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

FORM 10-K

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

For the fiscal year ended December 31, 2025

☐ 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 333-258528

RETINALGENIX TECHNOLOGIES INC.
(Exact name of registrant as specified in charter)

Delaware	**82-3936890**
(State or jurisdiction of Incorporation or organization)	I.R.S. Employer Identification No.
409 Apollo Beach Blvd, Suite 6 Apollo Beach, FL	**33572**
(Address of principal executive offices)	(Zip code)

(415) 578-9583
(Registrant's telephone number, including area code)

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

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**

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 Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition 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 by Rule 12b-2 of the Exchange Act) Yes ☐ No ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $15,506,590 (based upon the closing sale price of the registrant's common stock reported on that date). This calculation excludes shares held by the registrant's current directors and executive officers and stockholders that the registrant has concluded are affiliates of the registrant.

Number of shares of common stock outstanding as of April 15, 2026 was 18,754,739.

Documents Incorporated by Reference: None.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements in this Annual Report on Form 10-K about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan" and "would." For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our common stock and future management and organizational structure are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Annual Report on Form 10-K. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include, but are not limited to:

- our business strategies;
- the timing of regulatory submissions;
- our ability to obtain and maintain regulatory approval of our existing product candidates and any other product candidates we may develop, and the labeling under any approval we may obtain;
- risks relating to the timing and costs of clinical trials and the timing and costs of other expenses;
- risks related to market acceptance of products;
- intellectual property risks;
- risks associated to our reliance on third party organizations;
- our competitive position;
- our industry environment;
- our anticipated financial and operating results, including anticipated sources of revenues;
- assumptions regarding the size of the available market, benefits of our products, product pricing and timing of product launches;
- management's expectation with respect to future acquisitions;
- statements regarding our goals, intentions, plans and expectations, including the introduction of new products and markets; and
- our cash needs and financing plans.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements. You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed as exhibits to the Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this Annual Report on Form 10-K is accurate as of the date hereof. Because the risk factors referred to in this Annual Report on Form 10-K could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this Annual Report on Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors," together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risk Related to our Financial Position and Need for Capital

- We have generated no revenue from commercial sales and our future profitability is uncertain.
- Failure to obtain the capital necessary to fund our operations, we will be unable to continue our product development and you will likely lose your entire investment.
- Raising additional capital may cause dilution to our existing stockholders.
- There is substantial doubt about our ability to continue as a going concern.
- We have incurred net losses every year and expect to continue to incur increased expenses.
- Failure to maintain effective internal control over in accordance with Section 404 of Sarbanes-Oxley could cause our financial reports to be inaccurate.

Risk Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

- Our revenues from sales of our products will be dependent upon pricing and reimbursement guidelines.
- We will depend upon our suppliers to provide the components we require.
- Our commercial and financial success depends on our products being accepted in the market.
- We may face substantial competition in the future.
- Product liability lawsuits against us could cause us to incur substantial liabilities.
- We are dependent on information technology systems.
- If the quality or delivery of our products does not meet our customers' expectations, our reputation could suffer and ultimately our sales and operating earnings could be negatively impacted.
- Failure to comply with data privacy and security laws could have a material adverse effect on us
- We may not be successful in hiring and retaining key employees, including executive officers.
- Our management overlaps substantially with the management and our principal stockholder.
- We may acquire other businesses that could negatively affect our operating results and dilute our stockholders' ownership.
- Our failure to accurately forecast demand for our products could result in additional costs.
- If our facilities were to experience catastrophic loss, our operations would be seriously harmed.
- Changes in general economic conditions and geopolitical and other conditions may adversely impact our business and operating results.
- The future of drug negotiation prices under President Trump's administration is uncertain
- We will be dependent upon third parties for the distribution of our products.

Risk Related to our Intellectual Property Rights

- Our intellectual property may not be sufficient to protect our products from competition.
- We may not be able to enforce our intellectual property rights throughout the world.
- Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

Risks Relating to Government Regulations

- Our failure to obtain and maintain FDA clearances or approvals on a timely basis, or at all, would prevent us from commercializing our products in the U.S., which could severely harm our business.
- Our promotional practices will be subject to extensive government scrutiny.
- Our product candidates require significant clinical testing before seeking regulatory approval.
- Healthcare reform measures could hinder or prevent the commercial success of our product candidates.
- Our success depends upon our ability to advance our product candidates.
- We do not have experience conducting clinical trials.
- A shutdown of the U.S. federal government may adversely affect our business**.**
- Inadequate funding, government shutdowns, workforce reductions or other policy changes affecting government agencies could hinder our business.
- Legislative or regulatory reform of the health care system in the U.S. may adversely impact our business.
- We are subject to stringent domestic and foreign medical device regulations.
- We will also be subject to stringent government regulation in foreign countries.
- Failure by us or our distributors to comply with foreign regulations applicable to the products we design, manufacture, install or distribute could expose us to enforcement actions or other adverse consequences.
- We will be subject to ongoing requirements and inspections.
- We could be subject to substantial fines or damages and possible exclusion from participation in federal or state health care programs if we fail to comply with the laws and regulations applicable to our business.
- If we fail to develop and successfully introduce new products our operating results may suffer.

Risks Related to Owning our Securities

- Our stock price may be volatile.
- Future sales and issuances of our securities could result in additional dilution.
- We have never paid cash dividends and have no plans to pay cash dividends in the future.
- The “penny stock” rules of the SEC make transactions in our stock cumbersome.
- Certain of our stockholders control a significant number of shares of our common stock.
- We have availed ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.
- Our First Amended and Restated Certificate of Incorporation (“Certificate of Incorporation”) and our Bylaws (the “Bylaws”) and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.
- Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming.
- Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of Sarbanes-Oxley could cause our financial reports to be inaccurate.
- Our Certificate of Incorporation and Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

PART I

ITEM 1. BUSINESS

Overview

RetinalGenix Technologies Inc. ("RetinalGenix" or the "Company") is an ophthalmic research and development company focused on developing technologies to screen, provide information and treat eye health disorders (ophthalmic, optical, and sight-threatening disorders), Our devices described below are designed to facilitate the early detection of such diseases and empowering patients and their clinicians with secure personal healthcare information and our therapeutic medications are being designed to treat multiple systemic diseases, while empowering patients and their clinicians with secure personal healthcare information.

Our mission is to improve patients' lives by providing them and their physicians critical information to treat eye diseases and other general health conditions.

Our products and services are built on four pillars: (i) genetic testing; (ii) retinal imaging; (iii) patient information base and (iv) pharmaceutical therapies. Our Genetic Tests will be our first products to be launched which is currently planned for late 2026 with our GPS oral swab tests. A second genetic test is being developed to identify positive responders to treatment for wet AMD, which is targeted for launch in 2027. The Retinal Imaging Platform is being developed for capturing quality economic pictures of the eyes and is expected to be in Beta tests in 2026 and potentially approved for commercialization in 2027. The Patient Informational Database is being designed to securely combine patient genetic and imaging data anonymously. Our Repurposed Pharmaceutical products, RTG-2023 for the treatment of dry age-related macular degeneration (dry AMD) and RTG-2024 for the treatment of Alzheimer's syndrome dementia are expected to continue development for age-related macular degeneration and Alzheimer's syndrome dementia, subject to adequate funding.

The Company's first two devices described below are being designed to foster the Company's active pursuit of its mission to prevent vision loss and blindness due to ocular diseases, including diabetic retinopathy and maculopathy:

1. *Retinal Imaging Screening Device*, a portable, retinal imaging system providing a wide field of view without requiring pupil dilation; and

2. RetinalCam^{TM}, an in-home/remote location patient-activated monitoring and imaging device offering real-time communication and alerting system for physicians available 24/7 and does not require dilation of the consumer's pupil. We intend to launch RetinalCam^{TM} by the end of 2026.

In addition to the above medical devices, as announced in October 2023, we are engaged with Pearl IRB, a provider of diagnostic testing services for its Institutional Review Board ("IRB") to conduct a study to personalize medical evaluations for patients receiving direct intraocular injections into their eyes as treatment for wet macular degeneration to help determine whether there is a genetic basis for the success or the failure of the procedure and to help patients evaluate whether the treatment is necessary, which was previously announced on October 30, 2023. We have engaged phlebotomists from Seven Springs Surgery Center to facilitate the blood draw process necessary for the Pearl IRB study. We anticipate an expansion of the IRB to multistate physicians in the winter of 2026 and the initial analysis by the first half of 2027, which will inform our clinical trial plans.

In addition to the above medical device and IRB advancements, we continue to make progress in our planning/and guidance to move forward, via our contracted clinical resource organization, to conduct pharmaceutical clinical studies for our two products

1. RTG-2023 for the treatment of dry age-related macular degeneration (dry AMD); and
2. RTG-2024 for the treatment of Alzheimer's syndrome dementia.

Our wholly owned subsidiary, DNA/GPS Inc., through pharmacogenetic mapping and testing is linking high resolution retinal imaging to retinal and systemic disease biomarkers to enable the discovery and treatment of sight-threatening and systemic diseases using our proprietary high resolution retinal imaging device. This genetic testing can also lead to drug re-purposing (i.e., new uses of previous drugs now off patent based on genetics).

We are developing a secure and interoperable database system for genetic information and images controlled by patients for use with their physicians, the RetinalGenix Eye Care Anonymized AI database (RECADTM AI system). This database is being designed to combine pharmacogenetic mapping capabilities with our retinal imaging capabilities on a secure information system controlled by the patient (like a patient electronic health record), who can share information with their selected physicians.

To date, we have devoted substantially all of our resources to organizing, business planning, raising capital, designing and developing product candidates, and securing manufacturing and sales/distribution partners. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the private placement of common stock.

We anticipate that we will need approximately an additional $7,000,000 to (i) complete and sell genetic testing products with our DNA/GPS mapping technology; (ii) complete the product design and testing for the RetinalCam^{TM} in our Imaging platform; (iii) develop and advance the networking agreements with various service optical and clinical networking groups; and (iv) create and test our RetinalGenix Eye Care Anonymized AI database (RECAD AI system). We intend to obtain such funds through the sales of our equity and debt securities and/or through potential strategic partnerships; however, no assurance can be provided that funds will be available to us on acceptable terms, if at all. We do not expect that the RetinalCam^{TM} will require FDA approval.

We expect to generate revenues from the sale of DNA/GPS' laboratory developed consumer test kits. We do not expect to generate any revenues from sales of the RetinalCam^{TM} or the Patient Informational database (RECAD AI system), until we successfully complete their development. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, strategic partnerships, collaborations and licensing arrangements or other capital sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates.

We issued shares of our common stock pursuant to a private placement raising approximately $3.0 million from the sale of 3,070,000 shares of common stock from 2019 through January 2022. In October 2021, the registration statement on Form S-1 (the "Registration Statement") that we filed with the Securities and exchange Commission (the "SEC") pursuant to which we registered for resale shares of common stock, including shares of common stock issuable upon exercise of outstanding options and warrants was declared effective. No funds were raised by the Company pursuant to the Registration Statement.

We commenced a private placement of common stock in 2024 at $2.25 per share. During the year ended December 31, 2025, the Company sold 232,444 of its common stock at $2.25 per share for gross proceeds of $548,000, including $125,000 which was recorded as a stock subscription receivable at December 31, 2025, and was received in January 2026. During 2024, we issued 290,262 shares of common stock and raised approximately $653,000, including $150,000 which was recorded as a stock subscription receivable at December 31, 2024 and was received in January 2025. There can be no assurance that we will be able to raise capital when needed.

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

Strategic Pillars:

The Company's strategic portfolio has 4 pillars:

1. *Genetic testing*: Pharmacogenetic mapping, highlighting key health biomarkers for eye and systemic diseases, through RetinalGenix's DNA/GPS Inc and partnered organizations.
2. Retinal Imaging platform: Retinal camera and operating system for economically capturing high definition optical images for analysis by healthcare providers, using *RetinalCam*^{TM}, existing clinical images and RetinalGenix's Imaging System.
3. Patient Informational database: Secure and interoperable database system for genetic information and images controlled by patients for use with their physicians, using RetinalGenix Eye Care Anonymized AI database (RECAD^{TM} AI system).
4. Pharmaceutical Therapies: Developing pharmaceutical products for treating eye and systemic diseases with partnered support, with RTG-2023 (dry age-related macular degeneration) and RTG-2024 (Alzheimer's syndrome dementia).

The Company is working to bring these four pillars as described below together to empower the patient and their chosen physician(s) to make better clinical decisions to improve eye and general health.

1) Genetic Testing:

On July 5, 2022, we entered into an Exchange Agreement (the "Exchange Agreement") with Dr. Lawrence Perich pursuant to which we acquired all the outstanding shares of DNA/GPS Inc., a pharmacogenetics company based in Tampa, Florida ("DNA/GPS"), in exchange for the issuance of 2,000,000 shares of our common stock. We accounted for this transaction as an asset acquisition in the year ending December 31, 2022, and recorded the estimated purchase consideration and related expenses as in process research and development in the accompanying consolidated statement of operations.

Through RetinalGenix's DNA/GPS Inc and supported by partnered organizations, we are developing genetic testing kits. The DNA/GPS Inc. acquisition secured the team to develop these genetic tests. Significant research has been enacted to identity key biomarkers of eye and systemic diseases that correlate with genetic variations. With these identified biomarkers, we worked with a third-party to develop oral swab genetic testing kits.

Patients will be able to purchase and use these swab-based tests that will identify their genetic profiles with our third-party partner. These genetic profiles will be independently evaluated to provide the patient a summary report showing their genetics compared to genetic norms. This information will be provided to the patient who could share these results with their physicians or other care providers, where clinical decisions are made regarding diagnosis, treatment and monitoring. In addition, this genetic information would also be fully and securely anonymized to create a patient-blinded genetic profile to be shared back to RetinalGenix's Eye Care Anonymized AI database for future analysis and research (see # 3 below), which the patient can in the future access and securely share with their physicians or others.

In 2026, we intend to begin selling these tests to patients. A third-party genetic testing company will provide manufacturing, distribution, clinical processing and reporting services. An independent analytics company will provide the genetic readings and reports for patients.

Pearl IRB Study

The Company is engaged with Pearl IRB, a provider of diagnostic testing services for its Institutional Review Board ("IRB") to conduct a study to personalize medical evaluations for patients receiving direct intraocular injections into their eyes as treatment for wet macular degeneration to help determine whether there is a genetic basis for the success or the failure of the procedure and to help patients evaluate whether the treatment is necessary, which was previously announced on October 30, 2023.

The study is enrolling patients and looks to evaluate up to 100 patients in 2026. The Company is working with a third-party lab company for this trial. Once completed, additional clinical evaluation may be pursued, potentially leading to FDA submission for improving patient selection of positive responders to this treatment for wet AMD in 2027.

This study will also economically secure additional biomarkers for RetinalGenix, that can be reviewed and evaluated for future genetic and systemic diseases research.

2) Retinal Imaging platform:

RetinalGenix is developing a retinal camera and operating system for capturing optical images for analysis by healthcare providers. This platform is being developed by third-party optical imaging consultants and a third-party medical device company.

This *RetinalCam*^{TM} is an economical portable camera for ophthalmic home screening and monitoring. This device will provide remote general and home use, using real-time communication and alerting system for physicians available 24/7. This camera does not require dilation of the consumer's pupil. It is anticipated that in late 2026, the next generation of this camera will be completed by a leading optical design, engineering, and fabrication firm. We do not believe FDA approval is required as the camera is used for screening and monitoring.

Image information from these RetinalCam^{TM} units will be incorporated into RetinalGenix's Imaging System for secure patient and physician utilization. This Imaging System is being developed with a third-party, ADM Tronics Unlimited, Inc. ("ADM Tronics").

Additionally, this Imaging System can also utilize quality eye images (Fundus or OTC) from existing ophthalmic devices which will facilitate market entry before our lower cost (with multiple unique advanced functions) RetinalCam^{TM} further penetrates the market.

Images taken by these RetinalCam^{TM} in a clinical office setting, would be owned by the practitioner's office. Images secured by patients outside such clinics, would be owned and controlled by the patient, who could securely share such images with their doctors.

RetinalCam^{TM} images would also be securely anonymized to create a patient-blinded image that is shared back to RetinalGenix's Eye Care Anonymized AI database for future analysis and research (see # 3 below). These images and the genetics data would be anonymously secured within this database.

3) Patient Informational database, the RetinalGenix Eye Care Anonymized AI database (RECAD^{TM} AI system):

The Company is developing a secure and interoperable database system for genetic information and images controlled by patients for use with their physicians, the RetinalGenix Eye Care Anonymized AI database (RECAD^{TM} AI system). This database will combine pharmacogenetic mapping capabilities with our retinal imaging capabilities on a secure information system controlled by the patient (like a patient electronic health record), who can share information with their selected physicians.

The anonymized system with privacy (HIPAA & PII) protections empowers users to control their health and medical information.

The database is expected to allow patients to obtain their genetic, systemic biomarkers and imaging information privately, discreetly, and confidentially.

While this anonymized database protects personal information, the secure system is intended to identify, monitor, profile, and screen patients for ocular and systemic diseases, including cardiovascular, stroke, diabetes, Alzheimer's, dementia, and Parkinson's, at a fraction of the cost of existing methods.

These features enable patients and physicians to improve healthcare access to data and benefit patient care decisions. This cost-effective approach also expands the early detection of eye and health issues from specialized labs to thousands of locations, including hospitals, nursing homes, community care centers, schools, pharmacies, assisted living, walk-in clinics, doctors' offices, ambulatory surgery centers, optical outlets, etc.

This system will also facilitate better drug development, by creating future research opportunities using new tools and artificial intelligence (AI) to see correlations and clinically significant learnings from the combined genetic data and optical images, that can enable new discoveries to improve patient care. These learnings and future intellectual property could be important benefits for the Company.

4) Pharmaceutical Therapies:

RetinalGenix is continuing to make progress in its planning/and guidance to move forward, via our contracted clinical resource organization, to conduct pharmaceutical clinical studies for our two products.

- *RTG-2023* for the treatment of dry age-related macular degeneration (dry AMD); and
- *RTG-2024* for the treatment of Alzheimer's syndrome dementia.

For future clinical development of these products, the Company is pursuing potential collaborations and partnerships with pharmaceutical or other healthcare companies to support such clinical programs in the future.

Market Opportunity

Through the eye, we believe we can improve sight and overall health economically for patients with their care providers.

Unmet need – the early diagnosis of systemic diseases

- 6 in 10 adults in the US have a chronic disease. The leading causes of death and disability and leading drivers of $4.1 trillion in annual health care costs.
- Lack of cost-efficient and easy-to-operate high-resolution screening technology enabling early diagnosis
- Inefficient, requiring the patient to access specialty centers and approvals away from home
- Sophisticated technicians needed to implement MRI, CT, PET scan, ultrasound, echocardiogram, blood draws at specialty labs, retinal testing, etc.
- Results of diagnoses generally are not immediate or confidential
- Diagnostic equipment is based at universities, large clinics, and hospitals
- Geographic accessibility (Rural even more limited)

Worsening Doctor-to-Patient Ratio

- Delay in early treatment of eye and systemic diseases
- There is expected to be physician workforce shortages throughout the country in 2030
- Specialists needed to interpret test results
- Inefficient, limited, and costly use of eyecare specialists
- Staffing shortages: The healthcare workforce is facing provider and nursing shortages in many geographies
- Decreasing medical professional population. The US faces a projected shortage of between 37,800 and 124,000 physicians within 12 years
- 30+ million people in the US are without health insurance
- Worldwide, 4.5 billion people were not fully covered by essential health services

Escalating Blindness/Ocular Disease

- Escalating blindness due to maculopathy, age-related macular degeneration (wet and dry), diabetic retinopathy and other eye diseases
- Insufficient number of ophthalmologists and optometrists worldwide <600,000
- Lack of early detection of central visual loss or changes due to therapeutic toxicity and various other causes
- Drug toxicity from many sources, including therapeutics, metabolic and infectious diseases, auto-immune and vascular disorders

RetinalCam™ and Home/Remote Monitoring Market:

The US Target market consists of thousands of locations including hospitals, nursing homes, community care centers, schools, pharmacies, assisted living, walk-in clinics, doctors' offices, ambulatory surgery centers, optical outlets, etc.

In addition to age-related macular degeneration, we are addressing early detection of Diabetic Retinopathy ("DR") which happens when too much blood sugar (glucose) associated with diabetes damages the blood vessels in the retina. As a result, the retina does not get enough oxygen and nutrients, and blood vessels can leak blood into the retina. According to the Mayo Clinic, DR is the leading cause of new cases of blindness in people 20 to 74 years of age in the United States. According to the Centers for Disease Control and Prevention ("CDC") 2022 National Diabetes Statistics Report, more than 130 million adults are living with diabetes or prediabetes in the United States. The American Diabetes Association reports that diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in American adults. The number of individuals with diabetic retinopathy is predicted to increase by nearly 50% to over 11 million people by 2030. According to the CDC, 34.2 million patients in the U.S. have diabetic maculopathy with 26.9 million diagnosed and 7.3 million undiagnosed. In addition, 88 million adult Americans are pre-diabetics of which 84%, or 74 million, are undiagnosed. Diabetic maculopathy affects 500 million patients globally.

Drug Development market:

Age-Related macular degeneration - Market size:

There are two forms of Age-Related macular degeneration (AMD): wet and dry. The wet form is the leading cause of permanent central vision loss. The dry form can progress to the wet type if not monitored closely by a doctor. There are 18 million cases of dry AMD in the US. Most of those 18 million do not even know that they are at risk. 200 million people worldwide are estimated to have AMD, and by 2040, this number is projected to rise to close to 300 million. The current estimated global market size is $16.8 billion in 2025 with about $7.1 billion in North America.

Alzheimer's syndrome and related dementias - Market size:

Alzheimer's is the seventh leading cause of death in the United States and is projected to cost the U.S. economy nearly one trillion dollars by 2050. In the United States alone there were 6.7 million in 2022 and projected to be 139 million by 2050. There are over 55 million people worldwide living with dementia and 2020 a reach 78 million in 2023 and 139 million by 2050. The North American Alzheimer's therapeutic market size is estimated to be $13.7 billion by 2030. In 2022 there were 6.7 million cases in the US costing $345 billion in 2023 and that did not include the value of unpaid caregiving. Over 11 million Americans provide unpaid care for people with Alzheimer's or other dementias. In 2022, unpaid caregivers provided an estimated 18 billion hours of care valued at $339.5 billion - nearly doubling the cost burden of this disease.

Genetic Tests -Pearl IRB for diagnostic testing services - Market size:

IRB for diagnostic testing services to personalize medical evaluations for patients receiving treatment for wet macular degeneration. (AMD)

Currently, the treatment for AMD mainly involves repeated intravitreal injection of anti-vascular endothelial growth factor (VEGF) drugs. Although it can preserve vision, repeated injections are an invasive treatment modality, which may lead to serious complications and reduce patient adherence to treatment.

Currently, patients who suffer from blindness are receiving intravitreal injections that may or may not be effective in treating their condition. Such injections are very expensive and can cost up to $2,000 per eye on average. Moreover, these injections need to be administered for the rest of the patient's life, which poses a significant financial burden for insurance companies as well as Medicare.

