INC.
BALANCE SHEETS

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 32,626,768	$ 5,933,702
Collaboration receivable	7,500,000	-
Prepaids and other current assets	1,069,557	1,251,264
Total current assets	41,196,325	7,184,966
Fixed assets, net	65,949	93,310
Deferred financing costs	-	1,117,290
Total assets	$ 41,262,274	$ 8,395,566
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,155,656	$ 1,815,270
Accrued expenses	2,973,215	2,008,361
Deferred collaboration revenue	923,109	-
Total current liabilities	5,051,980	3,823,631
Deferred collaboration revenue	574,685	-
Convertible promissory notes	-	12,965,480
Total liabilities	5,626,665	16,789,111
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Series A convertible preferred stock, $0.0001 par value: 10,000,000 shares authorized, none and 7,500,713 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	-	8,793,637
Common stock, $0.0001 par value; 200,000,000 shares authorized; 14,405,325 and 2,590,197 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	1,441	259
Additional paid-in capital	61,501,801	681,106
Subscription receivable	(11,250)	-
Accumulated deficit	(25,856,383)	(17,868,547)
Total stockholders' equity (deficit)	35,635,609	(8,393,545)
Total liabilities and stockholders' equity (deficit)	$ 41,262,274	$ 8,395,566

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

COYA THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2023	**2022**
Collaboration revenue	$ 6,002,206	$ -
Operating expenses:		
Research and development	5,501,527	4,412,498
In-process research and development	543,186	525,000
General and administrative	7,833,481	4,847,080
Depreciation	27,361	27,361
Total operating expenses	13,905,555	9,811,939
Loss from operations	(7,903,349)	(9,811,939)
Other income:		
Change in fair value of convertible promissory notes	-	(2,496,510)
Other income, net	639,365	63,673
Pre-tax loss	(7,263,984)	(12,244,776)
Income tax expense	(723,852)	-
Net loss	$ (7,987,836)	$ (12,244,776)
Share information:		
Net loss per share of common stock, basic and diluted	$ (0.79)	$ (4.73)
Weighted-average shares of common stock outstanding, basic and diluted	10,163,850	2,590,173

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

COYA THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Convertible Preferred Stock Series A		Common Stock		Additional Paid-In	Subscription	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Equity
Balance as of December 31, 2021	7,500,713	$ 8,793,637	2,590,051	$ 259	$ 473,602	$ -	$ (5,623,771)	$ 3,643,727
Exercise of stock options	-	-	146	-	158	-	-	158
Stock-based compensation expense	-	-	-	-	207,346	-	-	207,346
Net loss	-	-	-	-	-	-	(12,244,776)	(12,244,776)
Balance as of December 31, 2022	7,500,713	8,793,637	2,590,197	259	681,106	-	(17,868,547)	(8,393,545)
Conversion of convertible preferred stock upon initial public offering	(7,500,713)	(8,793,637)	1,316,926	132	8,793,505	-	-	-
Conversion of convertible promissory notes upon initial public offering	-	-	2,736,488	274	12,965,206	-	-	12,965,480
Sale of common stock in initial public offering and over-allotment option, net of issuance costs of $2.3 million	-	-	3,287,804	329	14,136,099	-	-	14,136,428
Exercise of stock options, net of share settlements	-	-	85,528	8	89,939	-	-	89,947
Exercise of warrants	-	-	1,500	-	11,250	(11,250)	-	-
Stock-based compensation expense and vesting of restricted stock units	-	-	16,500	2	872,246	-	-	872,248
Sale of common stock in 2023 Private Placement, net of issuance costs of $2.5 million	-	-	4,370,382	437	23,952,450	-	-	23,952,887
Net loss	-	-	-	-	-	-	(7,987,836)	(7,987,836)
Balance as of December 31, 2023	-	$ -	14,405,325	$ 1,441	$ 61,501,801	$ (11,250)	$ (25,856,383)	$ 35,635,609

