

**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, 2021

☐ **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

(State or jurisdiction
of Incorporation or organization)

82-3936890

I.R.S. Employer
Identification No.

1450 North McDowell Boulevard, Suite 150, Petaluma, CA

(Address of principal executive offices)

94954

(Zip code)

(415) 578-9583

(Registrant's telephone number, including area code)

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

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. ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of February 24, 2022, the first date on which the registrant's stock was quoted on the OTC Markets, was approximately \$8.9 million based on the closing price of the shares of \$3.00 as reported on the OTC Markets on such date. The registrant has elected to use February 24, 2022, as the calculation date because on June 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately held company. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

Number of shares of common stock outstanding as of April 14, 2022 was 14,282,314.

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 on page 10 of 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. If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development.

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

- The marketing approval process is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for the product candidates we intend to develop, our business may be substantially harmed.
- We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities. If we are not able to obtain any required regulatory approvals for our product candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited.

- Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.
- We rely on and intend to rely on third parties to conduct our clinical trials, to assist us with pre-clinical development and for manufacturing and marketing of our proposed product candidates. If we are not able to secure favorable arrangements with such third parties, or such third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products and our business and financial condition could be harmed.
- Even if our product candidates are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing U.S. Food and Drug Administration regulations or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.
- Our revenue stream will depend upon third-party reimbursement.
- Our products will face significant competition, and if they are unable to compete successfully, our business will suffer.
- If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

Risk Related to our Intellectual Property Rights

- Our business depends upon us securing and protecting critical intellectual property.
- We rely upon licenses granted to us by various licensors, and if such licensors do not adequately defend such licenses, our business may be harmed.
- Patent positions in our industry are highly uncertain and involve complex legal and factual questions.

Risk Related to our Company

- We have expanded and may continue to expand, our business through the acquisition of rights to new drug candidates that could disrupt our business, harm our financial condition and may also dilute current shareholders' ownership interests in our Company.
- If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.
- Any international operations we undertake may subject us to risks inherent with operations outside of the United States.
- Our Amended and Restated Bylaws provide that the Eighth Judicial District Court of Clark County, Nevada will be the sole and exclusive forum for certain disputes which could limit shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

General Risk Factors

- Market and economic conditions may negatively impact our business, financial condition and share price.
- Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.
- We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

PART I

ITEM 1. BUSINESS

Overview

We are an ophthalmic research and development company focused on developing technologies to screen, monitor, diagnose and treat ocular, optical, and sight-threatening disorders. Our mission is to prevent vision loss and blindness due to diabetic retinopathy and maculopathy through two devices: (1) *Retinal Imaging Screening Device*, a portable, retinal imaging system providing a 200-degree field of view without requiring pupil dilation; and (2) *RetinalCam™*, a home monitoring and imaging device offering real-time communication with physicians available 24/7.

One of the effects of diabetes is retinopathy, and subsequent diabetic maculopathy, characterized by loss of visual function through occlusion of image transmission externally, internally or by destruction of the image sensors in the macula themselves. The macula contains the majority and highest density of color and vision light sensors with providing maximum visual image resolution. Signals are passed through the retinal nerve fiber layer to the optic nerve, an extension of the brain, accumulating retinal nerve bundles forming trunks of connections to pass signals to the brain. The final images are processed at the occipital lobe. When the retina degenerates, patients experience loss of vision due to bleeding, retinal detachment, and other factors. Retinopathy in diabetes can also lead to a degenerative maculopathy, a progressive disease that can lead to vision loss and permanent blindness. Early detection for all causes of visual loss leading to macula disruption, destruction and occlusion are critical in preventing blindness in any form, and most importantly where progression is possible. We believe if detected early and properly treated, the progression of retinopathy can be slowed or even stopped, so that vision can be maintained.

Currently, the standard of care requires patients physically go into an office to have their pupil dilated, which, among other things, is costly, time consuming and may cause the patient discomfort. Instead of dilating pupils, some physicians opt to instead use a microscope-like device to detect early signs of diabetic retinopathy, but most such devices have a fixed field of view, typically between 20 to 50 degrees, and therefore, because the limited field of view, do not allow view of the periphery, where retinopathy typically begins, and may not detect signs of retinopathy. By the time the retinopathy reaches the center of the eye and can be seen by such instruments with a limited field of view, it can be too late to treat and may result in blindness. Currently, the only way for a physician to see changes in the periphery of the eye is by an exam after dilation through use of an instrument that has a 200 degree field of view. A patient, when seen without a dilated eye exam, may be misled to believe there is no evidence of retinopathy during the early stages, because, without dilation, such diagnosis can be easily missed.