According to the BrightFocus Foundation and JAMA Ophthalmology, approximately 20 million people in the United States have AMD, and nearly 1.5 million Americans have the advanced form (wet) of the disease. For the 18.5 million with dry AMD who can progress to wet AMD, understanding their genetic profiles may improve future clinical decisions.

Genetic Testing for Biomarkers

Through our DNA/GPS platform, we can assess millions of DNA snippets (a small portion of DNA associated with one or more genes or attributes) more rapidly than most current providers and at a significantly reduced cost.

The Company intends to offer DNA/RNA GPS™ laboratory home-use test kits to help evaluate a patient's disease risk profile. The data from these test kits may be combined in our RetinalGenix Eye Care Anonymized AI database (RECAD™ AI system) to provide a non-invasive and cost-effective way to assess disease risk. RetinalGeniX DNA/RNA/GPS™ laboratory home-use test kits will be available for purchase via clinician offices, direct-to-consumers and distributors.

The goal here is to facilitate better drug selection, analysis, and validation and enable the early detection of systemic diseases. Understanding the structure and function of DNA has helped accelerate the investigation of disease pathways, assess an individual's genetic susceptibility to specific diseases, diagnose genetic disorders, and formulate new drugs. It is also critical to the identification of pathogens.

- The analysis of retinal imaging provides a non-invasive and cost-effective way to evaluate a patient's disease risk profile
- The patient will update the database via an app, which includes current medical diagnosis, medications, illnesses, allergies, diet, and lifestyle. Medical history software application (in development).

Competition

Devices:

In the device market, the ophthalmic medical technology industries utilize rapidly advancing technologies and are characterized by intense competition. There is a strong emphasis on intellectual property and proprietary products. In the device market, we face competition from different sources including ophthalmic medical technology companies, academic institutions, government agencies, and public and private research institutions.

Our critical competitive differentiators within the medical device market segment include in-home and out-of-home monitoring, 24/7 real-time auto-alert to physician's office and home, simultaneous internal and external imaging, patient-operated (no technician needed), voice-activated operation to conduct monitoring, physician referral network, embedded patient data directory, easily portable for home monitoring use, high-resolution external imaging standard, high-resolution retinal imaging standard, price range (our pricing is well below the industry average even for those devices that do not pose a direct competitive threat.), auto-compensation (no corrective lens needed), no eye dilation is needed.

Genetic Testing for Systemic and Ocular Diseases

Through our DNA/GPS platform, we can assess millions of DNA snippets (a small portion of DNA associated with one or more genes or attributes) more rapidly than most current providers and at a significantly reduced cost.

Combined in our RetinalGenix Eye Care Anonymized AI database (RECAD™ AI system), the genetic mapping and retinal imaging analyses is being designed to provide a non-invasive and cost-effective way to assess disease risk.

Therapeutic drugs:

Candidate RTG 2023 for Age-Related Macular Degeneration (Dry). There are no FDA-approved drugs to prophylactically treat or stop dry AMD.

Candidate RTG 2024 for Alzheimer's syndrome: There are 11 Alzheimer FDA-approved solutions, three for disease modifying and eight for symptom management. The disease modifying category of products is expected to significantly grow in the coming years.
Many of our competitors have significantly greater financial resources and expertise in research and development, medical device development and obtaining regulatory approvals than us, as well as more established distribution networks and relationships with healthcare providers. Mergers and acquisitions in the ophthalmic medical technology industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified personnel, as well as in acquiring technologies complementary to our products.

Manufacturing and Distribution

In December 2025, the Company contracted with third-party optical engineering designing consultants to develop the RetinalGenix^{TM} camera hardware. Development of these camera prototypes is expected to be available in 2026.

On June 24, 2021, we entered into an Amended and Restated Master Services Agreement ("Master Services Agreement") with ADM Tronics Unlimited, Inc. ("ADM Tronics"), pursuant to which ADM Tronics will provide us with software design, engineer and provide regulatory services related to RetinalGeniX^{TM} and RetinalCam^{TM}. This agreement has been renewed in 2025 to support the ongoing new camera system development.

Avania Clinical has been contracted as the initial advisor for therapeutic drug development, specifically for the RTG-2023 and RTG-2024 product candidates. Additionally, we have formed an institutional review board to launch a 100-patient clinical study intended to validate the relative suitability of anti-VEGF ocular injection treatments for patient candidates with wet AMD.

Intellectual Property Portfolio

Our success depends in large part on our ability to protect our proprietary technologies and information, and to operate without infringing the proprietary rights of third parties. We intend to rely on a combination of patent, trade secret, trademark, and copyright laws, as well as confidentiality and other agreements, to establish and protect our proprietary rights. In addition, we rely on trade secrets, proprietary know-how, and continuing technological advances to develop and maintain our competitive position. Our goal is to obtain, maintain and enforce patent protection for our products, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties.

Sublicense Agreement with Sanovas Ophthalmology LLC

On June 24, 2021, we entered into a sublicense agreement ("Sublicense Agreement") with Sanovas Ophthalmology LLC ("Sanovas Ophthalmology"), a company for which our Chief Executive Officer is also the managing member, pursuant to which Sanovas Ophthalmology granted us an exclusive worldwide ("Territory") license to certain intellectual property, including six patents, two patent applications, and two trademark applications, licensed to Sanovas Ophthalmology by Sanovas Intellectual Property LLC relating to certain technologies for eye and ocular visualization and monitoring ("Licensed IP") for uses related to the screening, examination, diagnosis, prevention and/or treatment of any eye disease, medical condition or disorder, or any disease, medical condition or disorder affecting the eye. The Licensed IP which has been issued by the USPTO and relates to methods of use and systems expires on dates ranging from September 2034 to December 2034, and the Licensed IP which is still pending before the USPTO also relates to methods of use and systems. Pursuant to the Sublicense Agreement, commencing on the date of the first commercial sale of a Licensed Product (as defined in the Sublicense Agreement), in each country in the Territory and continuing on a country by country basis until the expiration or termination of the last Valid Claim (as defined herein) of a licensed patent in such country (the "Royalty End Date"), we shall pay Sanovas Ophthalmology a royalty equal to a mid-single digit percentage of any Net Sales (as defined in the Sublicense Agreement) of any Licensed Product. "Valid Claim" means an issued, unexpired patent claim contained in a licensed patent as long as the claim has not been admitted by Sanovas Intellectual Property, LLC, the owner of the Licensed IP, or otherwise caused to be invalid or unenforceable through reissue, disclaimer or otherwise, or held invalid or unenforceable by a tribunal or governmental agency of competent jurisdiction from whose judgment no appeal is allowed or timely taken. The Sublicense Agreement shall continue until the Royalty End Date, unless earlier terminated pursuant to its terms. The Sublicense Agreement may be terminated by either party if the other party materially breaches the Sublicense Agreement in a manner that cannot be cured, or materially breaches the Sublicense Agreement in a manner that can be cured, and such breach remains uncured for more than 30 days after the receipt by the breaching party of notice specifying the breach. Furthermore, we may terminate the Sublicense Agreement at any time upon 90 days written notice to Sanovas Ophthalmology.

Government Regulations

Our business is subject to extensive, complex, and rapidly changing federal and state laws and regulations. Various federal and state agencies have discretion to issue regulations and interpret and enforce healthcare laws. While we believe we comply in all material respects with applicable healthcare laws and regulations, these regulations can vary significantly from jurisdiction, and interpretation of existing laws and regulations may change periodically. Federal and state legislatures also may enact various legislative proposals that could materially impact certain aspects of our business.

United States Regulations

In the U.S., medical devices are subject to regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and its implementing regulations. The FDCA and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative and judicial sanctions, such as FDA refusal to grant requests for 510(k) clearance, *de novo* classification, or premarket approval of new products or modified products, issuance of warning letters or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject only to the general regulatory controls. Class II devices are moderate risk. They are subject to general controls and may also be subject to special controls. Class III devices are generally the highest risk devices. They are required to obtain premarket approval and comply with post-market conditions of approval in addition to general regulatory controls.

We believe RetinalGeniX™ is a Class II medical device that will require 510(k) clearance from the FDA. In addition, we believe RetinalCam™ will be considered a Class II exempt medical device because it is non-diagnostic in nature, and therefore, we do not anticipate needing 510(k) clearance *from the FDA to market such product. Pursuant to FDA product classification codes for ophthalmic cameras under 21 C.F.R. § 886.1120, "PJZ"* cameras are prescription devices indicated only for the capture and storage of images of the eye and surrounding area in the general population. PJZ cameras cannot be indicated for any specific population (e.g., pediatrics, AMD patients, etc.), cannot contain any type of "diagnostic" or "aid in diagnosis" claims in the indication for use, and cannot reference any specific disease. PJZ cameras do not exceed group 1 radiant exposure limits for ultraviolet, visible, and infrared radiation under all light energy conditions, as defined in the ANSI Z80.36-2016 standard Light Hazard Protection for Ophthalmic Instruments. PJZ cameras also have other design and performance characteristics that are described by FDA in the product code description.

If the RetinalGeniX™ were to be classified as a Class II medical device, such classification would require us to submit a premarket notification submission to FDA prior to marketing. We anticipate the submission will require clinical evidence of safety and efficacy, generated through a regulated, randomized clinical trial or field evaluation. FDA clearance for ophthalmological devices usually require about 170 days.

We intend to launch RetinalCam™ in 2027. We do not intend to apply for 510(k) clearance for RetinalGeniX™ because we do not believe such clearance is necessary.

FDA Pre-Market Authorization and Notification

Under FDA regulations, all devices, including Class I devices, are subject to general controls, which are the basic authorities of the Medical Device Amendments that provide the FDA with the means of regulating devices to ensure their safety and effectiveness (e.g., labeling, facility registration and device listing and adherence to Quality System Regulation ("QSR") requirements). For Class III devices, a pre-market approval ("PMA") application will be required unless the device is a pre-amendment device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) or is exempted from submission of a PMA. In that case, a 510(k) will be the route to market. A 510(k) clearance will be granted if the submitted information establishes that the proposed device is substantially equivalent to a legally marketed Class I or II medical device, or to a Class III medical device for which the FDA has not required a PMA. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device or that additional information or data are needed before a substantial equivalence determination can be made. A request for additional data may require that clinical studies of the device's safety and efficacy be performed.

While most Class I and some Class II devices may be marketed without prior FDA authorization, most other medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a PMA prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices; or (iii) authorized the device to be marketed through the *de novo* classification process, generally applicable for novel Class I or II devices. PMA applications, 510(k) premarket notifications, and *de novo* requests require payment of substantial user fees that are modified each fiscal year.

Commercial distribution of a device for which a 510(k) notification is required may begin only after the FDA issues an order finding the device to be substantially equivalent to a previously cleared device. Even in cases where the FDA grants a 510(k) clearance, it may take the FDA between four and nine months from the date of submission to grant a 510(k) clearance, but may take longer.

A "not substantially equivalent" determination, or a request for additional information, could delay the market introduction of new products that fall into this category and could have a material adverse effect on our business, financial condition and results of operations. For any of our products that are cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device will require new 510(k) submissions.

Any products manufactured or distributed by us are subject to pervasive and continuing regulation by the FDA, including record keeping requirements and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their establishments and list their devices with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies. The FDCA requires devices to be manufactured to comply with applicable QSR regulations which impose certain procedural and documentation requirements upon us with respect to design, development, manufacturing and quality assurance activities. The FDA enforces its requirements by market surveillance and periodic visits, both announced and unannounced, to inspect or re-inspect equipment, facilities, laboratories and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a Form 483, listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures or, if observed violations are sufficiently severe and urgent, a warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA make take enforcement action against the manufacturer or impose other sanctions or consequences.

We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors.

510(k) Premarket Notification Pathway

Product marketing in the U.S. for most Class II and a limited number of Class I devices typically follows the 510(k) premarket notification pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the "predicate device." A predicate device may be a previously 510(k)-cleared device placed in Class I or Class II via a finding of substantial equivalence to a lawfully marketed Class I or Class II device, or a Class III device that was in commercial distribution before May 28, 1976 and for which the FDA has not yet called for PMA applications, or a product previously placed in Class I or Class II through the *de novo* classification process. A finding of "substantial equivalence" means the FDA must conclude that the proposed device has the same intended use as a predicate device, and it either has the same technological characteristics, or it has different technological characteristics but submitted information (potentially including clinical data) shows it is as safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

The FDA has a user fee goal to apply no more than 90 calendar review days to 510(k) submissions. During the process, the FDA may issue an Additional Information request, which stops the clock. The applicant has no more than 180 days to respond (after which the submission is automatically terminated). Therefore, the total review time could be up to a maximum of 270 days.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval or *de novo* classification. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance for the modified device, the agency may retroactively require the manufacturer to seek 510(k) clearance, *de novo* classification, or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

Post-market Requirements

After a device is placed on the market, numerous general regulatory controls apply. These include: the QSR, labeling regulations, the medical device reporting regulations (which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). Failure to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject a manufacturer to warning letters, recalls, or other sanctions and penalties.

Labeling and promotional activities are subject to scrutiny by the FDA and by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses. We and our products are also subject to a variety of state laws and regulations in those states or localities where our products will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with such laws and regulations now or in the future. Such laws or regulations may have a material adverse effect upon our ability to do business.

Advertising, marketing and promotional activities for devices are also subject to FDA oversight and must comply with the statutory standards of the FDCA, and the FDA's implementing regulations. The FDA's oversight authority review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA also regulates industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context.

Manufacturers of medical devices are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses (i.e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for "off-label" uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off-label promotion. The failure to comply with prohibitions on "off-label" promotion can result in significant monetary penalties, revocation or suspension of a company's business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S. government that imposes significant administrative obligations and costs.

Violations of the FDCA relating to the inappropriate promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

For a Class II or Class III device meeting certain requirements, the FDA also may require post-market surveillance requirements. Additionally, the FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, all classes of devices must comply with quality-control, manufacture, packaging, and labeling procedures under the QSR, and manufacturers are subject to periodic inspections by the FDA for compliance. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with the QSR. The FDA may withdraw product approvals or recommend or require product recalls if a company fails to comply with regulatory requirements.

Export of our products is regulated by the FDA and subject to the FDCA, 21 U.S.C. §§381-384f, and other statutes FDA administers, which greatly expanded the export of approved and unapproved United States medical devices. Some foreign countries require manufacturers to provide a specific type of FDA export certificate (such as a Certificate to Foreign Government or Certificate of Exportability), which may require the device manufacturer to certify the device is lawfully marketed in the United States, including in conformance with QSR requirements, labeling regulations, premarket notification, and other requirements. The FDA will refuse to issue any export certificate if significant outstanding QSR violations exist.

European Union Regulations

In the European Union ("EU"), there are four main medical device classes: I, IIa, IIb and III. Similar to the US classification system, the EU classification system is a risk-based system, depending on the potential risk associated with the device. In the EU, we believe the RetinalCam™ would be considered a Class IIa medical device, which would require the grant of a CE marking prior to launching in the EU. To obtain a CE marking, the device manufacturer must be certified to ISO 13485, and the product must meet certain harmonized standards for its design, development and testing. If the manufacturer is not self-certifying, outside agencies (known as Notified Bodies) will be required to test and certify that the device meets the applicable requirements, including clinical evidence of safe and effective use prior to the product being released for general market introduction.

U.S. Drug Approval Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act (the "PHSA"), and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product for its intended use;
- submission to the FDA of an New Drug Application (NDA) for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical trial and clinical study sites that generated the data in support of the NDA; and
- FDA review and approval, or licensure, of the NDA.

Before testing any drug candidate in humans, the candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve 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. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases; these phases may overlap or be combined:

- *Phase 1*. The product candidate is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the targeted disease.
- *Phase 2*. The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

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

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

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

U.S. Review and Approval Processes

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

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee on approved products. 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. No user fees are assessed on NDA a for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. For a Fast Track biological product, the FDA may consider review of completed sections of a NDA on a rolling basis provided the sponsor provides, and the FDA accepts, a schedule for the submission of the completed sections of the NDA. Under these circumstances, the sponsor pays any required user fees upon submission of the first section of the NDA. A Fast Track designated drug candidate may also qualify for priority review, under which the FDA reviews the NDA in six months rather than ten months after it is accepted for filing.

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

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

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

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to a NDA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Post-Approval Requirements

Any products for which we receive FDA approvals will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

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

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry. These laws include anti-kickback, false claims, transparency and health information privacy laws and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act. Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and medical device companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the Civil Monetary Penalties Law statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by HIPAA, which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

Further, pursuant to the ACA, CMS issued a final rule that requires certain manufacturers of prescription drugs to collect and annually report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data are made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, or that apply regardless of payor. In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Further, certain states require the posting of information relating to clinical trials and their outcomes. In addition, certain states require medical device companies to implement compliance programs and/or marketing codes.

Privacy and Data Protection Laws

Data privacy and security regulations by both the federal government and the states in which business is conducted may also be applicable. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations and requires covered entities to implement security measures to protect health information that they maintain in electronic form. Among other things, HITECH made HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers about their data collection, use and sharing practices and provide such consumers new data protection and privacy rights, including the ability to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. On November 3, 2020, California voters approved a new privacy law, the CPRA, which significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. Many of the CPRA's provisions will become effective on January 1, 2023. State laws are changing rapidly and there is discussion in the U.S. of a new comprehensive federal data privacy law.

Healthcare Reform

The U.S. government and other governments have shown significant interest in pursuing continued healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. Changes in applicable laws, rules, and regulations or the interpretation of existing laws, rules, and regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of its business. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In August 2022, the Inflation Reduction Act ("IRA") was enacted, which, among other things, requires the U.S. Department of Health and Human Services ("HHS") to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. 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. These provisions have been, and may continue to be, subject to legal challenges. Although full economic effect of the IRA on our business and the pharmaceutical industry in general is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also reduce our profitability. We expect pricing pressures will continue globally.

Additionally, on April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory Most-Favored-Nation demonstration models under Medicare Parts B and D, respectively. If these rules or other Most-Favored-Nation pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of Most-Favored-Nation pricing initiatives.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities.

Employees-Human Capital

As of December 31, 2025, we had no employees. We utilize a certain portion of Sanovas' sole employee (Jerry Katzman) for our business and are allocated the proportion of payroll costs applicable to such usage from Sanovas. In addition, we utilize the services of other consultants.

Effective January 1, 2026, M. Cory Zwerling was appointed as Chief Financial Officer and Interim Chief Operating Officer. In March 2026, Mr. Zwerling resigned.

Properties

In September 2024, the Company entered into an office suite lease. The term of the lease is for a period of 12 months. The Lease auto-renews for an additional 2 years, unless the Owner is notified. The Company intends to renew the lease. The payments under the lease commence at $650 per month and escalates to $690 per month over the three years.

We believe this arrangement is adequate for our current needs.

Legal Proceedings

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Corporate Information

We were incorporated in Delaware on November 17, 2017. Our principal executive offices are located at 409 Apollo Beach Blvd, Ste 6 Apollo Beach, FL 33572-2281 and our telephone number is (415) 578-9583. Our website address is *www.retinalgenix.com*. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our securities.

Available Information

Our website address is *www.retinalgenix.com*. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov. The information contained in the SEC's website is not intended to be a part of this filing.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risk Related to our Financial Position and Need for Capital

We have generated no revenue from commercial sales to date and our future profitability is uncertain.

We were incorporated in November 2017, have a limited operating history, and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with development and expansion of a new business enterprise. To date, we have not designed a product that is ready for commercialization. Since inception, we have incurred losses and expect to continue to operate at a net loss for at least the next several years. Our net losses for the years ended December 31, 2025 and December 31, 2024 were $2,428,595 and $4,320,827, respectively, and our accumulated deficit as of December 31, 2025 and December 31, 2024 was $17,858,617 and $15,430,022, respectively. There can be no assurance that the products under development by us will be cleared for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are cleared they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.

We will need to continue to seek capital from time to time to continue development of our products and we cannot provide any assurances that any revenues they may generate in the future will be sufficient to fund our ongoing operations. We believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our products. We anticipate that we will need approximately an additional $7,000,000 to (i) complete product design and testing for the RetinalGeniX^{TM} and RetinalCam^{TM} and submit RetinalGeniX^{TM} for FDA clearance (we anticipate that the RetinalCam^{TM} will not require FDA clearance); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS' genetic mapping technology; Pearl IRB anti-VEGF blood draw study, and (iii) build the infrastructure for our sustained growth.

Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned, and this would require additional capital. However, we may not be able to secure funding when we need it or on favorable terms. We may not be able to raise sufficient funds to commercialize the products we intend to develop.

If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale back or eliminate our research and development activities or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to certain major geographic markets. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs; the time and cost necessary to obtain regulatory clearance; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our products on unfavorable terms to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and 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, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, or declaring dividends and may require us to grant security interests in our assets. 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, or products 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 when needed, we may need to curtail or cease our operations.

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

As of December 31, 2025, we had cash of $14,774. In addition, as of December 31, 2025, we had liabilities of $2,323,652. As of the date of this report, we do not have adequate resources to fund our operations for the next twelve months without advances from affiliates or any future capital raising transactions. In fact, as of December 31, 2025, we only had enough cash to run our operations for the next few weeks. Although our current private placement is still open, we have not yet sold any securities subsequent to December 31, 2025.

We will need to raise additional funding to complete the development of our products and commence the market launch, assuming regulatory approval is obtained. We do not know whether additional financing will be available when needed, whether it will be available on favorable terms, or if it will be available at all. These factors raise substantial doubt about our ability to continue as a going concern. In the event that we are unable to obtain additional financing, we may be unable to continue as a going concern. There is no guarantee that we will be able to secure additional financing. Changes in our operating plans, our existing and anticipated working capital needs, costs related to legal proceedings we might become subject to in the future, the acceleration or modification of our development activities, any near-term or future expansion plans, increased expenses, potential acquisitions or other events may further affect our ability to continue as a going concern. Similarly, the report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2025 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

We have incurred losses every year and expect to continue to incur increased expenses. Our net losses for the year ended December 31, 2025 and December 31, 2024 were $2,428,595 and $4,320,827, respectively, and our accumulated deficit as of December 31, 2025 and December 31, 2024 was $17,858,617 and $15,430,022, respectively. We anticipate that we will need approximately an additional $7,000,000 to (i) complete product design and testing for the RetinalGeniX™ and RetinalCam™ and submit RetinalGeniX™ for FDA clearance (we anticipate that the RetinalCam™ will not require FDA clearance); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS' genetic mapping technology; Pearl IRB anti-VEGF blood draw study, and (iii) build the infrastructure for our sustained growth. We intend to obtain such funds through the sales of our equity and debt securities and/or through potential strategic partnerships; however, no assurance can be provided that funds will be available to us on acceptable terms, if at all.

Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of Sarbanes-Oxley could cause our financial reports to be inaccurate.

We are required pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Although we prepare our financial statements in accordance with accounting principles generally accepted in the United States, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities. If we fail to implement any required improvements to our disclosure controls and procedures, we may be obligated to report control deficiencies, in which case we could become subject to regulatory sanction or investigation. Further, such an outcome could damage investor confidence in the accuracy and reliability of our financial statements.