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

COYA THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (7,987,836)	$ (12,244,776)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation	27,361	27,361
Change in fair value of convertible promissory notes	-	2,496,510
Stock-based compensation, including the issuance of restricted stock	872,248	207,346
Debt issuance costs	-	997,367
Acquired in-process research and development assets	543,186	525,000
Changes in operating assets and liabilities:		
Collaboration receivable	(7,500,000)	-
Prepaids and other current assets	181,707	(920,002)
Accounts payable	298,816	845,284
Accrued expenses	877,913	826,556
Deferred collaboration revenue	1,497,794	-
Net cash used in operating activities	(11,188,811)	(7,239,354)
Cash flows from investing activities:		
Purchase of in-process research and development assets	(543,186)	(525,000)
Net cash used in investing activities	(543,186)	(525,000)
Cash flows from financing activities:		
Proceed from sale of common stock from 2023 Private Placement, net of offering costs	24,084,805	-
Proceeds from issuance of common stock upon IPO, net of offering costs	14,250,311	-
Payment of deferred financing costs related to the IPO	-	(113,883)
Proceeds from the issuance of convertible promissory notes	-	10,468,970
Payment of debt issuance costs	-	(997,367)
Proceeds from the exercise of stock options	89,947	158
Net cash provided by financing activities	38,425,063	9,357,878
Net increase in cash and cash equivalents	26,693,066	1,593,524
Cash and cash equivalents as of beginning of the year	5,933,702	4,340,178
Cash and cash equivalents as of end of the year	$ 32,626,768	$ 5,933,702
Supplemental disclosures of non-cash financing activities:		
Conversion of convertible preferred stock upon IPO	$ 8,793,637	$ -
Conversion of convertible promissory notes upon IPO	$ 12,965,480	$ -
Subscription receivable related to warrant exercise	$ 11,250	$ -
Financing costs related to the 2023 Private Placement in accrued expenses	$ 86,940	$ -
Financing costs related to the 2023 Private Placement in accounts payable	$ 44,978	$ -
Deferred financing costs related to the IPO in accrued expenses	$ -	$ 1,003,408

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

1. Organization and description of business

Coya Therapeutics, Inc. ("Coya", or the "Company") is a clinical-stage biotechnology company focused on developing proprietary new therapies to enhance the function of Regulatory T cells ("Tregs"). Coya's initial developmental programs are focused on neurodegenerative, chronic inflammatory, autoimmune, and metabolic diseases of high unmet medical need.

Going Concern and Liquidity

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of $25.9 million as of December 31, 2023. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. No assurance can be given that any such financing will be available when needed or that the Company's research and development efforts will be successful.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to assess its ability to continue as a going concern within one year after the date that the financial statements are issued (or when applicable, one year after the date that the financial statements are available to be issued). In the year ended December 31, 2023, the following events occurred: in January 2023, the Company received net proceeds of $14.1 million from the closing of its initial public offering (Note 8); in December 2023, the Company received net proceeds of $24.0 million from the closing of its private placement (Note 8), and in December 2023, the Company entered into a Development and License Agreement (the "DRL Development Agreement") with Dr. Reddy's Laboratories Ltd. ("DRL"), and its affiliate, Dr. Reddy's Laboratories SA (collectively, "Dr. Reddy's"), pursuant to which the Company received an upfront payment of $7.5 million in January 2024. As a result of these events, the going concern uncertainty that was disclosed in the financial statements for the year ended December 31, 2022 was alleviated during 2023. As of December 31, 2023, the Company had cash and cash equivalents of $32.6 million, which is expected to enable the Company to fund its operating expenses and capital expenditure requirements into 2026.

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Risks and uncertainties

The Company is subject to a number of risks associated with companies at a similar stage, including dependence on key individuals, competition from similar products and larger companies, volatility of the industry, ability to obtain adequate financing to support growth, the ability to attract and retain additional qualified personnel to manage the anticipated growth of the Company, and general economic conditions.

2. Basis of presentation and significant accounting policies

Basis of presentation

The accompanying financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the ASC and Accounting Standards Updates ("ASU") of the FASB.

Use of estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the financial statements in the period they are determined to be necessary.

Significant areas that require management's estimates include fair value of the Company's convertible promissory notes, the fair value of the Company's equity, prior to being publicly traded, and related inputs, including discount for lack of marketability and volatility, and the grant date fair value of stock options (Note 9), useful life of fixed assets, the allocation of transaction price as it relates to the Company's DRL Development Agreement, and accrued research and development expenses.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

Fair value of financial instruments

Management believes that the carrying amounts of the Company's cash equivalents, accounts payable, and accrued expenses approximate fair value due to the short-term nature of those instruments. Convertible promissory notes were recorded at fair value on a recurring basis (Note 3).

Collaboration Revenues

The Company's revenues have been solely generated through the DRL Development Agreement Note 12,which falls under the scope of ASC Topic 808, Collaborative Arrangements ("ASC 808") as both parties are active participants in the arrangement that are exposed to significant risks and rewards. While this arrangement is within the scope of ASC 808, the Company analogizes to ASC 606 for some aspects of this arrangement, including delivery of a good or service (i.e. unit of account). Revenue recognized by analogizing to ASC 606 is recorded as collaboration revenue on the statements of operations. The terms of the arrangement includes payments to the Company of the following: nonrefundable, up-front license fees; regulatory and commercial milestone payments and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps:(i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company's revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes regulatory or commercial milestone payments, the Company evaluates whether each milestone is considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated

milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting period, the Company assesses the probability of achievement of each milestone under its current agreements.