We are in the process of developing two products aimed at preventing loss of vision. Specifically, we are developing (1) the RetinalGeniX™ Imaging System, a diabetic non-mydratic mass retinal imaging and screening device and (2) the RetinalCam™, a real-time in-home retinal monitoring, imaging, and physician alert system.

RetinalGeniX™ Imaging System – Diabetic Non-Mydratic Mass Retinal Imaging and Screening Device

RetinalGeniX™ is a portable diabetic non-mydratic mass retinal imaging screening device with a high resolution 200-degree field of view. It is intended to be a cost-effective, ultra-wide imaging technology used to examine the periphery of the retina, without the need for dilation. It can also be used to screen patients for neurological diseases and detect early signs of diabetic retinopathy. We believe RetinalGeniX™ may detect a variety of health issues including diabetes, retinopathy, ocular tumors, Alzheimer's and autoimmune diseases, without the discomfort associated with pupil dilation. We believe RetinalGeniX™ will enable ophthalmologists, retinal specialists and optometrists to perform a more accurate screening with an improved field of view in less than one minute at a low-cost.

RetinalCam™ – Real-Time Patient In-Home Retinal Monitoring, Imaging, and Physician Alert System

RetinalCam™ is an in-home ocular and retinal monitoring device which allows individuals at high risk of vision loss or blindness to alert their physician of any vision changes on a real-time basis from their home. The images generated by RetinalCam™ may provide critical information in detecting abnormalities upon onset, potentially preventing degradation of a patient's ocular health that might result in vision loss of blindness, if left untreated. RetinalCam™ connects directly to the internet or uses Wi-Fi to capture and transmit high resolution digital images directly to doctors from a patient's home. Patients at risk include those with obesity, diabetes, cardiovascular disorders, macular degeneration, neurological disorders, ocular tumors, physical disabilities and individuals that lack regular access to eyecare. The images captured by RetinalCam™ may allow patients to detect any changes that may have occurred since their prior screenings.

We believe RetinalCam™ may offer an opportunity to prevent blindness by early detection of progression by high-risk individuals. In addition, we believe, future treatments targeted at COVID-19 may have toxic effects on the macula, which would result in a patient requiring close monitoring of their eyes. In July 2020, a study published in the European Association for the Study of Diabetes Journal, reported 46% of COVID-19 patients with diabetic maculopathy experienced vascular changes in the retina periphery. We anticipate the high incidence of microvascular changes may demonstrate a potential sign of the severity and a risk factor for death in COVID-19 patients with diabetic maculopathy.

As of the date of this prospectus, we do not have any products approved for sale and have not generated any revenue from product sales. We anticipate that we will need an additional \$5,000,000 to complete product design and testing for RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for FDA clearance as 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. We intend to obtain such funding 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.

Recent Developments

On December 27, 2021, we entered into an exchange agreement with Sanovas Ophthalmology, LLC pursuant to which we exchanged 28,014,540 shares of our common stock held by Sanovas Ophthalmology, LLC for a pre-funded warrant to purchase up to an aggregate of 28,014,540 shares of our common stock. The pre-funded warrant is immediately exercisable at an exercise price of \$0.0001 per share and terminates when exercised in full.

On November 21, 2021, our board of directors rescinded the 3,000,000 shares of Series F preferred stock issued to Halo Management Group LLC for lack of contract consideration.

Market Opportunity

According to Reuters, 2.1 billion people, or nearly 30% of the world's population is obese or overweight, and according to the World Health Organization, obesity has reached epidemic proportions with at least 2.8 million people dying each year as a result of being overweight or obese. Obesity is a major risk factor in diseases including, but not limited to, diabetes. Globally, 39% of adults and 18% of children and adolescents are overweight or obese. In most high income countries, about two-thirds of adults are overweight or obese, and in the U.S. 70% are overweight or obese. According to The International Federation of Diabetes, there were 463 million adults worldwide with diabetes in 2019, and it is estimated that by 2045, there will be 700 million adults worldwide with diabetes. Furthermore, a 2017 study published by the National Institutes of Health indicated that diabetic retinopathy affects approximately 35% of diabetics and is a leading cause of blindness worldwide. According to the Centers for Disease Control and Prevention, 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.