Our management has concluded that our internal controls over financial reporting were, and continue to be, ineffective, and as of December 31, 2025 as a result of a material weakness in our internal controls due to the lack of segregation of duties. While management is working to remediate the material weakness, it lacks the funding to remediate the weakness which requires hiring of additional personnel. Furthermore, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

Risks Relating to Our Business

Our revenues from sales of our products will be dependent upon pricing and reimbursement guidelines, and if pricing and reimbursement levels are inadequate to achieve profitability, our operations will suffer.

Our financial success will be dependent on our ability to price our products in a manner acceptable to government and private payors while still maintaining our profit margins. Numerous factors that may be beyond our control may ultimately impact the pricing of our products and determine whether we are able to obtain reimbursement or reimbursement at adequate levels from governmental programs and private insurance. If we are unable to obtain reimbursement or our products are not adequately reimbursed, we will experience reduced sales, our revenues likely will be adversely affected, and we may not become profitable. Obtaining reimbursement approvals is time-consuming, requires substantial management attention and is expensive. Our business will be materially adversely affected if we do not receive approval for reimbursement of our products under government programs and from private insurers on a timely or satisfactory basis. If reimbursement for our products is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business may be materially harmed.

If our suppliers cannot provide the components we require, our ability to develop and manufacture our products could be harmed.

We rely on third-party suppliers to provide us with components that will be used in the products we are developing. For example, we rely on third-party suppliers to provide us with sensors which will be used in both RetinalGeniX™ and RetinalCam™. Relying on third-party suppliers makes us vulnerable to component part failures or obsolescence and interruptions in supply including, but not limited to, as a result of war or pandemics, either of which could impair our ability to develop our products in a timely manner. Vendor lead times to supply us with ordered components vary significantly and can exceed three months or more. We cannot be sure that our suppliers will furnish us required components when we need them or be able to provide us with sufficient components to support the development and manufacture of our products.

Some of our suppliers may be the only source for a particular component, which makes us vulnerable to significant cost increases or shortage of supply. We have foreign suppliers for some of our parts in which we are subject to currency exchange rate volatility. Some of our vendors are small in size and may have difficulty supplying the quantity and quality of materials required for our products as our business potentially grows. Vendors that are the sole source of certain products may decide to limit or eliminate sales of certain components due to product liability or other concerns and we might not be able to find a suitable replacement for those products. Our inventory may run out before we find alternative suppliers and we might be forced to purchase excess inventory, if available, to last until we are able to qualify an alternate supplier. Any of these events could adversely impact our results of operations.

Our commercial and financial success depends on our products being accepted in the market, and if not achieved will result in our not being able to generate revenues to support our operations.

Even if we are able to obtain favorable reimbursement within the markets that we serve, commercial success of our products will depend, among other things, on their acceptance by retinal specialists, ophthalmologists, general practitioners, low vision therapists and mobility experts, hospital purchasing and controlling departments, patients, and other members of the medical community. The degree of market acceptance of any of our potential products will depend on factors that include:

- cost of treatment;
- pricing and availability of alternative products;
- the extent of available third-party coverage or reimbursement;
- perceived efficacy of our products relative to other products and medical solutions; and
- prevalence and severity of adverse side effects associated with treatment.

We may face substantial competition in the future and may not be able to keep pace with the rapid technological changes which may result from others discovering, developing or commercializing products before or more successfully than we do.

In general, the development and commercialization of new medical devices and drug products is highly competitive and is characterized by extensive research and development and rapid technological change. Our customers consider many factors including product reliability, product availability, inventory consignment, price and product services provided by the manufacturer. In addition, we compete with many larger organizations with market recognition. Market share can shift as a result of technological innovation and other business factors. Major shifts in industry market share have occurred in connection with product related problems, physician advisories and safety alerts and quality problems with processes, goods and services, any of which could harm our reputation and have a material adverse effect on our operations. In addition, our competitors may develop products or other novel technologies that are more effective, safer or less costly than our products. If we fail to develop new products or enhance our existing products, our business, financial condition and results of operations may be adversely affected.

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

We face an inherent risk of product liability exposure related to our products. Product liability claims may be brought against us by patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Prior to commercializing our products, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise and such insurance may not be adequate to cover all liabilities that we may incur. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If the quality or delivery of our products does not meet our customers' expectations, our reputation could suffer and ultimately our sales and operating earnings could be negatively impacted.

In the course of conducting our business, we will need to adequately address quality issues associated with our products, including in our engineering, design, manufacturing and delivery processes, as well as issues in third-party components included in our products. Because our products are highly complex, the occurrence of performance issues may increase as we continue to introduce new products and as we rapidly scale up manufacturing to meet increased demand for our products. There can be no assurance that we will be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, identifying the root cause of performance or quality issues, particularly those affecting third-party components, may be difficult, which increases the time needed to address quality issues as they arise and increases the risk that similar problems could recur. Finding solutions to quality issues can be expensive, and we may incur significant costs or lost revenue in connection with, for example, shipment holds, product recalls and warranty or other service obligations. In addition, quality issues can impair our relationships with new or existing customers and our reputation as a producer of high-quality products could suffer, which could adversely affect our business, financial condition or results of operations.

Failure to comply with data privacy and security laws could have a material adverse effect on our business.

We are subject to state, federal and foreign laws relating to data privacy and security in the conduct of our business, including state breach notification laws, the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and the California Consumer Privacy Act. These laws affect how we collect and use data of our employees, consultants, customers and other parties. Furthermore, these laws impose substantial requirements that require the expenditure of significant funds and employee time to comply, and additional states are enacting new data privacy and security laws, which will require future expansion of our compliance efforts. We also rely on third parties to host or otherwise process some of this data. Any failure by a third party to prevent security breaches could have adverse consequences for us. We will need to expend additional resources and make significant investments to comply with data privacy and security laws. Our failure to comply with these laws or prevent security breaches of such data could result in significant liability under applicable laws, cause disruption to our business, harm our reputation and have a material adverse effect on our business.

We may not be successful in hiring and retaining key employees, including executive officers.

Our future operations and successes depend in large part upon the strength of our management team. We rely heavily on the continued service of Jerry Katzman, our President and Chief Executive Officer. We do not have an insurance policy on Dr. Katzman's life; and we do not have "key person" life insurance policies for any of our other officers or advisors. Accordingly, if Dr. Katzman terminates his employment with us or is incapacitated or unable to perform his services, such a departure or inability to perform his services is expected to have a material adverse effect on our business. Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified financial, managerial, technical and regulatory personnel. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and workforce could adversely affect our ability to operate, grow and manage our business.

Our management overlaps substantially with the management and beneficial owners of our principal stockholder, which may give rise to potential conflicts of interest.

Our Chief Executive Officer also serves as the Chief Executive Officer of our principal stockholder, Sanovas, Inc. ("Sanovas"). Accordingly, there may be inherent, albeit non-specific, potential conflicts involved in the participation by members of each company's management.

We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

We may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our proprietary technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies other than our acquisition of DNA/ GPS Inc. and limited experience with forming strategic partnerships. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not realize the anticipated benefits of any acquisition, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of common stock as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

If we fail to accurately forecast demand for our products, we could incur additional costs or experience lost sales.

It will be very important that we accurately predict the demand for our products. If we overestimate the demand for our products, we may have excess inventory, which would increase our costs. If we underestimate demand for our products, we may have inadequate inventory, which could delay delivery of our products to our customers and result in the loss of customer sales. Any of these occurrences would negatively impact our business and operating results.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

Any failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

In connection with the pre-clinical and clinical development, sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

If our facilities were to experience catastrophic loss, our operations would be seriously harmed.

Our facilities could be subject to catastrophic loss such as fire, flood, unpredictable power outages or earthquakes. All of our research and development activities, our corporate headquarters and other critical business operations are located in California. California can experience catastrophic wildfires, as well as intermittent power outages. Any such loss at any of our facilities caused by fires, flooding, power outages or earthquakes could disrupt our operations and may have a material adverse effect on our business.

Declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. health care reform legislation and energy costs, geopolitical issues, including those in Eastern Europe, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession and stagnant economy for more than a decade. Additionally, political changes in the U.S. and elsewhere in the world have created a level of uncertainty in the markets. If the economic climate does not improve or deteriorate, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners. Tariffs, economic sanctions and other changes in U.S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U.S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition and results of operations.

In addition, the global macroeconomic environment could be negatively affected by, among other things, pandemics or epidemics, instability in global economic markets, 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, the war in the Middle East and other political tensions, 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.

We will be dependent upon third parties for the distribution of our products, and if such third parties are unable to establish and maintain effective sales, marketing and distribution capabilities, we will be unable to successfully commercialize our products.

We intend to use third parties to market and sell our products. We cannot guarantee that we will be able to enter into and maintain any distribution agreements with third parties on acceptable terms, if at all. If we enter into distribution agreements with third parties, and such third parties are unable to establish and maintain effective sales, marketing and distribution capabilities, we will be unable to successfully commercialize our products.

Risks Relating to Intellectual Property

Our intellectual property may not be sufficient to protect our products from competition, which may negatively affect our business.

We may be subject to competition despite the existence of intellectual property we license or may, in the future, own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we license, or may in the future own, or developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property rights could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property rights may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we license from a third party or may, in the future own. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition and the commercial viability of our product; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or may, in the future, own, and the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our products in the future. There can be no assurance that we will be able to successfully defend our intellectual property rights in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, among other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the U.S. Thus, we may not be able to protect our intellectual property rights and third parties may be able to market competitive products that may use some or all of our intellectual property rights.

Changes to patent law, including the Leahy-Smith America Invests Act, AIA or Leahy-Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and prosecution of patents. We can give no assurances that the patents of our licensor can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the United States Patent and Trademark Office ("USPTO"), courts and foreign government patent agencies, and patent protection could be reduced or eliminated for non-compliance with these requirements which may have a material adverse effect on our business.

We may become involved in future lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our future patents or the patents of our licensors. To counter infringement or unauthorized use, we may file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly and could put our or our licensors' potential patent applications at risk of not issuing.

The USPTO may initiate interference proceedings to determine the priority of inventions described in or otherwise affecting our future patents and patent applications or those of our licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, if we are the target of claims by third parties asserting that our products or intellectual property infringe upon the rights of others, we may be forced to incur substantial expenses or divert substantial employee resources from our business and, if successful, those claims could result in our having to pay substantial damages or prevent us from developing one or more of our products. Further, if a patent infringement suit were brought against us or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of the product that is the subject of the lawsuit.

If we experience patent infringement claims, or if we elect to avoid potential claims others may assert, we or our licensors may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our licensors were able to obtain a license, the rights may be non-exclusive, which would give our competitors access to the same intellectual property. Ultimately, we may be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our licensors are unable to enter into licenses on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial and may result in a diversion of our management's attention. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because they may have greater financial resources than us. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our future patents, or those that we license from our licensors, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought 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.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our products and the enforcement of intellectual property.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We may employ individuals who were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we intend to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and result in a diversion of management's attention.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators and other advisors to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

Risks Relating to Government Regulations

Our failure to obtain and maintain FDA clearances or approvals on a timely basis, or at all, would prevent us from commercializing our products in the U.S., which could severely harm our business.

Unless an exemption applies, each medical device that we market in the U.S. must first undergo premarket review pursuant to the FDA by receiving clearance of a 510(k) premarket notification, receiving clearance through the *de novo* review process, or obtaining approval of a PMA application. Even if regulatory clearance or approval of a product is granted, the FDA may clear or approve our products only for limited indications for use. Additionally, the FDA may not grant 510(k) clearance on a timely basis, if at all, for new products or uses that we propose. The traditional FDA 510(k) clearance process for our products may take between four to nine months. However, in some cases, the FDA is requiring applicants to provide additional or different information and data for 510(k) clearance than it had previously required, and that the FDA may not rely on approaches that it had previously accepted to support 510(k) clearance. As a result, FDA 510(k) clearance may be delayed for our products in some cases.

To support our product applications to the FDA, we may be required to conduct clinical testing of our products. Such clinical testing must be conducted in compliance with FDA requirements pertaining to human research. Among other requirements, we must obtain informed consent from study subjects and approval by institutional review boards before such studies may begin. We must also comply with other FDA requirements such as monitoring, record-keeping, reporting and the submission of information regarding certain clinical trials to a public database maintained by the National Institutes of Health. In addition, if the study involves a significant risk device, we are required to obtain the FDA's approval of the study under an Investigational Device Exemption. Compliance with these requirements can require significant time and resources. If the FDA determines that we have not complied with such requirements, the FDA may refuse to consider the data to support our applications or may initiate enforcement actions. Even if we obtain 510(k) clearance, if safety or effectiveness problems are identified with our products, we may need to initiate a recall of such devices. Furthermore, our products may be denied 510(k) clearance and be required to undergo the more burdensome PMA or *de novo* review processes. The process of obtaining a *de novo* classification or PMA approval is much more costly, lengthy and uncertain than the process for obtaining 510(k) clearance. *De novo* classification generally takes six months to one year from the time of submission of the *de novo* request, although it can take longer. Approval of a PMA generally takes one year from the time of submission of the PMA, but may be longer.

Some of our products or product features may also be exempted from the 510(k) process and/or other regulatory requirements in accordance with specific FDA regulations, guidance or policies. If the FDA changes its policy or concludes that our marketing of these products is not in accordance with its current policy, we may be required to seek clearance or approval of these devices through the 510(k), *de novo* or PMA processes.

Our promotional practices will be subject to extensive government scrutiny. We may be subject to governmental, regulatory and other legal proceedings relative to advertising, promotion, and marketing that could have a significant negative effect on our business.

We will be subject to governmental oversight and associated civil and criminal enforcement relating to medical device advertising, promotion, and marketing, and such enforcement is evolving and intensifying. In the United States, we are subject to potential enforcement from the FDA, the U.S. Federal Trade Commission, the Department of Justice, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Other parties, including private plaintiffs, also are commonly bringing suit against medical device companies, alleging off-label marketing and other violations. We may be subject to liability based on the actions of individual employees and contractors carrying out activities on our behalf, including sales representatives who may interact with healthcare professionals.

Our product candidates RTG-2023 and RTG-2024 require significant clinical testing before seeking regulatory approval. If they do not receive regulatory approval or if it is not successfully commercialized, our business will be harmed.

To date we have not conducted any clinical trials, nor have we had any product candidate approved for commercial sale. It is possible that we may never be able to develop a marketable product candidate.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to RTG-2023 and RTG-2024. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of our medical devices and RTG-2023 and RTG-2024, which may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of product candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market any product in the United States unless and until we receive approval from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in such countries. We have never submitted a request for marketing approval to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining FDA approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of a product for many reasons.

Our success depends largely upon our ability to advance our clinical product candidates, which are in early stages of development, through the various stages of drug development. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

Our clinical product candidates, RTG-2023 and RTG-2024 are in early stages of clinical development, and their commercial viability remains subject to the successful outcome of future clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of RTG-2023 and RTG-2024 may have a material adverse effect on our business. The long-term success of our business ultimately depends upon our ability to advance the development of RTG-2023 and RTG-2024 through clinical trials, appropriately formulate and consistently manufacture it in accordance with strict specifications and regulations, obtain approval for sale by the FDA or similar regulatory authorities in other countries, and ultimately successfully commercialize it directly or with a strategic partner or licensee. We cannot assure investors that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of RTG-2023 and RTG-2024 or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of RTG-2023 and RTG-2024.

RTG-2023 and RTG-2024 must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete its development and before it can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost-effective manufacturing processes, and obtain regulatory approval of RTG-2023 and RTG-2024. Despite these efforts, RTG-2023 and RTG-2024 may not:

- demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population;
- have the desired therapeutic or medical effects;
- be tolerable or free from undesirable or unexpected side effects;
- meet applicable regulatory standards;
- successfully commercialized by us or our licensees or collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure that the results of late-stage clinical trials will be sufficient to support the continued development of RTG-2023 and RTG-2024. Many, if not most, companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our RTG-2023 and RTG-2024 may not be predictive of the results we may obtain in future late-stage trials, especially in light of the fact that we have not yet begun clinical trials Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our clinical product candidates demonstrate a satisfactory safety, tolerability and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the United States, or other similar regulatory agencies in other jurisdictions, which would be required to market and sell the product.

Clinical trials are risky, lengthy and expensive. We incur substantial expense for, and devote significant time and resources to, preclinical testing and clinical trials, yet cannot be certain that these tests and trials will demonstrate that a product candidate is effective and well-tolerated, or will ever support its approval and commercial sale. clinical trials require adequate supplies of clinical trial material and sufficient patient enrollment to power the trial. Delays in patient enrollment can result in increased costs and longer development times. Even if we, or a licensee or collaborator, if applicable, successfully complete clinical trials for RTG-2023 and RTG-2024, we may not receive marketing approval for RTG-2023 and RTG-2024. We cannot assure you that RTG-2023 and RTG-2024 will successfully progress further through the drug development process, or ultimately will result in an approved and commercially viable product.

We do not have experience conducting clinical trials.

We are an early-stage clinical stage company, and our success is dependent upon our ability to obtain regulatory approval for and commercialization of RTG-2023 and RTG-2024, and we have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidate. The successful commercialization of any product candidate may require us to perform a variety of functions, including:

- undertaking preclinical development and successfully enroll subjects in clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

We have limited experience conducting and enrolling subjects in clinical trials. To date, we have no experience conducting clinical trials. In part because of this lack of experience, we cannot guarantee that planned clinical trials will be completed or that we will not require changes to our initial trial designs. Large-scale trials require significant additional financial and management resources, monitoring and oversight, and reliance on third-party clinical investigators, consultants and contract research organization (CROs). Relying on third-party clinical investigators, CROs and manufacturers, which are all also subject to governmental oversight and regulations, may also cause us to encounter delays that are outside of our control.

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize our clinical product candidates.

Our product candidates are still in clinical development and will require extensive additional clinical testing before we are prepared to submit an NDA for regulatory approval for any indication or for any treatment regime. We cannot predict with any certainty if or when we might submit a request for regulatory approval for our product candidates, or whether any such future application would be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. A product candidate in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of our Phase 1 clinical trial of the clinical product candidate as well as the pre-clinical results may not be predictive of the results of our to be proposed Phase 2 or Phase 3 trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing.

If we are required to conduct additional clinical trials or other testing of product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may not be able to:

- obtain marketing approval for our product candidates require additional funding not budgeted for;
- obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- and might be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our clinical product candidates could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

Healthcare reform measures could hinder or prevent the commercial success of our product candidates.

The U.S. government and other governments have shown significant interest in pursuing continued healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. Changes in applicable laws, rules, and regulations or the interpretation of existing laws, rules, and regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of its business. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In August 2022, the Inflation Reduction Act ("IRA") was enacted, which, among other things, requires the U.S. Department of Health and Human Services ("HHS") to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. 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. These provisions have been, and may continue to be, subject to legal challenges. Although full economic effect of the IRA on our business and the pharmaceutical industry in general is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also reduce our profitability. We expect pricing pressures will continue globally.

Additionally, on April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory Most-Favored-Nation demonstration models under Medicare Parts B and D, respectively. If these rules or other Most-Favored-Nation pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of Most-Favored-Nation pricing initiatives.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

We are subject to stringent domestic and foreign medical device regulations and any unfavorable regulatory action may materially and adversely affect our financial condition and business operations.

Our product candidates, development activities and manufacturing processes are subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our medical devices. The process of obtaining marketing approval or clearance from the FDA and comparable foreign bodies for new products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant, indeterminate amount of time;
- result in product shortages due to regulatory delays;
- require the expenditure of substantial resources;
- involve modifications, repairs or replacements of our products;
- require design changes of our products;
- result in limitations on the indicated uses of our products; and
- result in our never being granted the regulatory approval we seek.

Any of these occurrences that we might experience will cause our operations to suffer, harm our competitive standing and result in further losses that adversely affect our financial condition.

We will be subject to ongoing responsibilities under FDA and international regulations, both before and after a product is commercially released. For example, we are required to comply with the FDA's Quality System Regulation which mandates that manufacturers of medical devices adhere to certain quality assurance requirements pertaining, among other things, to validation of manufacturing processes, controls for purchasing product components and documentation practices. As another example, the Medical Device Reporting regulation requires us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury, or that a malfunction occurred which would be likely to cause or contribute to a death or serious injury upon recurrence. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize such medical devices, order a recall, repair, replacement, or refund of such devices, or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. Additionally, the FDA may restrict manufacturing and impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

A prolonged U.S. federal government shutdown could materially and adversely affect our business and operations.

Any disruption in the operations of the U.S. government, including as a result of the recent or future temporary or prolonged shutdowns resulting from the failure of Congress to enact appropriations bills or raise the federal debt ceiling, could materially and adversely affect our business, operations and financial condition. Recently, beginning on October 1, 2025, the U.S. federal government shut down and remained shut down through November 12, 2025, and again beginning on January 31, 2026 through February 3, 2026, during which times certain regulatory agencies, such as the FDA and the SEC, furloughed critical employees and stopped critical activities. Additionally, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. Furthermore, the recent federal government shutdown has resulted, and may continue for a prolonged period of time to result, in reduced availability of government services, and suspension or delay of activities by key agencies that regulate, fund, or interact with our business, including the SEC, the FDA, the Department of Health and Human Services, and the U.S. Patent and Trademark Office. As a result, the review and approval of our filings, applications, and submissions could be delayed, and we may be unable to access or rely upon certain government data or systems. In particular, it may lead to disruptions and delays in FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development program or pending applications.

Additionally, a prolonged or future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, the SEC announced that during the recent U.S. federal government shutdowns, it would not review or declare registration statements effective. In the event of an extended shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

Government shutdowns, if prolonged, can significantly impact the ability of government agencies upon which rely, such as the FDA and SEC, to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Even the threat of a government shutdown or prolonged budget negotiation uncertainty may adversely affect the broader U.S. economy, investor confidence, and capital markets. Such conditions could negatively impact our access to financing, timing of capital-raising transactions, and the liquidity or trading volume of our securities. Accordingly, the current or future federal government shutdowns, or uncertainty regarding the continuity of government operations, could have a material adverse effect on our business, results of operations, and stock price.

The pausing or termination of government grants by the United States government could have a major effect on the pharmaceutical industry, and as a result, our operations and prospects.

In January 2025, a memo issued by the Office of Management and Budget, had disclosed a freeze on federal loans and grants. That memo has since been rescinded; however, future memos, executive orders or other actions by the government could result in the freeze of existing or new grants, or the termination of previously approved grants. Such actions could have a material adverse effect on the pharmaceutical industry as a whole, a portion of which relies on governmental grants, and as a result, on the Company's operations and prospects.