Royalties: If the Company is entitled to receive sales-based royalties from its collaborator, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Amounts due to the Company for satisfying the revenue recognition criteria or that are contractually due based upon the terms of the collaboration agreements are recorded as collaboration receivable in the Company's balance sheet. Contract liabilities consist of amounts received prior to satisfying the revenue recognition criteria, which are recorded as deferred collaboration revenue in the Company's balance sheet. See Note 12 for a full discussion of the Company's collaboration arrangement.

There was no deferred revenue or receivables as of December 31, 2022.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in a money market account.

Deferred financing costs

The Company capitalizes costs that are directly associated with in-process equity and debt financing until such financings are consummated, at which time such costs are recorded against the gross proceeds from the applicable financing. If a financing is abandoned, deferred financing costs are expensed. During the year ended December 31, 2023, the Company had incurred $2.5 million and $1.2 million in fees associated with its 2023 Private Placement and IPO, respectively, which were recorded against gross proceeds of each respective financing event within additional paid-in capital in the balance sheet. During the year ended December 31, 2022, the Company incurred $1.1 million in fees associated with the IPO, which are recognized as deferred financing costs on the balance sheet as of December 31, 2022, and were subsequently recorded against gross proceeds upon the closing of the IPO in January 2023. The Company elected to account for its convertible promissory notes (Note 8) using the fair value option under ASC 815, and as such, issuance costs of $1.0 million were immediately expensed as a component of general and administrative expense in the statements of operations during the year ended December 31, 2022.

Research and development costs

Research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, regulatory compliance costs, and personnel and stock-based compensation expenses. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record a net prepaid or accrued expense relating to these costs.

Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered.

In-Process Research and Development

Research and development costs incurred in obtaining technology licenses are charged to in-process research and development expense if the technology licensed has not reached technological feasibility which includes manufacturing, clinical, intellectual property and/or regulatory success which has no alternative future use. The licenses purchased by the Company, which are further described in Note 7, require substantial completion of research and development and regulatory and marketing approval efforts in order to reach technological feasibility. As such, since inception, the purchase price of licenses acquired is classified as acquired in-process research and development expenses in the statements of operations.

Patent costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs were $0.1 million during the years ended December 31, 2023 and 2022, which are included in general and administrative expenses in the accompanying statements of operations.

Stock-based compensation

The Company measures share-based employee and nonemployee awards at their grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards. The Company accounts for forfeitures in the period in which they occur.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the estimated fair value of the Company's common stock, and, for stock options, the expected life of the options and stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in estimating the fair value of share-based awards represent management's estimate and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards.

The expected term of the stock options is estimated using the "simplified method" as the Company has no historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected term of the option. The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.

Fixed assets

Fixed assets, which consist mainly of lab equipment, are carried at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful life of the assets. Research medical equipment is depreciated over the assets estimated useful lives of five years.

Long-Lived Assets

Long-lived assets, such as fixed assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, then an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Considerable management judgment is necessary to estimate discounted future cash flows. Accordingly, actual results could vary significantly from such estimates.

The Company did not recognize any impairment of long-lived assets for the years ended December 31, 2023 or 2022.

Income taxes

Income taxes are accounted for under the asset and liability method. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities, and the expected benefits of net operating loss and income tax credit carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the period in which temporary differences are expected to be settled, is reflected in the Company's financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of December 31, 2023 and 2022, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest, or penalties in the accompanying financial statements. Although there are no unrecognized income tax benefits, when applicable, the Company’s policy is to report interest and penalties related to unrecognized income tax benefits as a component of income tax expense.

Net loss per share

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, common stock warrants and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, potentially dilutive securities are not included in the calculation when the impact is anti-dilutive. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no obligation to fund losses.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	As of December 31,	
	2023	**2022**
Series A Convertible Preferred Stock	-	1,316,926
Convertible promissory notes (as converted)	-	2,736,488
Common stock warrants	2,492,241	92,184
Stock options	1,134,145	478,570
	3,626,386	4,624,168

Amounts in the above table reflect the common stock equivalents.

Recently adopted accounting pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren’t measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. The Company adopted the guidance using a modified retrospective approach as of January 1, 2023 which resulted in no cumulative-effect adjustment to accumulated deficit.

Recently issued but not yet adopted accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (ASU 2023-07), which requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The Company is currently evaluating the effect of this pronouncement on its disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which expands the disclosure required for income taxes. This ASU is effective for fiscal years beginning after December 16, 2024, with early adoption permitted. The amendment should be applied on a prospective basis while retrospective application is permitted. The company is currently evaluating the effect of this pronouncements on its disclosures.