Competition

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. We face competition from different sources including ophthalmic medical technology companies, academic institutions, government agencies, and public and private research institutions. For example, we face competition from Optomed plc. ("Optomed"), Optos plc ("Optos") and Zeiss with respect to our RetinalGenix™ Imaging System. Optos has developed and is currently globally marketing a wide screen imaging system that has a 200 degree field of view that screens for diabetic retinopathy, and Optomed has developed and is currently globally marketing a wide screen imaging system that has a 150 degree field of view that screens for diabetic retinopathy. Zeiss has developed and is currently globally marketing a wide screen imaging system that has a 200 degree field of view that screens for diabetic retinopathy. Although we face competition with respect to our RetinalGenix™ Imaging System, we do not believe we face competition with respect to our RetinalCam™.

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 Supply

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 design, engineer and provide regulatory services related to RetinalGenix™ and RetinalCam™.

On October 8, 2019, we entered into an option exchange agreement (the “Option Exchange Agreement”) with Diopsys, Inc. (“Diopsys”) pursuant to which we shall issue Diopsys an option to purchase up to 10% of our issued and outstanding shares of common stock and Diopsys shall issue us an option to purchase up to 10% of the issued and outstanding shares of common stock of Diopsys on the Closing Date (the “Option Exchange”). “Closing Date” means a date that is within 30 days of the date that all of the contingencies set forth in the Option Exchange Agreement are satisfied including, but not limited to, approval of a product by the FDA. In addition, pursuant to the Option Exchange Agreement, upon the closing of the Option Exchange, we shall enter into an exclusive distribution agreement with Diopsys pursuant to which Diopsys shall act as our exclusive distributor of such product. The agreement was terminated on February 14, 2022.

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 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 to patent protection, 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”) pursuant to which Sanovas Ophthalmology granted us an exclusive worldwide (“Territory”) license to certain intellectual property, including four 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 Regulation

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 any 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 United States, medical devices are classified into one of three classes (e.g., Class I, II or III). The class to which the device is assigned determines, among other things, the type of pre-marketing submission and application required for FDA clearance or approval to market. If a device is classified as Class I or II, unless otherwise exempt, it requires a 510(k) pre-market notification and clearance, or grant a de novo request, prior to marketing. 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 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.

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. 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.

Labeling and promotion 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.

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.

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. 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 the fall of 2022 and we intend to apply for 510(k) clearance for RetinalGenix™ in 2022.

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.

Employees

As of April 14, 2022, we had no full-time employees and 1 part-time employee. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employee.

Our Corporate Information

We were incorporated in Delaware on November 17, 2017. Our principal executive offices are located at 1450 North McDowell Boulevard, Suite 150, Petaluma, CA 94954 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 U.S. Securities and Exchange Commission ("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. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating to Our Business

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

We were incorporated in November 2017 and 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. 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 year ended December 31, 2021 and December 31, 2020, were \$2,179,294 and \$2,077,993, respectively, and our accumulated deficit as of December 31, 2021 and December 31, 2020 was \$5,104,316 and \$2,925,022, 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.

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, 2020 and December 31, 2021, we had cash of \$2,219 and \$4,947, respectively. In addition, as of December 31, 2020 and December 31, 2021, we had current liabilities of \$141,463 and \$469,622, respectively. 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, 2021 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.

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 RetinalGeniXTM and RetinalCamTM. 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 COVID-19, 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 as a result of COVID-19 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 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. 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.

We are dependent on information technology systems, including systems from third parties, and if we fail to properly maintain the integrity of our data or if our products do not operate as intended, our business could be materially and adversely affected.

We are dependent on information technology systems for our products and infrastructure, and we rely on these information technology systems, including technology from third-party vendors, to process, transmit and store electronic information in our day-to-day operations. We continuously monitor, upgrade and expand the systems we operate to improve information systems capabilities. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop or contract new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, and the increasing need to protect patient and customer information. In addition, third parties may attempt to hack into our products or systems and may obtain data relating to patients or proprietary information. If we fail to protect our information systems and data integrity, we could lose existing customers; have difficulty attracting new customers; have difficulty preventing, detecting, and controlling fraud; be subject to regulatory sanctions, fines or penalties; be subject to increases in operating expenses; incur expenses or lose revenue; or suffer other adverse consequences.