Inadequate funding, government shutdowns, workforce reductions or other policy changes affecting the FDA, the SEC or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Our business depends on timely interactions with the FDA, including the review of regulatory submissions, scheduling of formal meetings, and oversight of clinical trials. Disruptions at the FDA and other federal agencies, including substantial leadership departures, personnel cuts, policy changes and those related to the federal government shutdown, may result in reduced staffing or suspension of non-essential FDA operations, which could delay or cancel meetings with the FDA, hinder regulatory guidance, cause delays in the implementation or enforcement of regulatory requirements in a timely fashion or at all, and postpone the review of IND applications, NDAs, and BLAs. These disruptions may also affect the initiation, conduct, and monitoring of clinical trials, particularly those requiring FDA authorization or ongoing regulatory engagement. Interruptions in FDA activities could materially delay our development timelines, increase operational costs, and adversely impact our ability to complete our ongoing and planned clinical trials and to advance product candidates toward approval and commercialization. Any such delays or uncertainties may have a significant negative effect on our business, financial condition, and results of operations.

In addition, government funding of the FDA, SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable, and spending allocation priorities may undergo significant changes through congressional budgeting and appropriations processes. Disruptions at the FDA and other agencies may also extend the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough employees, experience substantial funding cuts and pause or delay critical activities. If a prolonged government shutdown occurs, it could, for example, significantly impact the ability of (i) the FDA and/or the USPTO to review and process regulatory submissions in a timely matter, and (ii) the National Institutes of Health ("NIH") to conduct research or provide grants, all of which could have a material adverse effect on our business.

In addition, future government shutdowns could impact our ability to obtain necessary capital in order to properly capitalize and continue our operations. During such shutdowns, while the SEC's EDGAR system remains operational, the unavailability of the SEC staff to review filings, issue and resolve comments, or declare registration statements effective may delay our ability to complete public offerings and obtain timely regulatory approvals. These delays could impact our access to capital markets, hinder strategic transactions, and create uncertainty around our disclosure obligations. Additionally, the lack of interpretive guidance or exemptive relief during a shutdown may increase legal and compliance risks.

We will also be subject to stringent government regulation in foreign countries, which could delay or prevent our ability to sell our products in those jurisdictions.

We intend to pursue market authorizations for our products in foreign countries. For us to market our products in international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time and costs required to obtain approval may differ from that required to obtain an approval by the FDA. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. Violations of foreign laws governing use of medical devices may lead to actions against us by the FDA as well as by foreign authorities. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain all the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required for marketing our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally and may have a material adverse effect on our business.

Failure by us or our distributors to comply with foreign regulations applicable to the products we design, manufacture, install or distribute could expose us to enforcement actions or other adverse consequences.

We may be subject to the European Medical Device Regulation, which was adopted by the European Union ("EU") as a common legal framework for all EU member states. These regulations require companies that wish to manufacture and distribute medical devices in EU member states to meet certain quality system and safety requirements and ongoing product monitoring responsibilities, and obtain a "CE" marking (i.e., a mandatory conformity marking for certain products sold within the European Economic Area) for their products. Various penalties exist for non-compliance with the laws implementing the European Medical Device Regulations which, if incurred, could have a material adverse impact on our business, results of operations and cash flows.

Even if we obtain clearance or approval to sell our products, we will be subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance.

We, as well as any potential collaborative partners such as distributors, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to similar regulations in foreign countries. Even if regulatory clearance of a product is granted, the clearance may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with good manufacturing practice and other applicable regulatory requirements is strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain pre-market clearance or pre-market approval for devices, withdrawal of approvals previously obtained and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs which may have a material adverse effect on our business.

We could be subject to substantial fines or damages and possible exclusion from participation in federal or state health care programs if we fail to comply with the laws and regulations applicable to our business.

We are subject to stringent laws and regulations at both the federal and state levels governing the participation of durable medical equipment suppliers in federal and state health care programs. From time to time, the government may seek additional information related to our claims submissions, and in some instances government contractors may perform audits of payments made to us under Medicare, Medicaid, and other federal health care programs. These reviews may identify overpayments for which we submit refunds. We believe the frequency and intensity of government audits and review processes has intensified, and we expect this will continue in the future, due to increased resources allocated to these activities at both the federal and state Medicaid level, and greater sophistication in data review techniques.

If we are considered to have violated these laws and regulations, we could be subject to substantial fines, damages, possible exclusion from participation in federal health care programs such as Medicare and Medicaid and possible recoupment of any overpayments related to such violations. Failure to comply with applicable laws and regulations, even if inadvertent, could have a material adverse impact on our business.

If we fail to develop and successfully introduce new products and applications or fail to improve our existing products, our business prospects and operating results may suffer.

Our ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, which may include clinical trials that lead to the development of new products and new applications using our products. Our research and development process is expensive, prolonged, and entails considerable uncertainty. Due to the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully.

Successful commercialization of new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns.

Our ability to market and sell new products is subject to government regulation, including approval or clearance by the FDA and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

Risks Related to Owning our Securities

Our stock price may be volatile and you may not be able to resell your shares at or above the purchase price.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- our ability to execute our business plan;
- changes in our industry;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- additions or departures of key personnel;
- sales of our common stock;
- operating results that fall below expectations;
- regulatory developments;
- economic and other external factors;
- period-to-period fluctuations in our financial results;
- the public's response to press releases or other public announcements by us or third parties, including filings with the SEC;
- changes in financial estimates or ratings by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- the development and sustainability of an active trading market for our common stock;
- any future sales of our common stock by our officers, directors and significant stockholders; and
- other events or factors, many of which may be out of our control, including, but not limited to, pandemics such as COVID-19, war, or other acts of God.

In addition, the securities markets have from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders.

We expect that significant additional capital will be needed in the future to continue our planned operations. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution.

We have never paid cash dividends and have no plans to pay cash dividends in the future.

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our capital stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our capital stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock.

Our common stock is subject to the "penny stock" rules of the SEC and the trading market in the securities is limited, which makes transactions in the stock cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 under the Exchange Act, establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (a) that a broker or dealer approve a person's account for transactions in penny stocks; and (b) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must: (a) obtain financial information and investment experience objectives of the person and (b) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form: (a) sets forth the basis on which the broker or dealer made the suitability determination; and (b) confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of April 15, 2026, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 79% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We are an "emerging growth company" and are able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Our First Amended and Restated Certificate of Incorporation ("Certificate of Incorporation") and our Bylaws (the "Bylaws") and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Certificate of Incorporation and our Bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 40,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation and our Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Certificate of Incorporation and our Bylaws and Delaware law, as applicable, among other things provide the board of directors with the ability to alter the bylaws without stockholder approval.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we will incur significant additional legal, accounting and other expenses that we did not incur as a private company. The obligations of being a public company in the U.S. require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation, among other potential problems.

Our Certificate of Incorporation and Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Certificate of Incorporation and Bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law ("DGCL") or our Certificate of Incorporation or Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

These 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 and may result in increased costs to our stockholders, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find our choice of forum provisions contained in our Certificate of Incorporation or Bylaws 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBER SECURITY

We maintain a cyber risk management protocol designed to identify, assess, manage, mitigate, and respond to cybersecurity threats.

The underlying processes and controls of our cyber risk management protocol incorporate recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology ("NIST") Cybersecurity Framework ("CSF"). We have undertaken, on an annual basis, to conduct an assessment of our cyber risk management processes and controls to identify, quantify, and categorize material cyber risks. In addition, we have developed a risk mitigation plan to address such risks, and where necessary, remediate potential vulnerabilities identified through the annual assessment process.

In addition, we maintain policies over areas such as information security, access on/offboarding, and access and account management, to help govern the processes put in place by management designed to protect our IT assets, data, and services from threats and vulnerabilities. We consult with a third-party specialist with regard to our cyber risk management processes and controls.

Our management team is responsible for oversight and administration of our cyber risk management protocol, and for informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. RetinalGenix' management team has prior experience selecting, deploying, and overseeing cybersecurity technologies, initiatives, and processes and relies on threat intelligence as well as other information obtained from governmental, public, or private sources.

As part of its review of the adequacy of our system of internal controls over financial reporting and disclosure controls and procedures, the Board of Directors is specifically responsible for reviewing the adequacy of our computerized information system controls and security related thereof. The cybersecurity stakeholders, including member(s) of management assigned with cybersecurity oversight responsibility and/or third-party consultants providing cyber risk services, brief the Board of Directors on cyber vulnerabilities identified through the risk management process, the effectiveness of our cyber risk management program, and the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on RetinalGenix's processes to prevent, detect, and mitigate cybersecurity incidents. In addition, cybersecurity risks are reviewed by our Board of Directors at least annually, as part of the Company's corporate risk oversight processes.

We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. RetinalGenix acknowledges that the risk of cyber incidents is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of its business. To date, we have not had a cybersecurity incident. We proactively seek to detect and investigate unauthorized attempts and attacks against our IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to service delivery; however, potential vulnerabilities to known or unknown threats will remain. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject us to additional liability and reputational harm. See Item 1A. "Risk Factors" for more information on cybersecurity risks.

ITEM 2. PROPERTIES

In September 2024, the Company entered into an office suite lease. The term of the lease is for a period of 12 months. The lease auto-renews for an additional two years, unless the lessor is notified. The monthly payment is $650 and escalates to $690 over the three years. A security deposit of $1,995 was paid in connection with this lease.

We believe this arrangement is adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on the OTC Pink tier of the OTC Markets Group, Inc. under the symbol "RTGN." The following table sets forth, in U.S. dollars, high and low bid information for each of the calendar quarters indicated, as reported by the OTC Pink, for the past two fiscal years. Such OTC Pink quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

	High	Low
2025		
Quarter ended December 31	$ 4.01	$ 3.20
Quarter ended September 30	$ 5.02	$ 3.54
Quarter ended June 30	$ 5.02	$ 2.01
Quarter ended March 31	$ 6.36	$ 0.01
2024		
Quarter ended December 31	$ 1.62	$ 0.25
Quarter ended September 30	$ 1.60	$ 1.50
Quarter ended June 30	$ 1.50	$ 1.00
Quarter ended March 31	$ 3.50	$ 1.00

Shareholders

As of March 31, 2026, there were 120 stockholders of record of our common stock. 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. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have not paid any cash dividends on our capital stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. The decision whether to pay cash dividends on our common stock will be made by our board of directors, in their discretion, and will depend on our financial condition, results of operations, capital requirements and other factors that our board of directors considers significant.

Equity Compensation Plan Information

See Part III, Item 12 under the heading "Securities Authorized for Issuance Under Equity Compensation Plans" of this Annual Report on Form 10-K for equity compensation plan information.

Recent Sales of Unregistered Securities

We did not sell any equity securities during the year ended December 31, 2025 or subsequent thereto in any transactions that were not registered under the Securities Act other than as disclosed in our prior filings with the SEC and as set forth below.

We commenced a private placement of common stock in 2024 at $2.25 per share. During the year ended December 31, 2025, the Company sold 232,444 of its common stock at $2.25 per share for gross proceeds of $548,000, including $125,000 which was recorded as a stock subscription receivable at December 31, 2025, and was received in January 2026. During 2024, we issued 290,262 shares of common stock and raised approximately $653,000, including $150,000 which was recorded as a stock subscription receivable at December 31, 2024 and was received in January 2025. There can be no assurance that we will be able to raise capital when needed.

The issuances were exempt from registration under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

ITEM 6. RESERVED

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

Overview

We are an ophthalmic research and development company focused on developing technologies to screen, monitor, diagnose and treat eye health (ophthalmic, optical, and sight-threatening disorders) and facilitating the early detection and treatment of multiple systemic diseases through a combination of therapeutic medications and medical device technologies, while empowering patients and their clinicians with secure personal healthcare information.

Our mission is to prevent vision loss and blindness due to diabetic retinopathy and maculopathy, including the leading cause of retinal blindness (age related macula degeneration the dry and wet type).

We are actively pursuing our mission to prevent vision loss and blindness due to ocular diseases, including diabetic retinopathy and maculopathy, in ourfirst two devices:

1. *Retinal Imaging Screening Device*, a portable, retinal imaging system providing a wide field of view without requiring pupil dilation; and

2. *RetinalCam*^{TM}, an in-home/remote location patient-activated monitoring and imaging device offering real-time communication and alerting system for physicians available 24/7 and does not require dilation of the consumer's pupil.

We intend to launch RetinalCam^{TM} in the second half of 2026.

In addition to the above medical devices, as announced in October 2023, we are engaged with Pearl IRB, a provider of diagnostic testing services for its Institutional Review Board ("IRB") to conduct a study to personalize medical evaluations for patients receiving direct intraocular injections into their eyes as treatment for wet macular degeneration to help determine whether there is a genetic basis for the success or the failure of the procedure and to help patients evaluate whether the treatment is necessary, which was previously announced on October 30, 2023. We have engaged phlebotomists from Seven Springs Surgery Center to facilitate the blood draw process necessary for the Pearl IRB study. We anticipate an expansion of the IRB to multistate physicians in the winter of 2026 and the initial analysis by the first half of 2026, which will inform our clinical trial plans.

In addition to the above medical device and IRB advancements, we continue to make progress in our planning/and guidance to move forward, via our contracted clinical resource organization, to conduct pharmaceutical clinical studies for our two products

1. RTG-2023 for the treatment of dry age-related macular degeneration (dry AMD); and
2. RTG-2024 for the treatment of Alzheimer's syndrome dementia.

Our wholly owned subsidiary, DNA/GPS Inc., through pharmacogenetic mapping and testing is linking high resolution retinal imaging to retinal and systemic disease biomarkers to enable the discovery and treatment of sight-threatening and systemic diseases using our proprietary high resolution retinal imaging device. This genetic testing can also lead to drug re-purposing (i.e., new uses of previous drugs now off patent based on genetics).

We are developing a secure and interoperable database system for genetic information and images controlled by patients for use with their physicians, the RetinalGenix Eye Care Anonymized AI database (RECADTM AI system). This database will combine pharmacogenetic mapping capabilities with our retinal imaging capabilities on a secure information system controlled by the patient (like a patient electronic health record), who can share information with their selected physicians.

To date, we have devoted substantially all of our resources to organizing, business planning, raising capital, designing and developing product candidates, and securing manufacturing and sales/distribution partners. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the private placement of common stock.

We anticipate that we will need approximately an additional $7,000,000 to (i) complete and sell genetic testing products with our DNA/GPS mapping technology; (ii) complete the product design and testing for the RetinalCam; (iii) develop and advance the networking agreements with various service optical and clinical networking groups; and (iv) create and test our RetinalGenix Eye Care Anonymized AI database (RECAD AI system). We intend to obtain such funds through the sales of our equity and debt securities and/or through potential strategic partnerships; however, no assurance can be provided that funds will be available to us on acceptable terms, if at all. We do not expect that the RetinalCam will require FDA approval.

We expect to generate revenues in the future from the sale of DNA/GPS' laboratory developed consumer test kits. We do not expect to generate any revenues from sales of the RetinalCam or the Patient Informational database (RECAD AI system), until we successfully complete their development. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, strategic partnerships, collaborations and licensing arrangements or other capital sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates.

We issued shares of our common stock pursuant to a private placement raising approximately $3.0 million from the sale of 3,070,000 shares of common stock from 2019 through January 2022. In October 2021, the registration statement on Form S-1 (the "Registration Statement") that we filed with the Securities and exchange Commission (the "SEC") pursuant to which we registered for resale shares of common stock, including shares of common stock issuable upon exercise of outstanding options and warrants was declared effective. No funds were raised by the Company pursuant to the Registration Statement.

We commenced a private placement of common stock in 2024 at $2.25 per share. During the year ended December 31, 2025, the Company sold 232,444 of its common stock at $2.25 per share for gross proceeds of $548,000, including $125,000 which was recorded as a stock subscription receivable at December 31, 2025, and was received in January 2026. During 2024, we issued 290,262 shares of common stock and raised approximately $653,000, including $150,000 which was recorded as a stock subscription receivable at December 31, 2024 and received in January 2025. There can be no assurance that we will be able to raise capital when needed.

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

Basis of presentation:

These accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, DNA/GPS, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

Components of Results of Operations

Revenue

We have not generated any revenue since our inception.

Research and Development Expenses

Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, product and prototype development, and testing of materials. Research and development expenses are charged to operations as incurred.

We accrue for costs incurred by external service providers based on our estimates of services performed and costs incurred. These estimates include the level of services performed by third parties and other indicators of the services completed.

We cannot determine with certainty the duration and costs of future clinical trials and product development or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing clearance. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of product development will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of product development, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

General and administrative Expenses

General and administrative expenses consist primarily of compensation and consulting related expenses. Administrative expenses also include professional fees and other corporate expenses, including legal fees relating to corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses, marketing activities and other operating costs that are not specifically attributable to research activities. We have no full-time employees and have had limited funding; therefore the Company has been required to eliminate or defer as many costs as possible based upon available resources.

We expect that our administrative expenses will increase in the future as we increase our personnel headcount to support our continued research activities and development of our product candidates. We also expect increased expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory and tax-related services associated with compliance with SEC requirements; director and officer insurance costs; and investor and public relations costs.

Interest Expense

Interest expense is principally the coupon interest rate charged on loans from stockholders.

Results of Operations

Comparison of the year ended December 31, 2025 and 2024

The following table sets forth key components of our results of operations for the years ended December 31, 2025 and 2024.

	For the year ended December 31,			
	2025	2024	Change	% Change
Revenues	$ -	$ -	$ -	
Expenses				
General and administrative	1,300,956	1,333,930	(32,974)	(2)%
Research and development	83,040	373,271	(290,231)	(78)%
Stock-based compensation	1,040,594	2,609,786	(1,569,192)	(60)%
Total Expenses	2,424,590	4,316,987	(1,892,397)	(44)%
Interest expense, net	4,005	3,840	165	4%
Net Loss	$ (2,428,595)	$ (4,320,827)	$ (1,892,232)	(44)%

Revenues

We did not recognize revenues for the years ended December 31, 2025 and 2024.

Research and Development Expenses

	For the year ended December 31,	
	2025	2024
Direct costs	$ 83,040	$ 348,971
Allocated costs from Sanovas	-	24,300
Total Research and Development expenses	$ 83,040	$ 373,271

Research and development expenses decreased by $290,231, or 78%, to $83,040 for the year ended December 31, 2025 from $373,271 for the year ended December 31, 2024. The decrease was primarily the result of a decrease in engineering and technology consultants, and pilot manufacturing costs due to a lack of funds.

Stock Based Compensation Expenses

Stock-based compensation expenses decreased by $1,569,192 or 60%, to $1,040,594 for the year ended December 31, 2025 from $2,609,786 for the year ended December 31, 2024. The decrease was primarily due to the recognition of expense for warrants issued in the first quarter of 2024, of which a significant portion was vested immediately. During 2025, there were a lesser amount of warrants issued as compared to 2024.

General and Administrative Expenses

	For the year ended December 31,	
	2025	2024
Direct costs	$ 639,456	$ 703,930
Allocated costs from Sanovas	661,500	630,000
Total general and administrative expenses	$ 1,300,956	$ 1,333,930

General and administrative expenses decreased by $32,974 or 3%, to $1,300,956 for the year ended December 31, 2025 from $1,333,930 for the year ended December 31, 2024. Administrative costs consisting of costs related to the executive from Sanovas, were allocated based upon the amount of effort spent by such personnel on our business, and increased by approximately $31,000 over the 2024 levels. Salaries allocated to the Company from Sanovas increased in 2025 since the majority of time spent by Sanovas' sole employee were on Company activities, and such employee received a contractual salary increase. Other administrative expenses, specifically legal, fund-raising activities and listing related expenses were lower in 2025 as we had more less opportunities at that time, and less funding to procure certain operations.

Liquidity and Capital Resources

To date, we have devoted substantially all of our resources to organizing, business planning, raising capital, designing and developing product candidates, and securing manufacturing and sales/distribution partners. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily from the sale of common stock, loans and advances from related parties and by utilizing Sanovas personnel and facilities. During the year ended December 31, 2025, we received $398,000 (net of $125,000 for stock subscribed in 2025 and paid in 2026) from the sale of common stock pursuant to a private placement and $150,000 pursuant to proceeds from a stock subscription receivable from 2024 that was paid in 2025. As of December 31, 2025, we had cash of $14,774 and liabilities of $2,379,244. As of the date of this report, we do not have adequate resources to fund our operations beyond April 2026 without considering any future capital raising transactions. In fact, the cash held on December 31, 2025 is expected to fund operations only for a few weeks. Although our current private placement is still open, we have not yet sold any securities after December 31, 2025.

We anticipate that we will need approximately an additional $7,000,000 in operating capital to (i) complete product design and testing for RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for FDA approval (we anticipate that the RetinalCam™ will not require FDA approval); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS' genetic mapping technology; and (iii) build the infrastructure for our sustained growth. We do not expect to generate any revenues from product sales unless and until we successfully complete development of RetinalGenix™ and RetinalCam™ and obtain regulatory approval for RetinalGenix™. We will also require additional operating capital as a result of us operating as a public company, including for legal, accounting, investor relations, compliance and other expenses.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, strategic partnerships, collaborations and licensing arrangements or other capital sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates.

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

Cash Flow Activities for the year ended December 31, 2025 and 2024

The following table sets forth a summary of our cash flows for the periods presented:

	For the year ended December 31,	
	2025	2024
Net cash used in operating activities	$ (558,350)	$ (741,936)
Net cash provided by financing activities	567,064	747,996
Net increase in cash	8,714	6,060
Cash at beginning of the period	6,060	0
Cash at end of the period	$ 14,774	$ 6,060

Operating Activities

Net cash used in operating activities was $558,350 for the year ended December 31, 2025. The cash flow used in operating activities in 2025 was principally driven by the net loss of $2,428,595 offset in part by non-cash stock-based compensation expense of $1,040,594. In addition, Sanovas billed us for allocated costs and expenses paid on behalf of and allocated to us in the amount of $661,500 during the year ended December 31, 2025. Accounts payable increased by $162,680.

Net cash used in operating activities was $741,936 for the years ended December 31, 2024. The cash flow used in operating activities in 2024 was principally driven by the net loss of $4,320,827 offset in part by non-cash stock-based compensation expense of $2,609,786, a non-cash charge for stock issued to a vendor for services rendered of $125,000, and an increase in accounts payable and accrued liabilities and accrued interest payable of $191,0033. In addition, Sanovas billed us for allocated costs and expenses paid on behalf of and allocated to us in the amount of $654,300 and we received net advances of $34,908 from related parties including $24,649 of net cash advances from Sanovas during the years ended December 31, 2024.

Financing Activities

Net cash provided by financing activities was $567,064 and $747,996 during the year ended December 31, 2025 and 2024, respectively. During the year ended December 31, 2025, we received approximately $398,000 from the sale of common stock pursuant to a private placement and $150,000 pursuant to proceeds from the stock subscription receivable from 2024.

Net cash provided by financing activities was $747,996 and $451,623 during the years ended December 31, 2024 and 2023, respectively. For 2024, the cash flow from operations is primarily attributable to sales of common stock of approximately $503,000, proceeds from the exercise of stock options of $210,000 and proceeds from advances from related parties and Sanovas of $34,908 in the years ended December 31, 2024.

Critical Accounting Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and related disclosures in the financial statements and accompanying notes. Management bases it estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Estimates are used in areas including, but not limited to: research and development expense recognition, valuation of stock options, allowances of deferred tax assets, accrued expenses and liabilities, and cash flow assumptions regarding going concern considerations.