3. Fair value measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

In accordance with the fair value hierarchy described above, the following table sets forth the Company's assets and liabilities measured at fair value on a recurring basis:

December 31, 2023

	Note Reference	Input Level	Fair Value	Carrying Value
Assets:				
Cash and cash equivalents (money market funds)		Level 1	$ 32,626,768	$ 32,626,768

December 31, 2022

	Note Reference	Input Level	Fair Value	Carrying Value
Assets:				
Cash and cash equivalents (money market funds)		Level 1	$ 5,933,702	$ 5,933,702
Liabilities:				
Convertible promissory notes	Note 8	Level 3	$ 12,965,480	$ 12,965,480

In April 2022 the Company issued unsecured convertible promissory notes to various investors. Due to the number of embedded provisions contained in the convertible promissory notes, the fair value option, as prescribed by ASC 815, was elected and applied in connection with the preparation of these financial statements. The fair value of the convertible promissory notes is determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various IPO, settlement, equity financing, corporate transaction and dissolution scenarios.

The Company adjusts the carrying value of the Notes to their estimated fair value at each reporting date, with qualifying increases or decreases in the fair value recorded as change in fair value of convertible promissory notes in the statements of operations.

Changes in the fair value resulting from changes in the instrument-specific credit risk will be presented separately in other comprehensive income, however, through December 31, 2022, these changes have not been material to the financial statements. The Company measured the change in fair value related to instrument-specific credit risk by isolating the change in the fair value of the Notes resulting from the change in CCC option-adjusted spreads between measurement dates.

In connection with the IPO, the Company's convertible promissory notes converted into an aggregate of 2,736,488 shares of common stock. As a result, the remaining convertible promissory note balance, including accrued interest, was eliminated, increasing additional paid-in capital.

Balance January 1, 2022	$ -
Issuance of convertible promissory notes	10,468,970
Fair value adjustments	2,496,510
Balance at December 31, 2022	12,965,480
Conversion of convertible promissory notes upon IPO	(12,965,480)
Balance at December 31, 2023	$ -

4. Prepaids and other current assets

Prepaids and other current assets consist of:

	As of December 31,	
	2023	**2022**
Prepaid research and development	$ 125,000	$ 175,860
Prepaid insurance	858,541	1,051,329
Prepaid other	86,016	24,075
	$ 1,069,557	$ 1,251,264

5. Fixed assets, net

Fixed assets, net consist of:

	As of December 31,	
	2023	**2022**
Lab equipment	$ 136,804	$ 136,804
	136,804	136,804
Less: accumulated depreciation	(70,855)	(43,494)
	$ 65,949	$ 93,310

Depreciation expense for both the years ended December 31, 2023, and 2022 was $27,361.

6. Accrued expenses

Accrued expenses consist of:

	As of December 31,	
	2023	**2022**
Accrued research and development	$ 686,883	$ 135,864
Accrued payroll	1,081,262	927,006
Accrued professional fees	481,218	945,491
Accrued income tax	723,852	-
	$ 2,973,215	$ 2,008,361

7. Commitments and contingencies, including license and sponsored research agreements

License Agreements

Dr. Reddy's License and Supply Agreement

In March 2023, the Company entered into an exclusive License and Supply Agreement (the "DRL Agreement") with DRL. The DRL Agreement became effective on April 1, 2023. Pursuant to the terms of the DRL Agreement, the Company will in-license DRL's proposed abatacept biosimilar for use in the development of Coya's combination product for neurodegenerative diseases ("COYA 302"). COYA 302 is a dual biologic intended to suppress neuroinflammation via multiple immunomodulatory pathways, for the treatment of neurodegenerative conditions. The DRL Agreement also provides for the license of the Company's low dose IL-2 ("COYA 301") to DRL to permit the commercialization by DRL of COYA 302 in territories not otherwise granted to Coya. In consideration for the license the Company has paid a non-refundable upfront fee of $0.4 million. The Company will pay to DRL up to an aggregate of approximately $2.9 million of pre-approval regulatory milestone payments for the first indication in the Field (as defined in the DRL Agreement), of which the Company has paid an aggregate of $0.2 million to date, and an additional approximately $20.0 million if all other development, regulatory approval and sales milestones are incurred under the DRL Agreement. The Company will also pay to DRL a low-six figure milestone payment per additional indication. Further, pursuant to the DRL Agreement, the Company will pay to DRL single-digit royalties on Net Sales (as defined in the DRL Agreement).

ARS Agreement

In August 2022, the Company entered into a License Agreement (the "ARS License Agreement") with ARScience Biotherapeutics, Inc. ("ARS") pursuant to which ARS granted the Company an option to acquire an exclusive, royalty-bearing license for two patents, with the right to grant sublicenses through multiple tiers under these patents (the "ARS Option"). In consideration for the ARS Option, the Company paid ARS a one-time, non-refundable, non-creditable option fee of $0.1 million and a mid-six figure up-front fee, which were expensed as in-process research and development expense in the accompanying statements of operations for the year ended December 31, 2022.