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. Accordingly, if Dr. Katzman terminates his employment with us, such a departure may 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 work force could adversely affect our ability to operate, grow and manage our business.

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 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.

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.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, a novel strain of coronavirus, may materially and adversely affect our business and our financial results.

Public health epidemics or widespread outbreaks of contagious diseases could adversely impact our business. Any outbreak of contagious diseases, and other adverse public health developments, such as the novel strain of coronavirus (COVID-19), initially limited to a region in China and now affecting the global community, could impact our operations depending on future developments, which are highly uncertain, largely beyond our control and cannot be predicted with certainty. These uncertain factors include the duration of the outbreak, potential impact to our employees who may contract the disease or be subject to quarantine, new information which may emerge concerning the severity of the disease and the actions to contain or treat its impact, such as the temporary closure of facilities. These factors may cause disruptions in our supply chain or disruptions or restrictions on our employees' ability to work which may disrupt our research and development efforts. These or other currently unforeseen consequences of a health epidemic, pandemic or other outbreak, including the current COVID-19 outbreak, may have a material adverse effect on our business, financial condition and results of operations.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns (including the current downturn related to the current COVID-19 pandemic), volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

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.

Our board of directors rescinded the 3,000,000 shares of Series F Preferred Stock issued to Halo Management LLC (“Halo”) and Halo may dispute such decision.

Halo was previously issued 3,000,000 shares of our Series F Preferred Stock. See “Description of Business - Legal Proceedings.” On November 21, 2021, our board of directors rescinded the 3,000,000 shares of Series F Preferred Stock issued to Halo for lack of contract consideration. Halo may dispute this decision; however, we believe Halo has no basis to dispute such decision, and we are prepared to vigorously defend our decision. Notwithstanding the foregoing, litigation can be expensive and time consuming and an adverse result in any litigation proceeding may have a material adverse effect on our business. 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.

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 Invents 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 Federal Food, Drug, and Cosmetic Act ("FDCA") by receiving clearance of a 510(k) premarket notification, receiving clearance through the *de novo* review process, or obtaining approval of a premarket approval ("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.

Legislative or regulatory reform of the health care system in the U.S. may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In March 2010, the Patient Protection and Affordable Care Act, and a related reconciliation bill were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the medical device industry and other healthcare related industries by imposing additional costs and changes to business practices. We cannot predict what healthcare reform initiatives may be adopted in the future. These reforms could have an adverse effect on our ability to obtain timely regulatory approval for new products and on anticipated revenues from our products, both of which may affect our overall financial condition.

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 products, 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.

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 are 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. In addition, our research and development process has been slowed by the impact of COVID-19, and should the COVID-19 economic restrictions worsen, it could delay and disrupt our research and development processes even further.

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 15c-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 January 19, 2022, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 81.00% 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 will be 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 of 1933, as amended (“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 \$1.07 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.” In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. 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.

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, 2021 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, 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.

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 2. PROPERTIES

None.

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. Notwithstanding the foregoing, Sanovas, Inc. (“Sanovas”), the majority stockholder of Sanovas Ophthalmology, LLC which is our majority stockholder, commenced an action in the Court of Chancery of the State of Delaware against Halo Management LLC (“Halo”) and Lawrence 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, our Company) are void or voidable and may be cancelled.