Stock-based Compensation

Stock-based compensation represents the cost related to stock-based awards granted to employees. We measure stock-based compensation costs at the grant date, based on the estimated fair value of the award and recognize the cost (net of estimated forfeitures) over the vesting period. Forfeitures are estimated on the date of grant and revised if actual or expected forfeiture activity differs materially from the original estimates. We estimate the fair value of stock options using a Black-Scholes valuation model. The fair value of common stock was determined based upon recent sales of common stock to third parties pursuant to common stock offering, since our common stock trades infrequently in the public markets.

The risk-free interest rate assumption is determined using the yield currently available on U.S. Treasury zero-coupon issues with a remaining term commensurate with the expected term of the award. Management has estimated expected volatility based on similar comparable industry sector averages. Expected life of the option represents the period of time options are expected to be outstanding. The estimate for dividend yield is 0% because we have not historically paid and does not intend to pay a dividend on its common stock in the foreseeable future.

Allocated costs from Sanovas

A substantial portion of our expenses are costs and expenses paid by Sanovas and costs and expenses allocated to us by Sanovas. We expect that to continue until we have sufficient resources to build our own team and infrastructure to support our operations. The allocations our payroll related expenses are based upon the estimated percentage of effort incurred by each employee on operations. Allocation of non-payroll related expenses are based upon whether the expense related to our operations.

Income taxes

We account for income taxes using the asset-and-liability method in accordance with Accounting Standards Codification 740, *Income Taxes*. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on the deferred tax assets and liabilities of a change in tax rate is recognized in the period that includes the enactment date. A valuation allowance has been recorded for all of the deferred tax assets.

JOBS Act

We are an "emerging growth company," as defined in Section 2(a) the Securities Act, as modified by the JOBS Act. For as long as we continue to be an emerging growth company, we also intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1.325 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act.

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company", as defined in Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will cease to be a smaller reporting company if we have (i) more than $250 million in market value of our shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter or (ii) more than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates more than $700 million as of the last business day of our second fiscal quarter.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item.

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.

RetinalGenix Technologies Inc.
Consolidated Financial Statements
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of RetinalGenix Technologies Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of RetinalGenix Technologies Inc. and Subsidiary (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the years in the two year period ended December 31, 2025, and the related notes to the consolidated financial statements (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations, and its cash flows for each of the years in the two year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note A to the financial statements, based on its projections, the Company anticipates that it will not have adequate resources to fund its operations through the next twelve months. Furthermore, the Company's losses from operations and working capital deficiency raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note A. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks.

Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the Board of Directors and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

/s/ Liebman Hymowitz, LLP

We have served as the Company's auditor since 2019.

Garden City, New York
April 15, 2026
PCAOB ID No. 473

RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash	$ 14,774	$ 6,060
Total Current Assets	14,774	6,060
Equipment, net of accumulated depreciation of $307 and $251 at December 31, 2025 and 2024, respectively	-	56
Operating lease right-of-use asset	4,272	6,835
Security deposit	1,995	1,995
TOTAL ASSETS	**$ 21,041**	**$ 14,946**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current Liabilities		
Accounts payable and accrued liabilities	$ 1,084,763	$ 922,083
Due to Sanovas	674,842	15,709
Due to related parties	489,224	467,793
Shareholders' notes payable	49,000	49,000
Lease liability – short term portion	2,860	988
Accrued interest payable	19,279	15,439
Total Current Liabilities	2,319,968	1,471,012
Lease liability – long term portion	3,684	6,544
Total liabilities	2,323,652	1,477,556
Commitments and contingencies		
Stockholders' Deficit:		
Preferred stock, $0.0001 par value; 40,000,000 shares authorized; Series F preferred stock - 3,000,000 shares designated, 0 issued and outstanding at December 31, 2025 and December 31, 2024	-	-
Common stock, $0.0001 par value; 80,000,000 shares authorized; 18,754,739 and 18,522,295 shares issued and outstanding at December 31, 2025 and 2024, respectively	1,875	1,852
Additional paid in capital	15,679,131	14,115,560
Stock subscription receivable	(125,000)	(150,000)
Accumulated deficit	(17,858,617)	(15,430,022)
Total Stockholders' Deficit	(2,302,611)	(1,462,610)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 21,041**	**$ 14,946**

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

RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31,	
	2025	**2024**
Revenues	**$ -**	**$ -**
Operating expenses:		
General and administrative	1,300,956	1,333,930
Research and development	83,040	373,271
Stock-based compensation	1,040,594	2,609,786
Total operating expenses	2,424,590	4,316,987
Interest expense, net	4,005	3,840
Net loss	$ (2,428,595)	$ (4,320,827)
Net loss per share - basic and diluted	$ (0.13)	$ (0.24)
Weighted average number of common shares outstanding during the period- basic and diluted	18,562,592	17,940,639

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

RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2025 AND 2024

	Common shares	Amount	Additional Paid in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Stockholder's Deficit
Balance as at December 31, 2024	**18,522,295**	**$ 1,852**	**$ 14,115,560**	**$ (150,000)**	**$ (15,430,022)**	**$ (1,462,610)**
Stock-based compensation expense	-	-	1,040,594	-	-	1,040,594
Collection of stock subscription receivable	-	-	-	150,000	-	150,000
Shares sold to investors	176,889	18	397,982	-	-	398,000
Stock subscribed by investors	55,555	5	124,995	(125,000)		
Net loss	-	-	-		(2,428,595)	(2,428,595)
Balance as at December 31, 2025	**18,754,739**	**$ 1,875**	**$ 15,679,131**	**(125,000)**	**$ (17,858,617)**	**$ (2,302,611)**
Balance as at December 31, 2023	**17,635,478**	**$ 1,764**	**$ 9,701,774**		**$ (11,109,195)**	**$ (1,405,657)**
Exercise of stock options	170,000	17	209,983		-	210,000
Settlement of account payable through issuance of common stock	75,000	7	149,993		-	150,000
Retirement of due to Sanovas through the issuance of shares of common stock to Sanovas Ophthalmology LLC	296,000	30	665,970			666,000
Stock-based compensation expense	-	-	2,609,786		-	2,609,786
Stock issued to vendor	55,555	6	124,994			125,000
Shares sold to investors	223,595	22	503,066		-	503,088
Stock subscribed by investors	66,667	6	149,994	(150,000)		-
Net loss					(4,320,827)	(4,320,827)
Balance as at December 31, 2024	**18,522,295**	**$ 1,852**	**$ 14,115,560**	**$ (150,000)**	**$ (15,430,022)**	**$ (1,462,610)**

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

RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December 31,	
	2025	**2024**
Cash Flows From (Used In) Operating Activities		
Net loss	$ (2,428,595)	$ (4,320,827)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Non-cash items:		
Stock-based compensation expense	1,040,594	2,609,786
Depreciation expense	56	100
Stock issued for services provided		125,000
Amortization of right of use asset	2,563	854
Expenses allocated by Sanovas on behalf of Company	661,500	654,300
Changes in operating assets and liabilities:		
Increase in accounts payable and accrued liabilities	162,680	187,163
Payment of lease liability	(988)	(157)
(Increase) in security deposit	-	(1,995)
Increase in accrued interest	3,840	3,840
Total adjustments	1,870,245	3,578,891
Net cash (used in) operating activities	(558,350)	(741,936)
Cash Flows From Financing Activities		
Proceeds from collection of stock subscription receivable	150,000	-
Proceeds from sale of common stock	398,000	503,088
Proceeds from exercise of stock options and warrants	-	210,000
Advances from related parties, net	19,064	34,908
Net cash provided by financing activities	567,064	747,996
Net increase in cash	8,714	6,060
Cash at beginning of period	6,060	0
Cash at end of period	$ 14,774	$ 6,060
Supplemental information:		
Interest paid	**$** -	$ -
Income taxes paid	**$** -	$ -
Operating Lease – at inception	$ -	$ 7,689
Retirement of due to Sanovas through the issuance of common stock to Sanovas Ophthalmology LLC (Note C)		$ 666,000
Settlement of account payable through the issuance of common stock	$ -	$ 150,000

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

NOTE A – HISTORY, BUSINESS PURPOSE, LIQUIDITY AND GOING CONCERN

RetinalGenix Technologies Inc. (the "Company"), a Delaware corporation, was formed in November 2017 by Sanovas Ophthalmology, LLC ("Sanovas Ophthalmology"), a majority owned subsidiary of Sanovas Inc. ("Sanovas"), a privately held research and development incubator. Since inception, a portion of the operations of the Company were conducted by Sanovas, who invoices the Company for costs and expenses paid for on behalf of the Company and costs and expenses allocated to the Company for services performed on behalf of the Company.

The Company was formed to develop technologies to screen, monitor, diagnose and treat ophthalmic and systemic disease. Its mission is to prevent vision loss and blindness due to diabetic retinopathy and maculopathy, including the leading cause of retinal blindness (age related macula degeneration the dry and wet type). The Company sublicensed certain technology initially developed by Sanovas from Sanovas Ophthalmology – See Note C.

The Company's subsidiary, DNA/GPS, Inc., through pharmacogenetic mapping and testing is linking high resolution retinal imaging to retinal and systemic disease biomarkers to enable the discovery and treatment of sight-threatening and systemic diseases using our proprietary high resolution retinal imaging device. This genetic testing can also lead to drug re-purposing (i.e., new uses of previous drugs now off patent based on genetics).

The Company's RetinalCam™ device is a portable ophthalmic home screening and monitoring device designed for remote general and home use employing real-time communication and alerting system for physicians available 24/7 and does not require dilation of the consumer's pupil.

In addition to the above medical device, as announced in October 2023, the Company is engaged with Pearl IRB, a provider of diagnostic testing services for its Institutional Review Board ("IRB") to conduct a study to personalize medical evaluations for patients receiving direct intraocular injections into their eyes as treatment for wet macular degeneration to help determine whether there is a genetic basis for the success or the failure of the procedure and to help patients evaluate whether the treatment is necessary. The Company has engaged phlebotomists from Seven Springs Surgery Center to facilitate the blood draw process necessary for the Pearl IRB study. The Company anticipates an expansion of the IRB to multistate physicians in the winter of 2026 and the initial analysis by the first half of 2026, which will inform its clinical trial plans.

In addition to the above medical device and IRB advancements, the Company continues to make progress in its planning/and guidance to move forward, via its contracted clinical resource organization, to conduct pharmaceutical clinical studies for our two products:

1. *RTG-2023* for the treatment of dry age-related macular degeneration (dry AMD); and
2. *RTG-2024* for the treatment of Alzheimer's syndrome dementia.

Liquidity and Going Concern

The Company has had net losses since inception and has an accumulated deficit of approximately $17,900,000 at December 31, 2025. As of December 31, 2025, the Company had liabilities of approximately $2,300,000, a significant portion of which is with related parties. The Company has minimal cash at December 31, 2025, and remains dependent on related parties for much of its financing. The Company expects that operating losses and negative cash flows from operations will occur for at least the next several years, and the Company will need to access additional funds to achieve its strategic goals with respect to the sublicensed technology. The Company is in discussions with investment bankers and individual investors with respect to raising additional capital for the Company and potentially up-listing to Nasdaq exchange.

Sanovas has paid a significant portion of the Company's operating expenses through December 2025, and was owed approximately $675,000 as of December 31, 2025 by the Company. During 2025, the Company sold 232,444 shares of common stock at $2.25 per share raising gross proceeds of $523,000, including $125,000 of stock subscribed for in 2025 and paid in 2026. During 2024, the Company sold 290,262 shares of common stock at $2.25 per share raising gross proceeds of $628,088, including $150,000 of stock subscribed for in 2024 and paid in 2025. The Company issued 296,000 shares of its common stock to offset amounts due to Sanovas for payment of expenses on behalf of the Company of $666,000 in the fourth quarter of 2024. In 2024, the Company also issued 75,000 shares of its common stock as settlement of an account payable of $150,000 due to a vendor and issued 55,555 shares of its common stock in the fourth quarter of 2024 valued at $125,000 to a vendor for investor relation services.

As of the date of this report, the Company does not have adequate resources to fund its operations through April 2027 without considering any potential future milestone payments that it may receive under any new collaborations that it may enter into in the future or any future capital raising transactions. The Company will need to raise additional funding to complete the development of its products and commence the market launch, assuming regulatory approval is obtained. The Company does not know whether additional financing will be available when needed, whether it will be available on favorable terms, or if it will be available at all. These factors raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE B - SIGNIFICANT ACCOUNTING POLICIES

A summary of significant accounting policies consistently applied in the preparation of the accompanying consolidated financial statements is as follows:

1. Basis of Presentation

The Company's consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). Certain amounts from the 2024 accounts have been reclassified to conform to the current presentation.

2. Cash Equivalents

For purpose of the consolidated statements of cash flows, the Company considers all short-term investments purchased with a maturity of three months or less to be cash equivalents.

3. Use of Estimates

In preparing the Company's consolidated financial statements in conformity with US GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

4. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. For the years ended December 31, 2025 and 2024, the Company did not have any tax expenses due to its losses, and at December 31, 2025 and 2024 all deferred tax assets were fully reserved.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 740-10 *Income Taxes*. ASC Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on the recognition, measurement, and classification of amounts relating to uncertain tax positions, accounting for and disclosure of interest and penalties, accounting in interim periods and disclosures. The application of that guidance did not result in the recognition of any unrecognized tax benefits at December 31, 2025 or 2024. The Company's policy is to expense any penalties and interest associated with this topic. At December 31, 2025 and 2024, there were no amounts accrued for penalties and interest.

5. Income (Loss) Per Common Share

The Company computes net income (loss) per share in accordance with ASC 260, *Earnings Per Share* ("EPS"). Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted-average number of common and common equivalent shares outstanding during the period. However, common shares that are considered anti-dilutive are excluded from the computation of diluted EPS. Since the Company had a net loss during the years ended December 31, 2025 and 2024, the basic and diluted net loss per share is the same.

Potentially dilutive securities not included in the computation of loss per share for the year ended December 31, 2025 are stock options to purchase 780,000 shares of common stock, Pre-funded Warrant to purchase 28,014,540 shares of common stock and warrants to purchase 1,800,000 shares of common stock.

Potentially dilutive securities not included in the computation of loss per share for the year ended December 31, 2024, include stock options to purchase 2,415,000 shares of common stock, Pre-funded Warrant to purchase 28,014,540 shares of common stock, and warrants to purchase 1,650,000 shares of common stock.

6. Stock-based compensation:

The Company recognizes expense for stock-based compensation in accordance with ASC Topic 718, *Stock-Based Compensation*. For stock-based awards, the Company calculates the fair value of the award on the date of grant using the Black Scholes option-pricing model. The expense is recognized over the service period for awards expected to vest. The estimate of stock-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from original estimates, such amounts are recorded as a cumulative adjustment in the period the estimates are revised. Stock options granted to non-employee consultants are revalued at the end of each reporting period until vested and the changes in their fair value are recorded as adjustments to expense over the related vesting period.

7. Research and Development costs:

Research and development costs are expensed as incurred. Costs incurred in obtaining technology licenses outside of business combinations are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use. licensed has not reached technological feasibility and has no alternative future use.

8. Property and Equipment:

Property and equipment are stated at cost, net of accumulated depreciation using the straight-line method over their estimated useful lives (3 years), once the asset is placed in service. Expenditures for maintenance and repairs, which do not extend the economic useful life of the related assets, are charged to operations as incurred, and expenditures which extend the economic life are capitalized. When assets are retired or otherwise disposed of, the costs and related accumulated depreciation or amortization are removed from the accounts and any gain or loss on disposal is recognized in the consolidated statement of operations for the respective period.

The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

9. Leases

The Company determines if an arrangement is an operating or capital lease at inception. At December 31, 2025 and 2024, the Company had an operating lease for an office suite (see Note H) and no financing leases.

Operating leases are recorded as operating lease right-of-use ("ROU") assets and operating lease liabilities (current portion and long-term portion) on the accompanying consolidated balance sheets. Operating lease ROU assets and the related lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease ROU assets also include lease incentives and initial direct costs incurred. For operating leases, interest on the lease liability and the amortization of the ROU asset result in straight-line rent expense over the lease term. Leases may include options to extend or terminate the lease which are included in the operating lease ROU assets and operating lease liability when they are reasonably certain of exercise. Certain leases include lease and non-lease components, which are accounted for as one single lease component. Operating lease expense associated with minimum lease payments is recognized on a straight-line basis over the lease term.

10. Recent Accounting Pronouncements:

A variety of proposed or otherwise potential accounting standards are currently under study by standard-setting organizations. Due to the tentative and preliminary nature of those proposed standards, management has not determined whether the implementation of such proposed standards would be material to the consolidated financial statements of the Company**.**

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses (DISE)*, which specifies additional disclosure requirements. The new guidance requires additional disclosures, including the composition of certain income expense line items (such as purchases of inventory, employee compensation, and "other expenses") and a separate disclosure for selling expenses. This change is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, however, early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on the consolidated financial statements and disclosures and anticipates disclosing any impact of the adoption in the annual report on Form 10-K for the fiscal year ended December 31, 2027.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The Company adopted ASU 2023-09 in 2025, with prospective application. The adoption of ASU 2023-09 has not had a material effect on the Company's statements and disclosures.

In November 2023, the FASB issued Accounting Standards Update 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which improves reportable segment disclosure requirements, primarily through enhanced disclosures related to significant segment expenses. The Company has adopted the provisions of ASU 2023-07 for the year ended December 31, 2025, but there was no significant impact as the company operates in only segment.

NOTE C - RELATED PARTY TRANSACTIONS

Sanovas

The Company is related to Sanovas through common ownership and management. Sanovas Opthalmology is a majority owned subsidiary of Sanovas and Jerry Katzman, the Company's Chief Executive Officer, is also a director of Sanovas Ophthalmology and in such capacity has the right to vote and dispose of the securities held by such entity. Jerry Katzman is also the Chief Executive Officer of Sanovas.

Commencing in 2019, Sanovas began paying expenses on behalf of the Company, and began allocating a portion of expenses and infrastructure costs to the Company and other entities where Sanovas was performing shared services. Included in such allocated costs is approximately $662,000 and $630,000 in costs related to an officer of the Company, whose salary is through an employment agreement with Sanovas, in the years ending December 31, 2025 and 2024, respectively.

The following summarizes the transactions between the Company and Sanovas for the years ended December 31, 2025 and 2024:

	Year ended	
	December 31, 2025	December 31, 2024
Balance due to Sanovas – beginning of period	**$ 15,709**	**$ 2,760**
Costs of Sanovas allocated to the Company	661,500	654,300
Retirement of due to Sanovas through the issuance of shares to Sanovas Ophthalmology	-	(666,000)
Cash advances from Sanovas to the Company, net	(2,367)	24,649
Balance due to Sanovas - end of period	**$ 674,842**	**$ 15,709**

The Company issued 296,000 shares of its common stock to Sanovas to offset amounts due to Sanovas for payment of expenses on behalf of the Company of $666,000 in December 2024. No such offset occurred during the year ended December 31, 2025.

Sublicense

On September 24, 2021, the Company entered into a sublicense agreement ("Sublicense Agreement") with Sanovas Ophthalmology pursuant to which Sanovas Ophthalmology granted the Company an exclusive worldwide ("Territory") license to certain intellectual property licensed to Sanovas Ophthalmology by Sanovas Intellectual Property LLC relating to certain technologies for eye and ocular visualization and monitoring ("Licensed IP") for uses related to the screening, examination, diagnosis, prevention and/or treatment of any eye disease, medical condition or disorder, or any disease, medical condition or disorder affecting the eye. Pursuant to the Sublicense Agreement, commencing on the date of the first commercial sale of a Licensed Product (as defined in the Sublicense Agreement), in each country in the Territory and continuing on a country by country basis until the expiration or termination of the last Valid Claim (as defined in the Sublicense Agreement) of a licensed patent in such country (the "Royalty End Date"), the Company is obligated to pay Sanovas Ophthalmology a royalty equal to a mid-single digit percentage of any Net Sales (as defined in the Sublicense Agreement) of any Licensed Product. The Sublicense Agreement continues until the Royalty End Date, unless earlier terminated pursuant to its terms. The Sublicense Agreement may be terminated by either party if the other party materially breaches the Sublicense Agreement in a manner that cannot be cured, or materially breaches the Sublicense Agreement in a manner that can be cured and such breach remains uncured for more than 30 days after the receipt by the breaching party of notice specifying the breach. Furthermore, the Company may terminate the Sublicense Agreement at any time upon 90 days written notice to Sanovas Ophthalmology. No royalties have been paid through December 31, 2025 under this Sublicense Agreement.

Due to affiliates

From time to time, an officer of the Company, a shareholder of the Company and other related parties advanced funds or paid expenses on behalf of the Company. There is no formal notes or repayment plan for such advances. At December 31, 2025 and 2024, the Company had received an aggregate of $489,224 and $467,793, respectively, pursuant to such advances.

Shareholders' notes payable – See Note G

NOTE D - COMMON AND PREFERRED STOCK

Pursuant to the Company's Amended and Restated Certificate of Incorporation (the "Amended and Restated Certificate of Incorporation"), filed with the Delaware Secretary of State on January 8, 2018, the Company is authorized to issue 40,000,000 shares of preferred stock and 80,000,000 shares of common stock each with a par value of $0.0001 per share. The Company has designated 3,000,000 shares of preferred stock as Series F preferred stock.

In November 2020, Sanovas commenced an action in the Court of Chancery of the State of Delaware (the "Delaware Action") against Lawrence Gerrans and Halo Management LLC ("Halo"), an entity owned by Mr. Gerrans, seeking an order declaring that any rights that Halo and/or Mr. Gerrans may have with respect to any equity securities in Sanovas and each of its affiliated subsidiaries (including, but not limited to, the Company) are void or voidable and may be cancelled.

On November 21, 2021, the Company's Board of Directors adopted a resolution to rescind the 3,000,000 shares of Series F preferred stock purported to be issued to Halo for lack of contract consideration. The Company recorded this action into its accounts in the fourth quarter of 2021. On April 2, 2024, the Court of Chancery of the State of Delaware issued an order in the Delaware Action voiding and cancelling the 3,000,000 shares of Series F preferred stock issued to Halo and Mr. Gerrans' rights to any equity securities in the Company.

Common Stock

The following are the significant common stock transactions in 2025 and 2024:

In March 2024, the Company issued 75,000 shares of common stock valued at $150,000 in partial settlement of an account payable.

In 2024, stock options for 170,000 shares of common stock were exercised for a cash payment of $210,000.

In 2024, the Company commenced an offering of its common stock at $2.25 per share, and sold 223,595 shares of common stock for proceeds of $503,088. Also in 2024, one investor subscribed for the purchase of 66,667 shares under the same offering for a total of $150,000, which was recorded as a stock subscription receivable at December 31, 2024 and was received in January 2025.

See Note C for share transactions to settle payables to Sanovas.

During the year ended December 31, 2025, the Company sold 176,889 of its common stock at $2.25 per share for proceeds of $398,000. Also in 2025, two investors subscribed for the purchase of an aggregate of 55,555 shares under the same offering for a total of $125,000 which was recorded as a stock subscription receivable at December 31, 2025, and was received in January 2026.

Preferred Stock

As of December 31, 2025 and 2024, there were 3,000,000 shares of preferred stock designated as Series F preferred stock. There are no shares of Series F preferred stock outstanding at December 31, 2025 or 2024.