The Company may also owe tiered payments to ARS based on its achievement of certain developmental milestones. Under the ARS License Agreement, the Company will pay an aggregate of $13.3 million in developmental milestone payments for the first Combination Product (as defined in the ARS License Agreement) in a new indication. The Company will then pay an aggregate of $11.6 million in developmental milestone payments for each Combination Product in each subsequent new indication. Further, for the first Mono Product (as defined in the ARS License Agreement) the Company will pay an aggregate of $11.8 million in developmental milestone payments. The Company will then pay an aggregate of $5.9 million in developmental milestone payments for each Mono Product in each subsequent new indication, and an aggregate of $5.9 million if all developmental milestones are achieved for each new indication. The Company will also owe royalties on net sales of licensed products ranging from low to mid-single digit percentages. In the event the Company sublicenses its rights under the ARS License Agreement, the Company will owe royalties on sublicense income within the range of 10% to 20%.

Houston Methodist Agreements

In September 2022, the Company entered into an Amended and Restated Patent Know How and License Agreement, effective as of October 2020 (the "Methodist License Agreement"), with The Methodist Hospital ("Methodist") to make, sell and sublicense products and services using the intellectual property and know-how of Methodist. As part of the Methodist License Agreement, the Company will pay Methodist a four-figure license maintenance fee annually until the first sale of licensed product occurs. The term of the Methodist License Agreement is effective until no intellectual property patent rights remain, unless terminated sooner by (1) bankruptcy or insolvency, (2) the failure by the Company to monetize the intellectual property within five years of the date of the agreement (further discussed below), (3) due to breach of contract, or (4) at our election for any or no reason.

Patent reimbursements paid by the Company to Methodist and its attorneys are included in general and administrative expenses in the accompanying statements of operations. Such costs were immaterial for the years ended December 31, 2023 and 2022. In addition to the equity issuance and reimbursement of patent related expenses, the Methodist License requires the Company to make payments of up to $0.4 million per product candidate in aggregate upon the achievement of specific development and regulatory milestone events by such licensed product. The Company is also required to pay Methodist, on a licensed product-by-licensed product and country-by-country basis, tiered royalties (subject to customary reductions) equal to high-single digit to low-double digit percentages of annual worldwide net sales of such licensed product during a defined royalty term. The Company is also required to pay a low single digit percentage for certain licensed services. Commencing on January 1, 2025, the minimum amount which will be owed by the Company once commercialization occurs is $0.1 million annually.

The Methodist License Agreement provides that in the event the Company sublicense products and services covered by the Methodist License Agreement, then royalties owed to Houston Methodist would be computed as a percentage of payments received by the Company from the sublicensee. In addition, the termination provisions provide that Houston Methodist may only terminate the Methodist License Agreement, among other things, in the event that after five years the Company is not "Actively Attempting to Develop or Commercialize," as such term is defined in the Methodist License Agreement.

Sponsored Research Agreement

In February 2021, the Company entered into a one-year Sponsored Research Agreement ("SRA") with Houston Methodist Research Institute ("HRMI"), a Texas nonprofit corporation and an affiliate of Methodist, which can be extended or renewed by mutual agreement. Under the SRA, the Company agreed to fund up to $1.5 million in research in the area of neurodegenerative diseases performed by HRMI. In return, the Company will gain expanded access to data methods and know-how per the SRA, and, if the research produces intellectual property, the Company will have all first rights to the intellectual property. As of September 15, 2022, the Company provided notice to HMRI regarding termination of the SRA in expectation that a reduced yearly budget be negotiated post termination. On May 4, 2023, the Company executed the SRA with HMRI, in which the Company agreed to fund approximately $0.5 million through May 2024. The Company incurred $0.3 million and $1.6 million in research and development expenses under the SRA during the years ended December 31, 2023 and 2022, respectively.

Employment contracts

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment either by the Company without cause or by the employee for good reason, both as defined in the agreements. In addition, in the event of termination of employment following a change in control, as defined in each agreement, either by the Company without cause or by the employee for good reason, any unvested portion of the employee's initial stock option grant becomes immediately vested.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding.

8. Convertible promissory notes, convertible preferred stock and stockholders' equity (deficit)

Private Placement

On December 5, 2023, the Company entered into a securities purchase agreement with certain accredited investors for the issuance and sale in a private placement of 4,370,382 shares of its common stock at a price of $6.06 per share of common stock (the

"2023 Private Placement"). The offering resulted in net proceeds of $24.0 million after deducting placement agent commissions and other offering expenses. In connection with the 2023 Private Placement and as a form of payment for services provided by a co-placement agent and financial advisor, the Company issued warrants to purchase up to 319,004 shares of common stock at an exercise price of $7.58 per share. Such warrants have a term of four years from issuance, and will be exercisable beginning six months from the closing of the 2023 Private Placement.