Pursuant to the terms of an employment agreement dated January 1, 2012 (the “Effective Date”) by and between Sanovas, the majority stockholder of Sanovas Ophthalmology, LLC which is our majority stockholder, and Lawrence Gerrans, the then President and Chief Executive Officer of Sanovas (the “Original Employment Agreement”), in consideration for Mr. Gerrans’ services, Mr. Gerrans was to receive, among other consideration, the following equity securities: (i) 441,177 shares of restricted common stock of each of the wholly-owned subsidiaries of Sanovas, as of the Effective Date (the “Affiliate Subsidiaries”), representing 7.5% of the total equity capital of each such subsidiary issued and outstanding as of the date of grant; and (ii) 5,000 shares of Series F Preferred Stock of Sanovas and each of the Affiliate Subsidiaries. We were incorporated in Delaware on November 17, 2017, subsequent to the Effective Date, and as such these shares were never issued by us because we were not an Affiliate Subsidiary of Sanovas. Thereafter, in May 2015, Mr. Gerrans’ Original Employment Agreement was amended and restated with an effective date of January 1, 2012 (the “Amended and Restated Employment Agreement”), the same as the Effective Date of the Original Employment Agreement. Pursuant to the Amended and Restated Employment Agreement, in consideration for Mr. Gerrans’ services, Mr. Gerrans was to receive, among other consideration, the following equity securities: (i) 7.5% of the total equity capital of each of Sanovas’ Affiliate Subsidiaries as of the Effective Date or thereafter formed (collectively, the “New Subsidiaries”); and (ii) 5,000 shares of Series F Preferred Stock of Sanovas, each of the Affiliate Subsidiaries and each of the New Subsidiaries, including our Company. Subsequently, pursuant to a board resolution dated December 1, 2017 approved by Lawrence Gerrans, our then Chief Executive Officer, President and sole director, in 2018 we issued 27,000,000 shares of our common stock to Sanovas Ophthalmology LLC, and issued 3,000,000 shares of our Series F Preferred Stock to Halo Management LLC (“Halo”), an entity owned by Mr. Gerrans, for certain enumerated consideration that was purported to have been provided. Thereafter, and in part based upon the evidence and testimony presented, and verdict and conviction rendered, in the Criminal Action (discussed below), including, but not limited to, the fact that Mr. Gerrans misled and coerced the board of Sanovas regarding the terms and need for approval of the Amended and Restated Employment Agreement, our board of directors, acting in concert with the board of directors of Sanovas, carried out an investigation with respect to actions taken by Mr. Gerrans and have determined that Halo did not provide us with valid consideration for the Series F Preferred Stock, and we dispute whether any of the shares of the Company issued to Halo were validly issued.

In January 2020, a jury in the United States District Court for the Northern District of California found Mr. Gerrans guilty, in a criminal proceeding (the “Criminal Action”), on 12 felony counts of wire fraud, money laundering, perjury, contempt of court, witness tampering, and obstruction of justice in connection with his activities as an officer and director of Sanovas. Thereafter, in November 2020, Sanovas commenced an action in the Court of Chancery of the State of Delaware (the “Delaware Action”) against Halo and 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, our Company) are void or voidable and may be cancelled. The Delaware Action is currently still pending. We intend to take any and all actions required to assist Sanovas in obtaining a judgement against Halo and Mr. Gerrans in the Delaware Action declaring any shares issued to them void or voidable.

On November 21, 2021, our Board of Directors resolved to rescind the 3,000,000 shares of Series F Preferred Stock purported issued to Halo for lack of contract consideration. We recorded this action into our accounts in the fourth quarter of 2021. We are aware that the management/ownership of Halo may dispute this decision however, we are prepared to defend our decision in this case. In addition, we reserve the right to void the shares ab initio and adjust our filings accordingly if necessary.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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."

Shareholders

As of April 14, 2022, there were 104 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 others 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.

Recent Sales of Unregistered Securities

From January 1, 2022 to April 14, 2022, the Company issued an aggregate of 60,000 shares of its common stock for a purchase price of \$1.00 per share. The foregoing offers, sales and issuances were exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

From October 1, 2021 to December 31, 2021, the Company issued an aggregate of 302,700 shares of its common stock for a purchase price of \$1.00 per share. The foregoing offers, sales and issuances were exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

On December 27, 2021, the Company exchanged 28,014,540 shares of its outstanding common stock for a pre-funded warrant to purchase up to an aggregate of 28,014,540 shares of the Company's common stock at an exercise price of \$0.0001 per share.

ITEM 6. [RESERVED]

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with and our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

We are an ophthalmic research and development company focused on developing technologies to screen, monitor, diagnose and treat ocular, optical, and sight-threatening disorders. Our mission is to prevent vision loss and blindness due to diabetic retinopathy and maculopathy through two devices: (1) *Retinal Imaging Screening Device*, a portable, retinal imaging system providing a 200-degree field of view without requiring pupil dilation; and (2) *RetinalCam™*, a home monitoring and imaging device offering real-time communication with physicians available 24/7.

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 an additional \$5,000,000 to complete product design and testing for RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for FDA clearance as we anticipate that the RetinalCam™ will not require FDA clearance. 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 to generate any revenues from product sales unless and until we successfully complete development of RetinalCam™, and we do not expect to generate any revenues from product sales unless and until we successfully obtain regulatory clearance for RetinalGenix™. 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 have been issuing shares of our common stock pursuant to a private placement raising approximately \$3.0 million from the sale of 3,010,000 shares of common stock from 2019 through December 31, 2021. In October 2021, the registration statement on Form S-1 (the "Registration Statement") that we filed with 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.