The rights and privileges of the Series F preferred stock are summarized as follows:

Voting Privileges and Protective Features:

Each holder of outstanding shares of Series F preferred stock is entitled to cast the number of votes equal to the number of whole shares of common stock into which the Series F preferred stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. The holders of record of a majority of outstanding Series F preferred stock shall be entitled to elect two of the members of the Board of Directors of the Company. The right to elect two directors shall terminate on the date upon which there are less than 25,000 shares of Series F preferred stock issued and outstanding. There are currently no shares of Series F preferred stock issued and outstanding therefore this right has no current relevance.

For so long as at least 25,000 shares of Series F preferred stock remained outstanding, the vote or written consent of the holders of the majority of the outstanding shares of Series F preferred stock was necessary for the Company to conduct certain corporate actions, including, but not limited to, merger, consolidation or dissolution of the Company; certain amendments to the Certificate of Incorporation or bylaws of the Company; authorization or issuance of shares of any additional class or series of capital stock unless the same ranks on parity or junior to the Series F preferred stock with respect to voting rights. There are currently no shares of Series F preferred stock issued and outstanding therefore this right has no current relevance.

Redemption:

The Series F preferred stock does not have redemption features.

Dividends:

There are no stated dividends on the Series F preferred stock.

Conversion:

Each share of Series F preferred stock is convertible, at the option of the holder, at any time and from time to time into shares of common stock at a conversion rate as is determined by dividing the Series F Original Issue Price by the Series F Conversion Price. "Series F Original Issue Price" initially means $0.01 and "Series F Conversion Price" initially means $0.01, as adjusted for any dilutive transaction such as stock splits, certain dividends, mergers or acquisitions.

All of the outstanding shares of Series F preferred stock will automatically convert into shares of the Company's common stock upon the consummation of an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"), resulting in gross proceeds of at least $15,000,000 to the Company or upon written consent of at least 67% of the Series F preferred shareholders.

NOTE E - STOCK PLAN

The Company has reserved 10,000,000 shares of common stock for issuance to employees or consultants from the RetinalGenix Technologies Inc. 2017 Equity Incentive Plan (the "Plan"). The Company may grant stock options, restricted stock or other types of equity incentive instruments under the Plan.

The Company recognized $54,734 and $391,954 of stock-based compensation expense during the years ended December 31, 2025 and 2024, respectively, related to stock options which is included in the accompanying consolidated statements of operations. As of December 31, 2025, there was no unrecognized compensation expense related to non-vested stock options granted under the Plan.

At December 31, 2025, there were 7,290,000 shares available to be issued under the Plan. The intrinsic value of such outstanding and vested stock options is approximately $427,000 at December 31, 2025. The following table summarizes stock option activity of the Plan through December 31, 2025:

	Options Issued		Weighted-Average Exercise Price
Options outstanding – December 31, 2023	2,585,000	$	1.23
Granted	50,000		3.00
Canceled	-		-
Expired	(50,000)		-
Exercised	(170,000)		1.24
Options outstanding – December 31, 2024	2,415,000	$	1.27
Granted	-		-
Canceled	-		-
Expired	(1,635,000)		1.00
Exercised	-		-
Options outstanding – December 31, 2025	780,000	$	1.72

Additional information regarding the exercisable options and average remaining contractual life of the options outstanding as of December 31, 2025 is as follows:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable at December 31, 2025
$ 1.00	500,000	6.0 Years	500,000
3.00	280,000	2.0 Years	280,000
	780,000		780,000

The fair value of each option grant was estimated on the date of grant to be $2.11 per share using the Black-Scholes option-pricing model with the following assumption weighted-average in 2024:

Risk-free interest rates	3.08%
Expected life in years	5.0
Expected volatility	90%
Expected dividend yield	0%
Fair value of common stock	$ 2.25

The risk-free interest rate assumption is determined using the yield currently available on U.S. Treasury zero-coupon issues with a remaining term commensurate with the expected term of the award. Management has estimated expected volatility based on similar comparable industry sector averages. Expected life of the option represents the period of time options are expected to be outstanding. The estimate for dividend yield is 0% because the Company has not historically paid, and does not intend to pay a dividend on its common stock in the foreseeable future.

NOTE F - WARRANTS

During the first quarter of 2024, the Company issued warrants to purchase 1,550,000 shares of common stock to consultants, board members, and advisors at an exercise price of $3.00 per share vesting over periods from immediately to three years. Of those warrants, 635,000 warrants in aggregate were granted to officers and directors exercisable at $3.00 per warrant as follows: Jerry Katzman, MD 300,000 shares, Virender Ahluwalia 50,000 shares, Herbert Gould, MD 160,000 shares, Dessy Boneva, MD 50,000 shares, Vinay Mehindru, MD 75,000 shares. The warrants issued to Mr. Ahluwalia have since expired.

During the year ended December 31, 2025, the Company issued 1) warrants to purchase 100,000 shares of common stock to two consultants at an exercise price of $3.00 per share, with 50,000 vesting immediately and 50,000 vesting over one year, and 2) warrants to purchase 50,000 shares of common stock to a consultant pursuant to a Consulting Agreement at an exercise price of $3.20 per share, all of which vested immediately. The Consulting Agreement also provided for additional warrants to purchase 100,000 shares of common stock which were potentially issuable in the future pursuant to certain milestones, but the Consulting Agreement with the consultant was terminated by mutual agreement prior to issuance of the additional warrants.

The following table summarizes warrant activity of the Plan through December 31, 2025:

	Warrants Issued	Weighted-Average Exercise Price
Options outstanding – December 31, 2023	150,000	$ 1.10
Granted	1,550,000	3.00
Canceled	-	-
Forfeited	(50,000)	3.00
Exercised	-	-
Options outstanding – December 31, 2024	1,650,000	$ 2.83
Granted	150,000	3.12
Canceled	-	-
Forfeited	-	-
Exercised	-	-
Options outstanding – December 31, 2025	1,800,000	$ 2.85

Additional information regarding the warrants outstanding as of December 31, 2025 is as follows:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable
$ 1.10	150,000	2.6 Years	150,000
$ 3.00	1,600,000	8.4 Years	1,058,333
$ 3.20	50,000	3.0 years	50,000
	1,800,000		1,258,333

The fair value of such warrants was estimated on the date of grant to be $1.19 and $1.97 per share using the Black-Scholes option-pricing model with the following assumption weighted-averages in 2025 and 2024, respectively:

	2025	2024
Risk-free interest rates	4.22%	3.14%
Expected life in years	3.0	5.0
Expected volatility	90%	90%
Expected dividend yield	0%	0%
Fair value of common stock	$ 2.25	$ 3.00

The risk-free interest rate assumption is determined using the yield currently available on U.S. Treasury zero-coupon issues with a remaining term commensurate with the expected term of the award. Management has estimated expected volatility based on similar comparable industry sector averages. Expected life of the option represents the period of time options are expected to be outstanding. The estimate for dividend yield is 0% because the Company has not historically paid, and does not intend to pay, a dividend on its common stock in the foreseeable future.

The Company recognized stock-based compensation expense of $985,860 and $2,217,832 in the year ended December 31, 2025 and 2024, respectively, related to warrants which is included in the accompanying consolidated statements of operations. At December 31, 2025, there is approximately $210,000 remaining compensation expense to be recognized related to such warrants. That cost is expected to be recognized over a weighted-average period of approximately 0.5 years.

Pre-funded Warrant

On December 27, 2021, the Company entered into an exchange agreement with Sanovas Ophthalmology (the “Exchange Agreement”) pursuant to which it exchanged 28,014,540 shares of common stock (the “Exchange Securities”) held by Sanovas Ophthalmology for a pre-funded warrant (the “Pre-funded Warrant”) to purchase up to an aggregate of 28,014,540 shares of the Company’s common stock. The Pre-funded Warrant is exercisable at an exercise price of $0.0001 per share and terminates when exercised in full. As part of the Exchange Agreement, Sanovas Ophthalmology relinquished any and all rights related to the Exchange Securities.

In February 2025, the Exchange Agreement was amended such that the Pre-funded Warrant may not be exercised prior to the earlier of February 1, 2030 or the third anniversary of the Company’s uplisting to the Nasdaq Stock Market or NYSE American.

NOTE G – SHAREHOLDERS’ NOTES PAYABLE

During 2021, the Company borrowed an aggregate of $74,000 from several stockholders pursuant to note agreements bearing interest at 8% per annum and maturing December 31, 2022. The Company has informally extended the maturity date to December 31, 2026 under the same terms. At December 31, 2025 and 2024, $49,000 remained outstanding. Interest expense amounted to $3,840 for each of the years ended December 31, 2025 and 2024. The accrued interest payable at December 31, 2025 and 2024 was $19,279 and $15,439, respectively.

NOTE H - LEASE

In September 2024, the Company entered into an office suite lease. The term of the lease is for a period of 12 months. The Lease auto-renews for an additional 2 years, unless the owner is notified of a termination. The Company intends to renew the lease and therefore it was considered to be a 3-year lease for purposes of calculating the Right-of-Use. This lease is classified as an operating lease in the accompanying consolidated balance sheet. A security deposit of $1,995 was paid in connection with this lease. A discount rate of 8% was utilized upon recognition of the lease asset and liability. The initial present value of the lease payments was $7,689. The payments under the lease commence at $650 per month and escalate to $690 per month over the three years, and are summarized are as follows:

2026	$	8,114
2027		5,517
Total payments		13,631
Less interest		7,087
Total liability	$	6,544

The amounts recorded on the consolidated statement of financial position at December 31, 2025 were as follows:

Right-of-use asset, net of accumulated amortization	$	4,272
Lease liability -long term	$	3,684
Lease liability – short term	$	2,860

NOTE I – INCOME TAXES

The Company had no current income tax expense for the years ended December 31, 2025 or 2024 due to operating losses. The effective income tax rate for the years ended December 31, 2025 and 2024 is zero, as the deferred tax benefits are fully offset by the valuation allowance against such deferred income tax assets.

At December 31, 2025, the Company had net operating loss carryforwards (“NOL”) of approximately $6,200,000 for federal income tax purposes of which $5,412,000 has no expiration date and $775,000 which begins to expire in 2034. The Company also has approximately $6,200,000 for state income tax purposes which begin to expire in 2030.

The following summarizes the deferred tax assets as of December 31, 2025 and 2024:

		December 31, 2025		December 31, 2024
Net operating loss carryforwards	$	1,860,000	$	1,337,000
Accrued expenses		1,037,000		839,000
Stock compensation		2,239,000		1,927,000
Capitalized R&D costs, net		-		308,000
Intangible asset, net		508,000		508,000
Accrued interest		5,000		4,000
Subtotal		**5,649,000**		**4,923,000**
Less valuation allowance		**(5,649,000)**		**(4,923,000)**
Net deferred tax asset	**$**	**0**	**$**	**0**

The resulting gross deferred tax assets were $5,649,000 at December 31, 2025 and $4,923,000 at December 31, 2024. Such deferred tax assets have been fully reserved due to the uncertainty of future realization. The valuation allowance increased by approximately $726,000 and $1,196,000 at December 31, 2025 and 2024, respectively. In assessing the realizability of deferred tax assets, management considered whether it is more likely than not that some portion or all of the deferred taxes will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible.

Due to the change in ownership provisions of the Internal Revenue Code of 1986, as amended (the “Internal Revenue Code”), the availability of the Company’s NOL carryforwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the NOL carryforward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

NOTE J - SUBSEQUENT EVENTS

Subsequent events were reviewed through April 15, 2026, the date these consolidated financial statements were available for issuance and determined that no subsequent events have occurred that require recognition in the consolidated financial statements.

Effective January 1, 2026, the Company entered into an employment agreement (“Employment Agreement”) with M. Cory Zwerling to serve as its chief financial officer, which provided that Mr. Zwerling was entitled to receive warrants as compensation for his services. Under the Employment Agreement Mr. Zwerling was entitled to received 1) warrants to purchase 100,000 shares of common stock which were fully vested upon issuance, and 2) the potential to receive, upon the achievement of stated milestones, an additional grants of warrants to purchase an aggregate of 100,000 shares of common stock, all exercisable at $3.20 per share. Mr. Zwerling resigned in March 2026. To date, no warrants have been issued under the Employment Agreement.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. We are required to maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are designed to be effective in providing reasonable assurance that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report, is collected, recorded, processed, summarized, and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management 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, 2025, our Chief Executive Officer and our interim Chief Financial Officer concluded that, as of such a date, our disclosure controls and procedures were not effective due to the material weaknesses in our internal control over financial reporting, described below.

Management's Report on Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and interim Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act). In connection with the preparation of this Annual Report on Form 10-K, we carried out an evaluation based on the criteria in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, due to a material weakness in our internal control over financial reporting relating to a lack of segregation of duties, management concluded that our disclosure controls and procedures were ineffective as of December 31, 2025.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We are considering various remediation measures, including hiring internal accounting resources or using outside providers to provide additional resources and capabilities as well as implementing a more formal accounting and financial reporting system to mitigate such material weakness, but have not yet adopted or implemented any such measures. When we have sufficient business activity and funding available, we intend to begin to implement remediation measures to address our material weakness and improve our internal control over financial reporting and disclosure controls and procedures. We hope to complete the implementation, remediation and test of the new procedures in the second half of 2026, as resources permit us to spend time and money on building finance infrastructure.

Management is actively engaged in the planning for, and implementation of, remediation efforts to address our material weakness and improve our internal control over financial reporting and disclosure controls and procedures. We are developing new procedures that we are implementing and will be testing in the third and fourth quarters of 2026, and we hope to complete the implementation, remediation and test of the new procedures by the end of the year, subject to having raised sufficient capital.

Changes in Internal Control Over Financial Reporting

On November 30, 2023, we hired Mr. Ahluwalia to serve as our Interim Chief Financial Officer. Mr. Ahluwalia resigned August 18, 2024. On January 1, 2026, we hired Michael Cory Zwerling to serve as our Chief Financial Officer. Mr. Zwerling resigned in March 2026. Other than having Mr. Zwerling and Mr. Ahluwalia's services for this period of time there have been no changes in our internal controls over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

ITEM 9B. OTHER INFORMATION

During the fourth quarter of 2025, none of our directors or executive officers adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as each term is defined in Item 408(a) of Registration S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name, age and positions of our executive officers and directors.

NAME	AGE	POSITION
Jerry Katzman	73	Chief Executive Officer, President and Director
Herbert Gould	97	Director
Vinay Mehindru	58	Director
Dessislava (Dessy) Boneva	55	Director

The business background and certain other information about our directors and executive officers is set forth below.

Jerry Katzman. Jerry Katzman has served as the Company's Chief Executive Officer and President since December 2018 and a member of the Company's board of directors since August 2018. In addition, since December 2018, he has served as the Chief Executive Officer, President and Chairman of the board of directors of Sanovas Inc. In 2013, he founded Disruptor Technologies, a marketing and consulting company and served as founder, Chief Executive Officer and President. Dr. Katzman previously served in various capacities including ophthalmologist and founder of the Ophthalmology department at Brandon Surgical Group in Brandon, Florida; Founder, President, Chief Medical Officer and a director of Eye Care International, the national's largest non-insurance based discount vision network consisting of ophthalmologists, optometrists, opticians and optical outlets; Chief Medical Officer and director of Amacore Group, Inc., the successor of Eye Care International, Inc.; Chief Executive Officer and President of Clinical Control Systems, Inc., an electronic medical record development and marketing firm; and Executive Vice President of Strategic Development of Comprehensive Behavioral Care. Since August 2019, Dr. Katzman has served as a member of the board of directors of Paradigm Medical Industries, Inc. Dr. Katzman received his bachelor of science in biomedical engineering from Boston University and his M.D. from Universidad de Guadalajara in Jalisco, Mexico.

We believe Dr. Katzman is qualified to serve as a member of our board of directors because of his proven track record as a leader within the ophthalmology field.

Herbert Gould. Herbert Gould has served as a member of the Company's board of directors since April 2019. Since 2007, he has served as a Medical Director of Nutraceutical Delivery Corporation, a drug delivery system company. He previously served in various capacities including Medical Director of Diamond Vison Laser Center; Teaching Fellow and Assistant Clinical Professor in Ophthalmology at State University of New York; Associate Clinical Professor at New York Medical College; Instructor at American Academy of Ophthalmology; and Attending Surgeon at Westchester County Medical Center and New York Eye & Ear Infirmary. Dr. Gould also served as a Flight Surgeon for the U.S. Air Force. Since January 2019, Dr. Gould has served as a director of Sanovas, Inc., and since August 2019, he has served as a member of the board of directors of Paradigm Medical Industries, Inc. Dr. Gould received his bachelor-of-arts from Bowdoin College and his M.D. from Columbia University. Dr. Gould is a board-certified ophthalmologist.

We believe Dr. Gould is qualified to serve as a member of our board of directors because of his expertise and professional contacts in the ophthalmology field.

Vinay Mehindru. Vinay Mehindru has served as a member of the Company's board of directors since July 2022. Dr. Mehindru, is a multi-talented top-level executive with over 25 years of healthcare experience. He has been Chief Executive Officer of Exemplary Health, LLC from February 2019 to present. From January 2018 through January 2019, he was President of Advent Health Provider Network and from October 2014 through December 2017 he was the President of West Florida Health Network. His leadership spans population health and financial performance management. He has led multiple physician performance enhancement strategies and built stakeholder alliances with clinical and financial integration. He is currently serving on the board of Sanovas, Inc., SteriView™ Technologies, Inc., Intubation Science™, Inc, SinuGeniX™, Inc., OtoGeniX™ Inc., PulmoGeniX™ Technologies, Inc. and GastroGeniX™, Inc.

Dr. Mehindru graduated from medical school in India. At age 27, he served on the faculty of the Cleveland Clinic where he was a top-tier internal medicine resident and did research in gastroenterology. Dr. Mehindru has a second residency from the University of Florida in emergency medicine. For 16 years, he had been an instructor teaching difficult airway management for both cardiovascular life support and pediatric advanced life support.

At the University of Texas at Dallas, he received an Executive MBA with honors in 2009, earning the Beta Gamma Sigma Award offered only to the world's top 5% of business students.

We believe Dr. Mehindru is qualified to serve as a member of our board of directors because of his expertise healthcare field.

Dessislava (Dessy) Boneva. Dessy Boneva has served as a member of the Company's board of directors since December 4, 2023. Dr. Boneva is an experienced trauma surgeon skilled in trauma, surgical critical care, emergency surgery, and acute care surgery. She has been in practice with Kendall Regional Medical Center in Miami, Florida since 2011. With two decades of experience, she is board-certified in surgery and surgical critical care by the American Board of Surgery (ABS). In her academic role, Dr. Boneva serves as Surgery Clerkship Director/Clinical Assistant Professor of Surgery at Nova Southeastern University's Dr. Kiran C. Patel College of Allopathic Medicine. A Fellow of the American College of Surgeons (FACS), she is a member of the Society of Critical Care Medicine, the Panamerican Trauma Society, the Eastern Association for the Surgery of Trauma, and the American Association for the Surgery of Trauma. In addition, she holds certifications in Advanced Trauma Life Support (Instructor), Advanced Surgical Skills for Exposure in Trauma, Advanced Trauma Operative Management, Basic Life Support, and Pediatric Advanced Life Support.

Dr. Boneva performed her residencies in general surgery at the University of Maryland and Dartmouth College. This was followed by fellowship training at the Johns Hopkins University in Surgical Critical Care and the R Adams Cowley Shock Trauma Center in Trauma and Acute Care Surgery in 2010 and 2011, respectively.

We believe Dr. Boneva is qualified to serve as a member of our board of directors because of her expertise in the healthcare field.

Family Relationships

There are no family relationships among any of our executive officers and directors.

Arrangements between Officers and Directors

Except as set forth herein, to our knowledge, there is no arrangement or understanding between any of our officers or directors and any other person pursuant to which the officer or director was selected to serve as an officer or director.

Involvement in Certain Legal Proceedings

We are not aware of any of our directors or officers being involved in any legal proceedings in the past ten years relating to any matters in bankruptcy, insolvency, criminal proceedings (other than traffic and other minor offenses), or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics (the "Code of Ethics") that applies to all of our directors, officers and employees, including our principal executive officer and our principal financial and accounting officer. A copy of our Code of Ethics has been posted to the "Investors—Corporate Governance" section of our website *https://retinalgenix.com*. If we make any amendment to the Code of Ethics or grant any waivers, including any implicit waiver, from a provision of the Code of Ethics, we will disclose the nature of such amendment or waiver on our website *https://retinalgenix.com* to the extent required by the rules and regulations of the SEC. The information on the website is not and should not be considered part of this Annual Report and is not incorporated by reference in this Annual Report.

Insider Trading Policy

We maintain an insider trading policy, which is incorporated into our Code of Ethics, governing the purchase and sale of our securities by our employees, officers, directors, agents, and representatives at a time when such person is in possession of material non-public information about our company. We believe that our insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations. The insider trading policy also requires our company to comply with all insider trading laws, rules and regulations, and any applicable listing standards when engaging in transactions in our own securities. A copy of our insider trading policy is attached as an exhibit to this Annual Report.

Committees of Our Board of Directors

We presently do not have an audit committee, compensation committee or nominating and corporate governance committee or committee performing similar functions, as management believes that we are in an early stage of development to form an audit, compensation, or nominating committee. We currently do not have an audit committee financial expert for the same reason that we do not have board committees. Currently, our board of directors acts as our audit, nominating, corporate governance and compensation committees. We intend to appoint persons to the board of directors and committees of the board of directors as required to meet the corporate governance requirements of a national securities exchange, although we are not required to comply with these requirements until we are listed on a national securities exchange.

Medical Advisory Board

In 2019, the board of directors formed a Medical Advisory Board. The members of such board are Larry Perich, D.O., Jack M. Dodick, M.D., Marguerite B. McDonald, M.D., Lawrence A. Yannuzzi, M.D. and Ahmed Mohiuddin, M.D.

Larry Perich, D.O.

Dr. Perich, a board-certified Ophthalmologist, has been in practice for the past 39 years in the Tampa Bay Area, developing one of the first laser refractive centers in SE and 3 ambulatory surgery centers in addition to 6 offices in four counties with 94 employees. He has performed over 75,000 cataract surgeries in addition to excelling in corneal transplants, glaucoma, and cosmetic surgical procedures.

The Perich Eye Centers is also one of the largest providers of several Medicare advantage plans in the state of Florida for the past 37 years, providing eye care to over 120,000 patients annually.

Dr. Perich is the Program Director for an ophthalmology residency for HCA/USF Bayonet Point, presently training for the past 8 years.

He graduated from the University of Southern California in 1973, studying Biochemistry and cinema photography. Dr. Perich graduated from Chicago College of Osteopathic Medicine in 1978, an Internship at Sun Coast Hospital in Largo, Florida, and completed an Ophthalmology residency at Metropolitan Hospital in Grand Rapids, Michigan in 1983.

Larry Perich was born in Warren, Ohio to his parents, Pete and Anne, whose careers as a professional photography family, provided the education for Dr. Perich to excel in the photographic business. He used his skills as an accomplished photojournalist to become the editor /photographer for the yearbooks for high school, college, and medical school.