Initial Public Offering

On January 3, 2023, the Company completed its IPO in which the Company sold 3,050,000 shares of its common stock and accompanying warrants to purchase 1,525,000 shares of common stock. The warrants were sold at the rate of one warrant for every two shares of common stock purchased in the IPO, with each full warrant having an exercise price of $7.50 per share. Each share of common stock and accompanying warrant was sold at a combined offering price of $5.00. The Company received net proceeds of $13.0 million after deducting underwriting discounts, commissions, and other offering expenses paid by the Company, including additional costs incurred during the year ended December 31, 2023. The Company issued its underwriters 213,500 warrants with an exercise price of $6.25 per warrant and a contractual term of four years as additional consideration. In connection with the closing of the IPO, (i) all of the Company's outstanding shares of Series A convertible preferred stock ("Series A") converted into an aggregate of 1,316,926 shares of common stock, (ii) the Company's convertible promissory notes converted into an aggregate of 2,736,488 shares of common stock, and (iii) the Company filed an amended and restated certificate of incorporation to, among other things, increase the number of authorized shares of common stock to 200,000,000 and increase the number of authorized shares of preferred stock to 10,000,000.

In connection with the IPO, the Company granted its underwriters a 30-day over-allotment option ("Over-Allotment") to purchase up to an additional 290,000 shares of common stock and warrants to purchase 145,000 shares of common stock to cover over-allotments at a combined offering price of $5.00, less underwriting discount. The warrants have an exercise price of $7.50 per share. On January 25, 2023, the underwriters purchased 237,804 shares of common stock and 145,000 warrants to purchase common stock at a combined offering price of $5.00 per share in connection with Over-Allotment. Upon the sale of the Over-Allotment, the Company issued its underwriters an additional 16,646 warrants with an exercise price of $6.25 per warrant and a contractual term of four years. The Company received net proceeds of $1.1 million after deducting underwriting discounts for the common stock and warrants issued in connection with the Over-Allotment.

Common Stock Warrants

During its evaluation of equity classification for the Company's common stock warrants, the Company considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity*. The conditions within ASC 815-40 are not subject to a probability assessment. The warrants do not fall under the liability criteria within ASC 480 *Distinguishing Liabilities from Equity* as they are not puttable and do not represent an instrument that has a redeemable underlying security. The warrants do meet the definition of a derivative instrument under ASC 815, but are eligible for the scope exception as they are indexed to the Company's own stock and would be classified in permanent equity if freestanding. During the year ended December 31, 2023, warrants related to the IPO were exercised for 1,500 shares of common stock. Such shares of common stock were released to the warrant holder prior to the receipt of proceeds for the exercise price of $7.50 per share, resulting in a subscription receivable in the balance sheet as of December 31, 2023.

As of December 31, 2023, the Company had the following warrants outstanding to acquire shares of its common stock:

Warrant Type	Outstanding	Exercise price per share	Expiration date
Common stock warrants issued related to the IPO	1,523,500	$ 7.50	December 2024
Common stock warrants issued related to the Over-Allotment option	145,000	$ 7.50	December 2024
Common stock warrants issued to underwriters as compensation for IPO	230,146	$ 6.25	December 2026
Common stock warrants issued to placement agent as part of the convertible promissory notes conversion	182,407	$ 6.00	January 2028
Common stock warrants issued in connection with the Series A convertible preferred stock issued in 2020	92,184	$ 9.15	December 2025
Common stock warrants issued as compensation for the 2023 Private Placement	319,004	$ 7.58	December 2027
	2,492,241		

Reverse Stock Split

In December 2022, the Company effected a one-for-5.6955 reverse stock split of its common stock. No fractional shares were issued in connection with the reverse stock split. Any fractional share resulting from the reverse stock split was rounded down to the nearest whole share, and in lieu of any fractional shares, the Company paid cash to the holders of such fractional shares an amount equal to the fair value, as determined by the board of directors, of such fractional shares. All common stock, per share and related information presented in the financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split.

9. Stock-based compensation

In January 2021, the Company adopted the 2021 Equity Incentive Plan ("2021 Plan"). The 2021 Plan provides for the granting of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, equity appreciation rights, performance awards, and other equity-based awards. The Company's employees, officers, independent directors, and other persons are eligible to receive awards under the 2021 Plan. As of December 31, 2023, 1,244,857 shares of the Company's common stock were authorized to be issued, of which 24,746 shares were available for future issuance.

The amount, terms of grants, and exercisability provisions are determined and set by the Company's Board of Directors or compensation committee. The Company measures employee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. The Company has recorded stock-based compensation in the accompanying statements of operations as follows:

	Years Ended December 31,	
	2023	2022
General and administrative	$ 545,149	$ 91,635
Research and development	327,099	115,711
	$ 872,248	$ 207,346

Stock options

The Company has issued service-based stock options that generally have a contractual term of up to 10 years and may be exercisable in cash or as otherwise determined by the Board of Directors. Vesting generally occurs over a period of not greater than four years.

The following table summarizes the activity for the years ended December 31, 2023:

	Options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at January 1, 2023	478,570	$ 1.85	8.7	
Granted	760,042	$ 3.90		
Exercised	(85,528)	$ 1.17		$ 345,293
Forfeited	(18,939)	$ 3.48		
Outstanding at December 31, 2023	1,134,145	$ 3.24	8.7	$ 4,724,761
Exercisable at December 31, 2023	442,679	$ 2.53	8.2	$ 2,158,479
Vested and expected to vest at December 31, 2023	1,134,145	$ 3.24	8.7	$ 4,724,761

As of December 31, 2023, the unrecognized compensation cost was $1.8 million, and will be recognized over an estimated weighted-average amortization period of 2.1 years. During the year ended December 31, 2023, 2,784 options were net share settled, resulting in the issuance of 3,007 shares of common stock and 82,521 options were exercised on a cash basis.

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the estimated fair value of the underlying common stock at the grant date, expected term, estimated stock price

volatility, risk-free interest rate, and dividend yield. The fair value of stock options granted during the years ended December 31, 2023 and 2022 was determined using the methods and assumptions discussed below.

- The expected term of employee stock options with service-based vesting is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin ("SAB") No. 107, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data.
- The expected stock price volatility is based on historical volatility of comparable public entities within the Company's industry, which were commensurate with the expected term assumption as described in SAB No. 107.
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected term.
- The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.
- The Company's common stock became publicly traded on December 29, 2022. However, prior to the Company's common stock being publicly traded, its Board of Directors periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.*

The grant date fair value of each option grant for the years ended December 31, 2023 and 2022 was estimated using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Years Ended December 31,	
	2023	**2022**
Risk-free interest rate	4.0%	3.3%
Expected term (years)	5.8	5.6
Expected volatility	93.82%	83.48%
Expected dividend yield	-	-

Restricted Stock Unit Awards

During the year ended December 31, 2023, the Company issued restricted stock ("RSU") to external consultants which immediately vested upon grant. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. The Company recorded stock-based compensation expense of $0.1 million for the year ended December 31, 2023.

The following table summarizes activity related to RSU stock-based payment awards:

	Number of Shares	**Weighted average grant date fair value**
Beginning balance at January 1, 2023	-	$ -
Granted and Vested	16,500	4.61
Ending balance at December 31, 2023	16,500	$ 4.61

10. Income taxes

Income tax expense for the years ended December 31, 2023 and 2022 consists of the following:

	As of December 31,	
	2023	2022
U.S. federal		
Current	$ 718,582	$ -
Deferred	-	-
Total U.S. federal	718,582	-
State and local		
Current	5,270	-
Deferred	-	-
Total State and local	5,270	-
Income tax expense	$ 723,852	$ -

A reconciliation of income tax benefit at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	As of December 31,	
Rate reconciliation:	2023	2022
Federal tax benefit at statutory rate	(21.0) %	(21.0) %
Permanent differences	0.2	4.6
State income tax	(0.1)	-
Research and development credits	(2.9)	-
Change in tax rate	(0.2)	-
Change in valuation allowance	34.2	16.4
Other	(0.1)	-
Total provision	10.1 %	- %

Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which differences are expected to reverse.

Significant components of the Company's deferred tax assets consisted of the following:

	As of December 31,	
Deferred tax assets	2023	2022
Startup costs	$ 2,945,099	$ 1,502,023
Section 174 capitalization	1,860,806	873,687
Share-based compensation	144,105	51,795
Net operating losses	439,349	608,738
Accrued expenses and other	45,133	60,521
Capitalized license fees	47,526	47,250
Credit carryforwards	30,035	-
Deferred revenue	121,388	-
Fixed assets	(8,325)	(60)
Valuation allowance	(5,625,116)	(3,143,954)
Deferred tax assets, net of valuation allowance	$ -	$ -

As of December 31, 2023 and 2022, the Company had net operating loss carryforwards for federal income tax purposes of approximately $2.1 million and $2.9 million, respectively. Net operating losses are available to offset future federal taxable income. Generally, net operating losses generated after 2017 may be carried forward indefinitely but limited to 80% of federal taxable income each year.

In assessing the recoverability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has determined that it is more likely than not that certain future tax benefits may not be realized as a result of current and future income. Accordingly, a valuation allowance has been recorded against all of the Company's deferred tax assets.

Net operating loss and tax credit carry-forwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and are subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code. Based upon our analysis, we have determined that such an ownership change has occurred and a Section 382 limitation has been applied in the current year to limit the amount of tax attributes utilized.

The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. The Company had no interest or penalties related to uncertain tax positions. All tax years of the Company from inception are open to examination by federal tax and state tax authorities. To the extent utilized in future years' tax returns, net operating loss carryforwards as of December 31, 2023 will remain subject to examination until utilized. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years is under examination as of December 31, 2023.