Jack M. Dodick, M.D.

Jack M. Dodick M.D. is a world-renowned eye surgeon who has devoted his professional life to teaching, innovation, and patient care. He is currently Professor and formerly, Chairman, Department of Ophthalmology, at the New York University School of Medicine, one of the largest eye residency training programs in the United States. Prior to that, he served as Chairman, Department of Ophthalmology at the Manhattan, Eye, Ear and Throat Hospital in New York for over 20 years.

As a teacher and Departmental Chairman over the past 40 years, he has supervised and participated in training hundreds of eye surgeons who now practice throughout the United States and abroad. Dr. Dodick was a pioneer in the use of intraocular lens implants following cataract surgery. He is a past president of the American Society of Cataract and Refractive Surgery, the world's largest organization of Cataract and Refractive surgeons.

He has served as President of numerous other Ophthalmological Societies throughout his career. Dr. Dodick is the author of several publications and book chapters on the subject of Cataract and Implant surgery and has presented over two hundred lectures on the subject throughout the world. He has performed eye surgery to teach his techniques in over 20 countries worldwide.

Many of his students have gone on to render eye care to countless numbers of people worldwide. He has participated in several clinical trials of devices and drugs related to his field. His innovations include several surgical instruments which bear his name and the first to publish on a laser-based technology to remove human cataracts which he invented, developed, and received marketing approval from the FDA.

Marguerite B. McDonald, M.D.

Dr. MacDonald has been a legend in ophthalmology since she performed one of the first laser corrections of the human eye in 1994. She also performed the first wavefront-based laser surgeries in the U.S. Since then she has been globally recognized as an authority in laser refractive procedures and ocular surface disease. She has given nearly 600 presentations worldwide and published chapters in over 80 textbooks. She is a member of many prestigious ophthalmological societies. In 2012 she became the first person to receive the Visionary Woman Award from the group Ophthalmic Women Leaders. Dr. McDonald has also been nominated for woman of the year in ophthalmology by her alma mater, The Vagelos College of Physicians and Surgeons of Columbia University.

Lawrence A. Yannuzzi, M.D.

Dr. Yannuzzi is the founder of VRMNY as well as vice-chairman and director of the LuEsther T. Mertz Retinal Research Center of the Manhattan Eye, Ear & Throat Hospital. He is also the founder and president of The Macula Foundation, Inc., which has distributed several million dollars to eye research across the country.

Dr. Yannuzzi has made numerous innovative and lasting contributions in imaging, drug development, and therapeutic modalities. He was the first to use oral non-steroid anti-inflammatory medication for the treatment of cystoid macular edema and developed an eye drop to treat this condition.

He has described new diseases as well as new associations and manifestations of established entities and photosensitization. He has published over 550 scientific papers and 13 books, which have earned him respect and admiration in the ophthalmic-retinal community.

He is well recognized as a devoted and excellent educator, a superb clinical diagnostician, and a prolific organizer of retinal meetings worldwide.

Dr. Yannuzzi is the recipient of numerous awards, including an honorary doctorate by the University of Ancona, the Michelson Award for Retinal Vascular Disease, a Distinguished Alumnus Award by Boston University, the Henkind, Gass, and Patz Medals by The Macula Society, the Alcon Research Award, the Herman Wacker Award of the Club Jules Gonin, the Arthur J. Bedelle Award, the Retinal Research Award and the Gass Medal of the Retina Society, the Bietti Medal, the Pisart Award from the Lighthouse International, and the Lifetime Achievement Award by the American Academy of Ophthalmology.

Ahmed Mohiuddin, M.D.

Dr. Mohiuddin was the early adopter of telemedicine and established telemedicine programs in India and Dubai. He has been an advisor to several governments around the world. He is currently the Chairman and CEO New England Heart Center, Director, New England Heart Center Foundation, Diplomate, American Board of Internal Medicine, Diplomate, American Board of Cardiovascular Diseases, Fellow, American College of Cardiology, Chief Emeritus of Cardiology, New England Baptist Hospital in Boston, Affiliated with Brigham and Women's Hospital and Beth Israel Deaconess Medical Center (both are major Harvard Medical School hospitals).

Dr. Mohiuddin is an internationally renowned cardiologist seeing patients from many countries such as Greece, Saudi Arabia, all of the Gulf countries, India, Pakistan, Malaysia, China, and several South American countries.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information concerning the compensation awarded to, earned by, or paid to our Chief Executive Officer and Interim Chief Financial Officer (collectively referred to as "named executive officers") during the years ended December 31, 2025 and 2024.

Name and Principal Position	Year	Salary ($) (6)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Jerry Katzman (2)	2024	630,000	—	638,736(3)	—	1,238,736
Chief Executive Officer, President, Interim Chief Financial Officer and Director	2025	661,500	—	—	—	661,500
Virender Ahluwalia (4)	2024	—	—	106,456(3)	2,757(5)	109,213
Former Interim Chief Financial Officer						

(1) This column indicates the aggregate grant date fair value, as determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation — Stock-Based Compensation ("FASB ASC Topic 718"), of warrant awards granted as of their respective grant date. See "Note B, paragraph 6 — Stock-based compensation" of the Notes to Consolidated Financial Statements contained in this Annual Report for an explanation of the assumptions made in valuing these awards.

(2) Dr. Katzman has served as our Interim Chief Financial Officer since August 18 2024.

(3) Represents grants of warrants to purchase shares of our common stock. For further information, see below under "Narrative Disclosure to Summary Compensation Table."

(4) Mr. Ahluwalia served as our Interim Chief Financial Officer from November 2023 through August 18, 2024.

(5) Represents fees paid to Trendz Network, LLC, a limited liability company owned by Mr. Ahluwalia ("Trendz"), under a consulting agreement (the "Consulting Agreement").

(6) Represents the allocated salary of Jerry Katzman from Sanovas to Retinalgenix.

Narrative Disclosure to Summary Compensation Table

Jerry Katzman

We do not have any employment agreement or arrangement, whether written or unwritten, with Dr. Katzman.

On January 5, 2024, we granted to Dr. Katzman warrants to purchase up to 300,000 shares of our common stock, with an exercise price of $3.00 per share and an expiration date of November 30, 2027.

Virender Ahluwalia

During the year ended December 31, 2023, we entered into the Consulting Agreement with Trendz, pursuant to which Mr. Ahluwalia served as our Interim Chief Financial Officer. In connection therewith, Mr. Ahluwalia received $2,500 in December 2023 and was granted 50,000 warrants on January 5, 2024. The Consulting Agreement provided that Trendz would be compensated at the rate of $300 per hour, would be paid a base cash compensation of $15,000 over the term of the Consulting Agreement, with $2,500 paid upon signing of the Consulting Agreement, $2,500 due 45 days thereafter and the $10,000 balance subject to the Company's raising capital of $1,000,000. The Consulting Agreement may be terminated upon 30 days' notice by either party and immediately with notice upon a material breach. Mr Ahluwalia resigned as Interim Chief Financial Officer on August 18, 2024 and the Consulting Agreement was terminated.

On January 5, 2024, we granted to Mr. Ahluwalia warrants to purchase up to 50,000 shares of our common stock, with an exercise price of $3.00 per share and an expiration date of November 30, 2027. On August 18, 2024, Mr. Ahluwalia resigned, and such warrants expired unexercised and were cancelled during 2024.

Michael Cory Zwerling

In 2025, we entered into a consulting agreement with M. Cory Zwerling pursuant to which he provided to us financial services and received in November 2025 warrants to purchase 50,000 shares of common stock at an exercise price of $3.20 per share.

In 2025, we also entered into an employment agreement with Mr. Zwerling, effective January 1, 2026, pursuant to which he serves as our Chief Financial Officer and Interim Chief Operating Officer. As compensation for his services Mr. Zwerling received three-year warrants to purchase 100,000 shares of common stock at an exercise price of $3.20 per share. This employment agreement provides that Mr. Zwerling will be entitled to receive three-year warrants to purchase 50,000 shares of common stock at an exercise price of $3.20 per share on May 3, 2026, subject to his continued employment through such date, and warrants to purchase 50,000 shares of common stock at an exercise price of $3.20 per share upon the Company executing a financing agreement or receiving aggregate financing of $500,000 or more (the "contingent warrants"). The employment agreement has a one-year term and may be terminated by either party upon 10 days' notice.

In March 2026, Mr. Zwerling resigned, and such "contingent warrants" were cancelled.

Outstanding Equity Awards at December 31, 2025

As of December 31, 2025, there were no outstanding equity awards held by any of our executive officers, except as noted below:

On January 5, 2024, we granted to Dr. Katzman warrants to purchase up to 300,000 shares of our common stock, with an exercise price of $3.00 per share and an expiration date of November 30, 2027.

Non-Employee Director Compensation

The following table sets forth information regarding all forms of compensation that were both earned by and paid to our non-employee directors during the year ended December 31, 2025.

Name	Fees Earned or Paid in Cash ($)	Option Awards[1]	All Other Compensation ($)	Total
Herbert Gould	$ —	$ -	$ —	$ -
Vinay Mehindru	$ —	$ -	$ —	$ -
Dessislava Boneva	$ —	$ -	$ —	$ -

(1) This column indicates the aggregate grant date fair value, as determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation — Stock-Based Compensation ("FASB ASC Topic 718"), of option awards granted as of their respective grant date. See "Note B, paragraph 6 — Stock-based compensation" of the Notes to Consolidated Financial Statements contained in this Annual Report for an explanation of the assumptions made in valuing these awards.

The aggregate number of option and stock awards outstanding as of December 31, 2025 for each non-employee director was as follows:

Name	Option Awards (#)	Stock Awards (#)
Herbert Gould	175,000	—
Vinay Mehindru	575,000	—
Dessislava Boneva	50,000	—

2017 Equity Incentive Plan

Summary

Our 2017 Equity Incentive Plan (the "2017 Plan") was adopted by our board of directors on December 1, 2017 and by our stockholders on December 1, 2017. Having an adequate number of shares available for future equity compensation grants is necessary to promote our long-term success and the creation of stockholders' value by:

- Enabling us to continue to attract and retain the services of key service providers who would be eligible to receive grants;
- Aligning participants' interests with stockholders' interests through incentives that are based upon the performance of our common stock;
- Motivating participants, through equity incentive awards, to achieve long-term growth in our business, in addition to short-term financial performance; and
- Providing a long-term equity incentive program that is competitive as compared to other companies with whom we compete for talent.

The 2017 Plan permits the discretionary award of options, including non-qualified stock options ("NQSOs") and incentive stock options ("ISOs"), restricted shares, deferred stock, restricted stock units ("RSUs"), or stock appreciation rights ("SARs"). The 2017 Plan will remain in effect until the earlier of (i) December 1, 2027 and (ii) the date upon which the 2017 Plan is terminated pursuant to its terms, and in any event subject to the maximum share limit of the 2017 Plan. The 2017 Plan provides for the reservation of 10,000,000 shares of common stock for issuance thereunder.

Key Features of the 2017 Plan

Certain key features of the 2017 Plan are summarized as follows:

- If not terminated earlier by our board of directors, the 2017 Plan will terminate on December 1, 2027.
- Up to a maximum aggregate of 10,000,000 shares of common stock may be issued under the 2017 Plan. The maximum aggregate fair market value with respect to ISOs are exercisable for the first time by such grantee during any calendar year may not exceed $100,000.
- The 2017 Plan will generally be administered by the Board of Directors or a committee (the "Committee"), comprised of two or more directors who may be appointed by the board from time to time.
- Employees, consultants and board members are eligible to receive awards, provided that the Committee has the discretion to determine (i) who shall receive any awards, and (ii) the terms and conditions of such awards.
- Awards may consist of ISOs, NQSOs, restricted shares, deferred stock, RSUs and SARs.
- Stock options and SARs may not be granted at a per share exercise price below the fair market value of a share of our common stock on the date of grant. If stock options or SARs are granted to a ten percent owner, they may not be granted at a per share exercise price below 110% of the fair market value of a share of our common stock on the date of grant.
- The maximum exercisable term of stock options and SARs may not exceed ten years (five years if the grantee is a ten percent owner).

Eligibility to Receive Awards. Employees, consultants and board members of the Company and its subsidiaries are eligible to receive awards under the 2017 Plan. The Committee determines, in its discretion, the selected participants who will be granted awards under the 2017 Plan.

Shares Subject to the 2017 Plan. The maximum number of shares of common stock that can be issued under the 2017 Plan is 10,000,000 shares. The shares underlying forfeited or terminated awards (without payment of consideration), or unexercised awards become available again for issuance under the 2017 Plan.

Administration of the 2017 Plan. The 2017 Plan will be administered by the Committee, which shall consist of two or more directors who may be appointed by the board from time to time. Subject to the terms of the 2017 Plan, the Committee has the sole discretion, among other things, to:

- Select the individuals who will receive awards;
- Determine the terms and conditions of awards (including the number of shares to which an award will relate, any option price, grant price or purchase price, any limitation or restriction, any performance conditions, forfeiture restrictions, any performance goals and/or vesting schedules and the terms of the grants);
- Determine whether or not specific awards shall be granted in connection with other specific awards, and if so, whether they shall be exercisable cumulatively with, or alternatively to, such other specific awards and all other matters to be determined in connection with an award;
- Offer to exchange or buy out any previously granted award for a payment of cash, shares or other award; and
- Interpret the provisions of the 2017 Plan and outstanding awards.

Types of Awards.

Stock Options. A stock option is the right to acquire shares at a fixed exercise price over a fixed period of time, not to exceed ten years from its grant date. The Committee will determine, among other terms and conditions, the number of shares covered by each stock option and the exercise price of the shares subject to each stock option, but such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant of the stock option. The exercise price of each stock option granted under the 2017 Plan must be paid in full at the time of exercise, either with cash or through another method approved by the Committee. Stock options granted under the 2017 Plan may be either ISOs or NQSOs.

SAR. A SAR is the right to receive, upon exercise, an amount equal to the difference between the fair market value of the shares on the date of the SAR's exercise and the aggregate exercise price of the shares covered by the exercised portion of the SAR. The Committee determines the terms of SARs, including the exercise price (provided that such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant), the vesting and the term of the SAR. Settlement of a SAR may be in shares of common stock, in cash, or in other property or any combination thereof, as the Committee may determine.

Restricted Shares. A restricted share award is the grant of shares of our common stock to a selected participant and such shares may be subject to a substantial risk of forfeiture until specific conditions or goals are met. The restricted shares may be issued with or without cash consideration being paid by the selected participant as determined by the Committee. The Committee also will determine any other terms and conditions of an award of restricted shares.

Deferred Stock. Deferred stock is a right to receive shares at the end of a specified deferral period.

RSUs. RSUs are the right to receive an amount equal to the fair market value of the shares covered by the RSU at some future date after the grant. The Committee will determine all of the terms and conditions of an award of RSUs. Payment for vested RSUs may be in shares of common stock or in cash, or any combination thereof, as the Committee may determine. RSUs represent an unfunded and unsecured obligation for us, and a holder of a stock unit has no rights other than those of a general creditor.

Limited Transferability of Awards. Awards granted under the 2017 Plan generally are not transferrable other than by will or by the laws of descent and distribution. In addition, in the event a holder desires at any time to sell or otherwise transfer all or part of his shares (the "Offered Shares") under the 2017 Plan, then such holder shall first give us written notice of such proposed sale or transfer including the terms of such sale or transfer, and we shall have the right at any time, within 30 days after receipt of such notice, to elect to purchase all or any portion of the Offered Shares at the price and on the terms set forth in the notice. Furthermore, in the event the holders of a majority of our voting capital then outstanding determine to sell or otherwise dispose or all or substantially all of our assets or all or 50% or more of our capital stock to any person (other than to our affiliate(s) or to the Majority Shareholders (as defined in the 2017 Plan)), or to cause us to merge with or into or consolidate with any person (other than to our affiliate(s) or to the Majority Shareholders) in a bona fide negotiated transaction, each holder of shares issued under the 2017 Plan shall be obligated to and shall upon written request of the Majority Shareholders sell, transfer and deliver to the buyer his shares under the 2017 Plan.

Change in Control. In the event that we are a party to a merger or consolidation or similar transaction ("Corporate Transaction"), unless an outstanding award under the 2017 Plan is assumed by the surviving company or replaced with an equivalent award granted by the surviving company in substitution for such outstanding award, such award shall be vested and non-forfeitable and any conditions with respect to such award shall lapse. If an award becomes exercisable or non-forfeitable, the Committee may (i) permit the grantee to exercise such award of options or SARs within a reasonable period prior to the consummation of the Corporate Transaction and cancel any outstanding awards that remain unexercised upon consummation of such transaction or (ii) cancel any or all outstanding awards of options and SARs in exchange for a payment (in cash, securities or other property) in an amount equal to the amount that the grantee would have received (net of the option price and/or grant price) if such options and SARs were fully vested and exercised immediately prior to the consummation of the Corporate Transaction; provided, however, if the option price with respect to any outstanding option or grant price with respect to any outstanding SAR exceeds the fair market value of the shares immediately prior to the consummation of the Corporate Transaction, such awards shall be cancelled without any payment to the grantee.

Amendment and Termination of the 2017 Plan. The board generally may amend or terminate the 2017 Plan at any time and for any reason, except that it must obtain stockholder approval if required pursuant to federal or state laws or the rules of any stock exchange or quotation system on which our shares are then listed or quoted.

Company Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

We do not have a formal written policy in place with regard to the timing of awards of options in relation to the disclosure by us of material nonpublic information, our board does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Option grants are effective on the date the award determination is made by the board, and the exercise price of options is the closing market price of our common stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day. During the fiscal year ended December 31, 2025, our Named Executive Officers were not awarded any stock options, and we did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

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

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of March 31, 2026 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers and (iv) all of our directors and executive officers as a group. Except as otherwise indicated, the persons named in the table below have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

As of March 31, 2026, we had 18,754,739 shares of common stock outstanding. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the subject securities. Shares of common stock that are currently exercisable or convertible within 60 days of March 31, 2026 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage beneficial ownership of such person, but are not treated as outstanding for the purpose of computing the percentage beneficial ownership of any other person.

Beneficial Owner[1]	Shares of Common Stock Beneficially Owned	Percentage
Directors and Named Executive Officers:		
Jerry Katzman	35,810,704[3][4]	77.0%[2]
M. Cory Zwerling	150,000 [5]	*
Herbert Gould	175,000 [6]	*
Vinay Mehindru	575,000 [7]	1.2%
Dessislava Boneva	50,000 [8]	*
All current directors and executive officers as a group (4 persons)	36,610,704	78.7%
5% or Greater Shareholders:		
Sanovas Ophthalmology, LLC [4]	29,613,704 [9]	63.6%[2]
Bayern Capital, LLC [10]	4,290,300	9.2%
Capital Funding Partners, LLC [11]	5,897,000	12.7%

* Represents less than 1%

(1) The address of each person is c/o RetinalGenix Technologies Inc., 409 Apollo Beach Blvd, Ste 6 Apollo Beach, FL 33572-2281 unless otherwise indicated herein.

(2) The calculation is based upon 18,754,739 shares of common stock outstanding on March 31, 2026 and the Pre-funded Warrant to purchase 28,014,540 shares of common stock held by Sanovas Ophthalmology LLC.

(3) Represents (i) 5,897,000 shares of common stock held by Capital Funding Partners, LLC; (ii) 1,599,164 shares of common stock held by Sanovas Ophthalmology LLC (iii) Pre-funded Warrant to purchase up to 28,014,540 shares of common stock held by Sanovas Ophthalmology and (iv) a warrant to purchase 300,000 shares of common stock all of which are currently exercisable warrants with an exercise price of $3.00 per shares and expire on November 30, 2027. Jerry Katzman is the sole member of Capital Funding Partners, LLC and in such capacity has the right to vote and dispose of the securities held by such entity. Jerry Katzman is the Manager of Sanovas Ophthalmology and in such capacity has the right to vote and dispose of the securities held by such entity.

(4) Jerry Katzman is the Manager of Sanovas Ophthalmology LLC and in such capacity has the right to vote and dispose of the securities held by such entity.

(5) Includes 50,000 warrants issued in November 2025 and 100,000 warrants which the Company agreed to issue in January 2026 with an exercise price of $3.20 per share. Mr. Zwerling resigned in March 2026.

(6) Includes 150,000 warrants of which 100,000 are fully vested and 75,000 which vested over 3 years (fully vested as of March 2026) with an exercise price of $3.00 per shares and expire on November 30, 2027.

(7) Vinay Mehindru holds fully-vested options to purchase 500,000 shares of common stock at $1.00 per share, and warrants to purchase 75,000 shares of common stock which vested over 3 years (fully vested as of March 2026) with an exercise price of $3.00 per shares and expire on November 30, 2027.

(8) Includes 50,000 warrants which vested over 3 years (fully vested as of March 2026) with an exercise price of $3.00 per shares and expire on November 30, 2027,

(9) Represents 1,599,164 shares of common stock held by Sanovas Ophthalmology LLC and a Pre-funded Warrant held by Sanovas Ophthalmology LLC to purchase up to 28,014,540 shares of the Company's common stock.

(10) Steven Bayern is the Manager of Bayern Capital, LLC and in such capacity has the right to vote and dispose of the securities held by such entity. The address of Bayern Capital, LLC is 403 East Boardwalk, Suite 601, Long Beach, NY 11561.

(11) Jerry Katzman is the sole member of Capital Funding Partners, LLC and in such capacity has the right to vote and dispose of the securities held by such entity. The address of Capital Funding Partners, LLC is P.O. Box 24866, Tampa, FL 33623.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table shows information regarding our equity compensation plans as of December 31, 2025.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (c)
Equity compensation plans approved by security holders (1)	2,415,000	$ 1.72	7,290,000
Equity compensation plans not approved by security holders		-	
Total	2,415,000		7,290,000

(1) **2017 Equity Incentive Plan.** On December 1, 2017, our Board adopted the 2017 Equity Incentive Plan (the "2017 Plan") was adopted by our board of directors (the "2017 Plan"). The purpose of our Plan is to advance the best interests of the company by providing those persons who have a substantial responsibility for our management and growth with additional incentive and by increasing their proprietary interest in the success of the company, thereby encouraging them to maintain their relationships with us. Further, the availability and offering of stock options and common stock under the plan supports and increases our ability to attract and retain individuals of exceptional talent upon whom, in large measure, the sustained progress, growth and profitability which we depend. The total number of shares available for the grant of either stock options or compensation stock under the plan is 10,000,000 shares, subject to adjustment.

Our Board administers our plan and has full power to grant stock options and common stock, construe and interpret the plan, establish rules and regulations and perform all other acts, including the delegation of administrative responsibilities, it believes reasonable and proper. Any decision made, or action taken, by our Board arising out of or in connection with the interpretation and administration of the plan is final and conclusive.

The Board, in its absolute discretion, may award common stock to employees of, consultants to, and directors of the company, and such other persons as the Board or compensation committee may select, and permit holders of common stock options to exercise such options prior to full vesting therein and hold the common stock issued upon exercise of the option as common stock. Stock options may also be granted by our Board or compensation committee to non-employee directors of the company or other persons who are performing or who have been engaged to perform services of special importance to the management, operation or development of the company.

In the event that our outstanding common stock is changed into or exchanged for a different number or kind of shares or other securities of the company by reason of merger, consolidation, other reorganization, recapitalization, combination of shares, stock split-up or stock dividend, prompt, proportionate, equitable, lawful and adequate adjustment shall be made of the aggregate number and kind of shares subject to stock options which may be granted under the plan.

Our Board may at any time, and from time to time, suspend or terminate the plan in whole or in part or amend it from time to time in such respects as our Board may deem appropriate and in our best interest.

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

The following includes a summary of transactions since January 1, 2024 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this Annual Report on Form 10-K. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

Transactions with Sanovas, Inc.

On June 24, 2021, we entered into a sublicense agreement ("Sublicense Agreement") with Sanovas Ophthalmology pursuant to which Sanovas Ophthalmology granted us an exclusive worldwide ("Territory") license to certain intellectual property licensed to Sanovas Ophthalmology by Sanovas Intellectual Property LLC relating to certain technologies for eye and ocular visualization and monitoring ("Licensed IP") for uses related to the screening, examination, diagnosis, prevention and/or treatment of any eye disease, medical condition or disorder, or any disease, medical condition or disorder affecting the eye. Pursuant to the Sublicense Agreement, commencing on the date of the first commercial sale of a Licensed Product (as defined in the Sublicense Agreement), in each country in the Territory and continuing on a country by country basis until the expiration or termination of the last Valid Claim (as defined in the Sublicense Agreement) of a licensed patent in such country (the "Royalty End Date"), the Company shall pay Sanovas Ophthalmology a royalty equal to a mid-single digit percentage of any Net Sales (as defined in the Sublicense Agreement) of any Licensed Product. The Sublicense Agreement shall continue until the Royalty End Date, unless earlier terminated pursuant to its terms. The Sublicense Agreement may be terminated by either party if the other party materially breaches the Sublicense Agreement in a manner that cannot be cured, or materially breaches the Sublicense Agreement in a manner that can be cured and such breach remains uncured for more than 30 days after the receipt by the breaching party of notice specifying the breach. Furthermore, the Company may terminate the Sublicense Agreement at any time upon 90 days written notice to Sanovas Ophthalmology. No royalties have been paid through December 31, 2025 under this Sublicense Agreement.

Commencing in 2019, Sanovas began paying invoices on behalf of the Company, and began allocating a portion of salaries and infrastructure costs to the Company. There were no specific terms of repayment. For the years ended December 31, 2025 and 2024, Sanovas allocated an aggregate of $661,500 and $654,300, respectively to the Company. As of December 31, 2025, the Company owed Sanovas $674,842. For the years ended December 31, 2025 and 2024, the Company paid/(received) $2,367_and $24,609, net from Sanovas, respectively. A portion of the balance of the payments due to Sanovas have been discharged pursuant to the issuance by the Company of shares of its common stock. The Company issued 296,000 shares of its common stock to offset amounts due to Sanovas for payment of expenses on behalf of the Company of $666,000 during the year ended December 31, 2024. The Company did not issue any shares of its common stock to offset amounts due to Sanovas for payment of expenses on behalf of the Company during the year ended December 31, 2025. The Company is related to Sanovas through common ownership and management.

The following summarizes the transactions between the Company and Sanovas for the years ended December 31, 2025 and 2024:

	Years ended	
	December 31, 2025	December 31, 2024
Balance due to Sanovas – beginning of year	$ 15,709	$ 2,760
Costs of Sanovas allocated to the Company	661,500	654,300
Retirement of due to Sanovas through the issuance of shares to Sanovas Ophthalmology	-	(666,000)
Net cash (paid to) received from Sanovas to the Company	(2,367)	24,649
Balance due to Sanovas - end of year	$ 674,842	$ 15,709

The Company issued 296,000 shares of its common stock to offset amounts due to Sanovas for payment of expenses on behalf of the Company of $666,000 during the year ended December 31, 2024.

Pre-funded Warrant

On December 27, 2021, the Company entered into an exchange agreement with Sanovas Ophthalmology (the "Exchange Agreement") pursuant to which it exchanged 28,014,540 shares of common stock (the "Exchange Securities") held by Sanovas Ophthalmology for a pre-funded warrant (the "Pre-funded Warrant") to purchase up to an aggregate of 28,014,540 shares of the Company's common stock. The Pre-funded Warrant is immediately exercisable at an exercise price of $0.0001 per share and terminates when exercised in full. As part of the Exchange Agreement, Sanovas Ophthalmology relinquished any and all rights related to the Exchange Securities.

In February 2025, the Pre-funded Warrant was amended such that the warrant may not be exercised prior to the earlier of February 1, 2030 or the third anniversary of the Company's uplisting to the Nasdaq Stock Market or NYSE American.

Due to affiliates

From time to time, an officer of the Company, a shareholder of the Company and affiliates of Sanovas advances funds or paid expenses on behalf of the Company. There is no formal notes or repayment plan for such advances. As of December 31, 2025 and December 31, 2024, the Company had received an aggregate of $489,224 and $467,793 pursuant to such advances.

Stockholders' loans payable

During 2021, the Company borrowed an aggregate of $74,000 from several stockholders pursuant to note agreements bearing interest at 8% per annum and maturing December 31, 2024. The Company has informally extended the maturity date to December 31, 2026. During the year ended December 31, 2023, one of the noteholders exercised outstanding warrants with an aggregate exercise price of $25,000 through the offset of the note payable due to them from the Company, such that $49,000 remain outstanding at December 31, 2025 and 2024.

Warrant Issuances

During the first quarter of 2024, we issued warrants to officers and directors exercisable at $3.00 per warrant as follows: Jerry Katzman, MD 300,000 shares, Virender Ahluwalia 50,000 shares, Herbert Gould, MD 160,000 shares, Dessy Boneva, MD 50,000 shares, Vinay Mehindru, MD 75,000 shares. Mr. Ahluwalia's warrants expired unexercised and were cancelled in 2024.

In 2025, we entered into a consulting agreement with M. Cory Zwerling pursuant to which he provided to us financial services and received in November 2025 warrants to purchase 50,000 shares of common stock at an exercise price of $3.20 per share. In 2025, we also entered into an employment agreement with Mr. Zwerling, effective January 1, 2026, which replaced the consulting agreement, pursuant to which he served as our Chief Financial Officer and Interim Chief Operating Officer. As compensation for his services, the employment agreement provided that we would grant to Mr. Zwerling three-year warrants to purchase 100,000 shares of common stock at an exercise price of $3.20 per share. This employment agreement also provided that Mr. Zwerling will be entitled to receive additional grants of three-year warrants to purchase 50,000 shares of common stock at an exercise price of $3.20 per share on May 3, 2026, subject to his continued employment through such date, and warrants to purchase 50,000 shares of common stock at an exercise price of $3.20 per share upon the Company executing a financing agreement or receiving aggregate financing of $500,000 or more. In March 2026, Mr. Zwerling resigned. To date, no warrants have been issued under the employment agreement.

Our Policy Regarding Related Party Transactions

Our board of directors recognizes the fact that transactions with related persons present a heightened risk of conflicts of interest and/or improper valuation (or the perception thereof). Our board of directors has adopted a policy, which is not written, on transactions with related persons. Under the policy, any related person transaction, and any material amendment or modification to a related person transaction, must be reviewed and approved or ratified by the board, which may approve or disapprove such transactions.

In connection with the review and approval or ratification of a related person transaction management must disclose to the board, among other information, the name of the related person and the basis on which the person is a related person, the material terms of the related person transaction, including the approximate dollar value of the amount involved in the transaction, and all the material facts as to the related person's direct or indirect interest in, or relationship to, the related person transaction.

Director Independence

Although our common stock is not listed on any national securities exchange, for purposes of independence we use the definition of independence applied by The Nasdaq Stock Market. Our board of directors has determined that each of Herbert Gould, Vinay Mehindru and Dessislava Boneva is "independent" in accordance with such definition.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees billed by Liebman Hymowitz, LLP as described below:

	2025	2024
Audit Fees	$ 71,750	$ 63,425
Audit Related Fees	0	0
Tax Fees	0	0
All Other Fees	0	0
Total	$ 71,750	$ 63,425

Audit Fees: Audit fees consist of fees billed for professional services performed by Liebman Hymowitz, LLP for the audit of our annual consolidated financial statements, the review of interim consolidated financial statements, and related services that are normally provided in connection with registration statements. There were $71,750 and $63,425 of such fees incurred by the Company in the fiscal years ended December 31, 2025 and 2024, respectively.

Audit-Related Fees: Audit related fees may consist of fees billed by an independent registered public accounting firm for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements. There were no such fees incurred by the Company in the fiscal years ended December 31, 2025 and 2024.

Tax Fees: Tax fees may consist of fees for professional services, including tax compliance performed by Liebman Hymowitz, LLP. There were no such fees incurred by the Company in the fiscal years ended December 31, 2025 and 2024, respectively.

All Other Fees: There were no such fees incurred by the Company in the fiscal years ended December 31, 2025 and 2024.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Consolidated Financial Statements:

The consolidated financial statements required by this Item are included beginning at page F-1.

(1) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the consolidated financial statements or the notes thereto.

(b) Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit
3.1	First Amended and Restated Certificate of Incorporation of RetinalGenix Technologies Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021 (File No. 333-258528))
3.2	Bylaws of RetinalGenix Technologies Inc. (Incorporated by reference to Exhibit 3.2 the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021 (File No. 333-258528))
4.1	Description of Registrant's Securities (Incorporated by reference to Exhibit 4.1 the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on April 1, 2024 (File No. 333-258528))
4.2	Form of Warrant (Incorporated by reference to Exhibit 4.1 the Company's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 31, 2025 (File No. 333-258528))
10.1	Option Exchange Agreement, by and between the Company and Diopsys, Inc., dated October 8, 2019 (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021 (File No. 333-258528))
10.2+	RetinalGenix Technologies Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021(File No. 333-258528))
10.3	Amended and Restated Master Services Agreement, by and between the Company and ADM Tronics Unlimited Inc., dated June 24, 2021 (Incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021 (File No. 333-258528))
10.4#+	Sublicense Agreement, by and between the Company and Sanovas Ophthalmology LLC, dated June 24, 2021 (Incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021 (File No. 333-258528))

10.5	Termination of Option Exchange Agreement, by and between the Company and Diopsys, Inc., dated February 17, 2022 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on February 17, 2022 (File No. 333-258528))
10.6+	Exchange Agreement, by and between the Company and Sanovas Ophthalmology, LLC, dated May 9, 2022 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2022 (File No. 333-258528))
10.7	Exchange Agreement, by and between the Company and Lawrence Perich, dated July 5, 2022 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on July 7, 2022 (File No. 333-258528))
10.8+	Consulting Agreement by and between RetinalGenix Technologies Inc. and Trendz Network, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on December 4, 2023 (File No. 333-258528))
10.9	Amendment to Pre-Funded Common Stock Purchase Warrant, dated February 19, 2025, by and between RetinalGenix Technologies, Inc. and Sanovas Ophthalmology, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on February 20, 2025 (File No. 333-258528))
10.10+*	Employment Agreement by and between RetinalGenix Technologies Inc. and Michael Cory Zwerling, effective January 1, 2026
19.1	Insider Trading Policy (Incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2025 (File No. 333-258528))
21.1	List of Subsidiaries (Incorporated by reference to Exhibit 21.1 the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on April 1, 2024 (File No. 333-258528).
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of the Principal Financial and Accounting Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101).

* Filed herewith.
\+ Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.
\# Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (iii) would be competitively harmful if publicly disclosed.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 15st day of April, 2026.

RETINALGENIX TECHNOLOGIES INC.

/s/ Jerry Katzman
Jerry Katzman
Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jerry Katzman, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Jerry Katzman Jerry Katzman	Chief Executive Officer, President and Director (Principal Executive Officer) Interim Chief Financial Officer (Principal Financial and Accounting Officer)	April 15, 2026
/s/ Herbert Gould Herbert Gould	Director	April 15, 2026
/s/ Vinay Mehindru Vinay Mehindru	Director	April 15, 2026
/s/ Dessislava Boneva Dessislava Boneva	Director	April 15, 2026

Exhibit 10.10

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement"), is entered into effective as of January 1, 2026 (the "Effective Date"), by and between RetinalGenix Technologies, Inc. ("Company"), having its principal place of business at 409 Apollo Beach Blvd, Ste 6 Apollo Beach, FL 33572-2281, and Michael Cory Zwerling, an individual living in California (hereinafter referred to as "Executive").

W I T N E S S E T H

WHEREAS, the Company desires to employ Executive, and Executive desires to be employed by the Company, pursuant to the terms and conditions hereof;

NOW THEREFORE, in consideration of the premises and of the mutual promises herein contained, the parties hereto agree as follows:

1. EMPLOYMENT. The Company hereby employs Executive and Executive hereby agrees to be employed by the Company, subject to the terms and conditions hereinafter set forth.

2. TERM. Executive's employment shall commence as of the Effective Date and unless earlier terminated as provided herein, the initial term of this Agreement will be for a period of one (1) year, commencing on the date of this Agreement (the "Initial Term"); provided that thereafter this Agreement may be extended upon the mutual agreement of the Company and Executive (the period of Executive's employment by the Company under this Agreement will be referred to as the "Term"). Notwithstanding anything herein to the contrary, however, either party may terminate this Agreement at any time at its sole discretion by providing no less than 10 days' written notice. Such early termination shall not relieve the parties of existing obligations.

3. DUTIES. The Executive shall perform such duties and functions as the Chief Financial Officer and Interim Chief Operating Officer of the Company as are determined from time to time by the Company's Chief Executive Officer. In the performance of his duties, Executive shall comply with the policies of and be subject to the reasonable direction of the Board of Directors (the "Board") of the Company. The Executive agrees to devote substantially his entire working time, attention and energies to the performance of the business of the Company and of any of its subsidiaries or affiliates by which he may be employed; and Executive shall not, directly or indirectly, alone or as a member of any partnership, or as an officer, director or employee of any other corporation, partnership or other organization, be actively engaged in or concerned with any other duties or pursuits which interfere with the performance of his duties hereunder, or which, even if non-interfering, may be inimical to or contrary to the best interests of the Company. Executive's services shall be performed remotely.

4. COMPENSATION. As compensation for the services to be rendered by Executive hereunder, the Company agrees to issue to Executive, and Executive agrees to accept, a grant of common stock purchase warrants to acquire 100,000 shares of the Company's restricted common stock exercisable at $3.20 per warrant, fully vested upon issuance and expiring three years from issuance.

5. ADDITIONAL COMPENSATION. The Executive shall be entitled to receive an additional grant of common stock purchase warrants to acquire 50,000 shares of the Company's restricted common stock exercisable at $3.20 per warrant, fully vested upon issuance and expiring three years from issuance upon a milestone of the Company executing a financing agreement(s) or receiving aggregate financing of $500,000 or more. The Executive shall also be entitled receive an additional grant of common stock purchase warrants to acquire 50,000 shares of the Company's restricted common stock exercisable at $3.20 per warrant, fully vested upon issuance and expiring three years from issuance on May 31, 2026, subject to Executive's continued employment through such date.

6. EMPLOYEE BENEFITS. During the period Executive is employed hereunder, Executive shall be permitted to participate in all group health, hospitalization and disability insurance programs, pension plans and similar benefits that are now or may become available to similarly situated executives of the Company, and will be included in the Company's director's and officer's insurance liability coverage During the period Executive is employed hereunder, Executive shall be entitled to vacations in accordance with the vacation policy of the Company.

7. REIMBURSEMENT OF EXPENSES. During the period Executive is employed hereunder, the Company shall reimburse Executive for reasonable and necessary out-of-pocket expenses advanced or expended by Executive or incurred by him for or on behalf of the Company in connection with his duties hereunder in accordance with its customary policies and practices; provided, however, that Executive shall not expend or incur any such expenses, individually or in the aggregate, in excess of Five Hundred Dollars ($500.00) without the prior approval of the Company.

8. REPRESENTATIONS AND AGREEMENTS OF EXECUTIVE. The Executive represents and warrants that he is free to enter into this Agreement and to perform the duties required hereunder, and that there are no employment contracts, restrictive covenants or other restrictions preventing the performance of his duties hereunder. The Executive represents and warrants that he is an "accredited investor," as such term is defined in Rule 501 of Regulation D promulgated by the United States Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act") and is not subject to any "bad actor" disqualification event in Rule 506(d)(1)(i)-(viii) of the Securities Act.

9. NON-COMPETITION.

(a) Executive agrees that if his employment is terminated for any reason or if he leaves the employ of the Company for any reason, for a period of one (1) year from the date of such termination of employment, he will not directly or indirectly, as owner, partner, joint venture, stockholder, employee, broker, agent, principal, trustee, corporate officer or director, licensor or in any capacity whatsoever engage in, become financially interested in, be employed by, render consulting services to, or have any connection with, any business which is competitive with the business activities of the Company or its subsidiaries ("Competitive Business"), in any geographic area where, during the time of his employment, the business of the Company or any of its subsidiaries is being or had been conducted in any manner whatsoever, or hire or attempt to hire for any Competitive Business any employee of the Company or any subsidiary thereof, or solicit, call on or induce others to solicit or call on, directly or indirectly, any customers or prospective customers of the Company for the purpose of inducing them to purchase or lease a product or service which may compete with any product or service of the Company; provided, however, that Executive may own any securities of any corporation which is engaged in such business and is publicly owned and traded but in an amount not to exceed at any one time one percent of any class of stock or securities of such company.

(b) If any portion of the restrictions set forth in paragraph (a) should, for any reason whatsoever, be declared invalid by a court of competent jurisdiction, the validity or enforceability of the remainder of such restrictions shall not thereby be adversely affected.

(c) The Executive declares that the foregoing territorial and time limitations are reasonable and properly required for the adequate protection of the business of the Company. In the event any such territorial or time limitation is deemed to be unreasonable by a court of competent jurisdiction, Executive agrees to the reduction of either said territorial or time limitation to such area or period which said court shall have deemed reasonable.

(d) The existence of any claim or cause of action by Executive against the Company or any subsidiary other than under this Agreement shall not constitute a defense to the enforcement by the Company or any subsidiary of the foregoing restrictive covenants, but such claim or cause of action shall be litigated separately.

10. NON-DISCLOSURE OF CONFIDENTIAL INFORMATION.

(a) The Executive shall not, during the term of this Agreement, and at any time following termination of this Agreement, directly or indirectly, disclose or permit to be known, to any person, firm or corporation, any confidential information acquired by him during the course of or as an incident to his employment hereunder, relating to the Company or any of its subsidiaries, the directors of the Company or its subsidiaries, any client of the Company or any of its subsidiaries, or any corporation, partnership or other entity owned or controlled, directly or indirectly, by any of the foregoing, or in which any of the foregoing has a beneficial interest, including, but not limited to, the business affairs of each of the foregoing. Such confidential information shall include, but shall not be limited to, proprietary information, trade secrets, know-how, market studies and forecasts, competitive analyses, the substance of agreements with clients and others, client lists and any other documents embodying such confidential information.

(b) All information and documents relating to the Company, its affiliates as hereinabove described (or other business affairs) shall be the exclusive property of the Company, and Executive shall use his best efforts to prevent any publication or disclosure thereof. Upon termination of Executive's employment with the Company, all documents, records, reports, writings and other similar documents containing confidential information, including copies thereof, then in Executive's possession or control shall be returned and left with the Company.

11. RIGHT TO INJUNCTION. The Executive recognizes that the services to be rendered by him hereunder are of a special, unique, unusual, extraordinary and intellectual character involving skill of the highest order and giving them peculiar value, the loss of which cannot be adequately compensated for in damages. In the event of a breach of this Agreement by Executive, the Company shall be entitled to injunctive relief or any other legal or equitable remedies. Executive agrees that the Company may recover by appropriate action the amount of the actual damage caused the Company by any failure, refusal or neglect of Executive to perform his agreements, representations and warranties herein contained. The remedies provided in this Agreement shall be deemed cumulative and the exercise of one shall not preclude the exercise of any other remedy at law or in equity for the same event or any other event.

12. AMENDMENT OR ALTERATION. No amendment or alteration of the terms of this Agreement shall be valid unless made in writing and signed by both of the parties hereto.

13. GOVERNING LAW. All matters concerning the validity, construction, interpretation and performance under this Agreement shall be governed by the laws of the State of Florida, without giving effect to any conflict of laws principles thereunder.

14. SEVERABILITY. The holding of any provision of this Agreement to be illegal, invalid or unenforceable by a court of competent jurisdiction shall not affect any other provision of this Agreement, which shall remain in full force and effect.

15. NOTICES. Any notice hereunder by either party to the other shall be given in writing by personal delivery or by registered mail, return receipt requested, addressed, if to the Company, to the attention of the Company’s Chief Executive Officer at the Company’s principal offices or to such other address as the Company may designate in writing to Executive, and if to Executive, to his most recent home address on file with the Company. Notice shall be deemed given, if by personal delivery, on the date of such delivery or, if by registered mail, on the date shown on the applicable return receipt.

16. WAIVER OR BREACH. It is agreed that a waiver by either party of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach by that same party.

17. ENTIRE AGREEMENT AND BINDING EFFECT. This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and shall be binding upon and inure to the benefit of the parties hereto and their respective legal representatives, heirs, distributees, successors and assigns.

18. ASSIGNMENT. This Agreement may not be transferred or assigned by either party without the prior written consent of the other party.

19. SURVIVAL. The termination of Executive's employment hereunder shall not affect the enforceability of Sections 9 and 10 hereof.

20. FURTHER ASSURANCES. The parties agree to execute and deliver all such further instruments and take such other and further action as may be reasonably necessary or appropriate to carry out the provisions of this Agreement.

21. HEADINGS. The Section headings appearing in this Agreement are for purposes of easy reference and shall not be considered a part of this Agreement or in any way modify, amend or affect its provisions.

22. COUNTERPARTS. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together, shall constitute one instrument.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date and year first above written.

RETINALGENIX TECHNOLOGIES, INC.	**EXECUTIVE:**
By: */s/ Jerry Katzman*	*/s/ M. Cory Zwerling*
Name: Jerry Katzman, M.D.	Michael Cory Zwerling
Title: Chairman, President & CEO	

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14 OR RULE 15D-14 OF THE SECURITIES ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jerry Katzman, certify that:

1. I have reviewed this Annual Report on Form 10-K of RetinalGenix Technologies Inc.;

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

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

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

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

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

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

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

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

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

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

Date: _April 15, 2026

/s/ Jerry Katzman
Jerry Katzman
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jerry Katzman, certify that:

1. I have reviewed this Annual Report on Form 10-K of RetinalGenix Technologies Inc.;

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

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

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

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

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

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

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

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

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

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

Date: April 15, 2026

/s/ Jerry Katzman
Jerry Katzman
Interim Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RetinalGenix Technologies Inc. (the "Company ") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jerry Katzman, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2026

/s/ Jerry Katzman

Jerry Katzman
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RetinalGenix Technologies Inc. (the "Company ") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jerry Katzman, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2026

/s/ Jerry Katzman

Jerry Katzman
Interim Chief Financial Officer
(Principal Financial Officer)