11. Related party transactions

During the year ended December 31, 2022, in connection with issuance of the convertible promissory notes, the Company incurred debt issuance costs of $1.0 million, of which $0.7 million was paid to a related party, which was expensed as a component of general and administrative expense in the statements of operations. In addition, the Company incurred $0.7 million placement agent fees in connection with the issuance of the Company's Series A, which were paid to an affiliate of the pre-Merger owners of Coya Therapeutics, Inc. As described in Note 8, the placement agent also received warrants for the purchase of 92,184 shares of the Company's common stock.

12. DRL Development Agreement

In December 2023, the Company entered into a Development and License Agreement (the "DRL Development Agreement") with DR. Reddy's, pursuant to which, among other things, the Company granted to DR. Reddy's an exclusive, royalty-bearing right and license (the "License") to commercialize COYA 302, a proprietary co-pack kit containing low dose IL-2 and CTLA4-Ig, ("COYA 302" or the "Product") solely for use in patients with amyotrophic lateral sclerosis ("ALS" or the "Field") in the United States, Canada, the European Union and the United Kingdom (collectively, the "New Territories"). The Company previously granted DRL an exclusive license to obtain regulatory approval and commercialize the Product for ALS and certain other indications in all other countries (other than the New Territories, Japan, Mexico, and in each country in South America), pursuant to the DRL Agreement entered between the Company and DRL, effective as of April 1, 2023 (Note 7). As part of the DRL Development Agreement, the Company is responsible for certain development activities to advance the Product through clinical development ("R&D Services").

The collaboration is managed by a joint steering committee ("JSC") which is comprised of representatives from both parties. Decisions of the JSC are made by consensus. If the JSC is unable to reach a consensus, and the parties' executives are not able to resolve the dispute, then Dr. Reddy's has final decision-making authority, subject to specified limitations (as set forth in the DRL Development Agreement).

Pursuant to the DRL Development Agreement, the Company is entitled to an up-front, nonrefundable payment of $7.5 million which was recorded as collaboration receivable as of December 31, 2023. Additionally, the Company is entitled to receive (i) an additional $4.2 million upon FDA acceptance of an Investigational New Drug, or IND, application for COYA 302 for the treatment of ALS and (ii) an additional $4.2 million payment upon the dosing of the first patient in the first phase 2 clinical trial for COYA 302 for the treatment of ALS in the United States. The DRL Development Agreement also calls for up to an aggregate of approximately $40.0 million in development milestones and up to an aggregate of approximately $677.3 million in sales milestones, related to the New

Territories, should all such development and sales milestones be achieved. The Company will also be owed royalties by Dr. Reddy's on Net Sales (as defined in the DRL Development Agreement) of the Product in the low to mid-teens.

Both parties shall discuss in good faith and agree in writing on the terms of a commercial supply agreement for the purpose of supply of COYA 302 to Dr. Reddy's. No such agreement has been entered into at the time of the filing of this Annual Report on Form 10-K.

The DRL Development Agreement expires on a country-by-country basis upon expiration of Dr. Reddy's obligation to make royalty payments for Product in each territory. Dr. Reddy's has the right to terminate the agreement upon specified prior written notice to the Company. Additionally, either party may terminate the agreement in the event of an uncured material breach of the agreement by, or insolvency of, the other party. Either party may terminate the agreement in the event that the other party commences a legal action challenging the validity, enforceability or scope of any licensed patent rights.

In accordance with the guidance, the Company identified the following commitments under the arrangement: 1) the License and 2) the R&D Services. The Company determined that these two commitments represent distinct performance obligations for purposes of recognizing revenue as the Company fulfills these performance obligations. The Company included the $7.5 million upfront payment in the transaction price as of the outset of the arrangement and allocated that transaction price to the two performance obligations based on the estimated stand-alone selling prices at contract inception. The stand-alone selling price of the License was based on a discounted cash flow approach and considered several factors including, but not limited to, discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential using an adjusted market approach. The stand-alone selling price of the R&D Services was estimated using the expected cost-plus margin approach. During the year ended December 31, 2023, the Company allocated the transaction price to the performance obligations and recorded $6.0 million in transaction price associated with the License as collaboration revenue for the year ended December 31, 2023. The Company will recognize the remaining transaction price of $1.5 million allocated to the R&D Services over the period of performance, using an inputs approach. Any portion of a change in transaction price that is allocated to a satisfied or partially satisfied performance obligation will be recognized as revenue (or as a reduction in revenue) in the period of the transaction price change on a cumulative catch-up basis. The commercial milestones and sales-based royalties will be recognized when earned (i.e., the later of when the subsequent sales occur or the performance obligation has been satisfied).

13. Subsequent events

The Company has evaluated subsequent events from the balance sheet date through March 19, 2024, the date at which the financial statements were issued and has determined that there are no such events to report outside of the below:

In January 2023, the Company received the up-front, nonrefundable payment of $7.5 million from Dr. Reddy's, pursuant to the DRL Development Agreement.