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.

Trends and Uncertainties—COVID-19

The global COVID-19 pandemic continues to evolve, and we continue to monitor the COVID-19 situation closely. The extent of the impact of COVID-19 on our business, operations, research and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its future impact on our operations, including our ability to obtain components such as sensors and other materials in a timely manner required to complete the development of RetinalGenix™ and RetinalCam™ and seek 510(k) regulatory clearance from the FDA for RetinalGenix™. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with many of our employees and consultants working remotely. We will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and clinical development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain.

Basis of presentation:

These accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) including all pronouncements of the SEC applicable to annual financial statements.

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.

Administrative Expenses

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 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 the coupon interest rate charged on loans from stockholders.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table sets forth key components of our results of operations for the years ended December 31, 2021 and 2020.

	For The Years Ended December 31,		Change	% Change
	2021	2020		
Revenue	\$ -	\$ -		
Expenses				
Administrative expenses	1,188,464	1,426,230	(237,766)	-17%
Research and development	680,293	431,557	248,736	58%
Stock-based compensation	307,918	220,206	87,712	40%
Total Expenses	2,176,675	2,077,993	98,682	5%
Interest expense	2,619	-	2,619	100%
Net Loss	\$ (2,179,294)	\$ (2,077,993)	101,301	5%

Revenues

We did not recognize revenues for the years ended December 31, 2021 and December 31, 2020.

Research and Development Expenses

	For The Years Ended December 31,	
	2021	2020
Direct costs	\$ 635,108	\$ 318,671
Allocated costs from Sanovas	45,185	112,886
Total Research and Development expenses	\$ 680,293	\$ 431,557

Research and development expenses increased by \$248,736, or 58%, to \$680,293 for the year ended December 31, 2021 from \$431,557 for the year ended December 31, 2020. The increase was primarily the result of an increase in prototype related expense, engineering and technology consultants, and pilot manufacturing.

Stock Based Compensation Expenses

Stock-based compensation expenses increased by \$87,712, or 40%, to \$307,918 for the year ended December 31, 2021 from \$220,206 for the year ended December 31, 2020. The increase was primarily due to the recognition of expense related to stock options and warrants issued in 2021.

Administrative Expenses

	For The Years Ended December 31,	
	2021	2020
Direct costs	\$ 361,580	\$ 207,732
Allocated costs from Sanovas	826,884	1,218,498
Total Administrative expenses	\$ 1,188,464	\$ 1,426,230

Administrative expenses decreased by \$237,766 or 17%, to \$1,188,464 for the year ended December 31, 2021 from \$1,426,230 for the year ended December 31, 2020. The decrease in administrative expenses was primarily due to a decrease in salaries from \$1,007,000 to \$654,000 during the years ended December 31, 2020 and 2021, respectively. This decrease was offset by increases in marketing and corporate legal, accounting and auditing expenses and professional fees of approximately \$220,000 during the year ended December 31, 2021 as compared to \$150,000 during the year ended December 31, 2020. Administrative costs consisting of costs related to executives and employees from Sanovas, were allocated based upon the amount of effort spent by such personnel on our business.

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 and by utilizing Sanovas personnel and facilities. We have settled a portion of the amounts due to Sanovas through the periodic issuance of shares of common stock.

Cash Flow Activities for the Year Ended December 31, 2021 and 2020

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

	Years Ended December 31,	
	2021	2020
Net cash used in operating activities	\$ (1,210,758)	\$ (1,422,303)
Net cash used in/provided by investing activities	-	-
Net cash provided by financing activities	1,213,486	1,370,141
Net (decrease) increase in cash	2,728	(52,162)
Cash at beginning of the year	2,219	54,381
Cash at end of the year	\$ 4,947	\$ 2,219

Operating Activities

Net cash used in operating activities was \$1,210,758 for the year ended December 31, 2021 and \$1,422,303 for the year ended December 31, 2020. The cash flow used in operating activities in 2021 was driven by the net loss of \$2,179,294 offset in part by non-cash stock-based compensation expense of \$307,918 and an increase in accounts payable of \$109,851. In addition, Sanovas bills for allocated costs and expenses paid on behalf and allocated to the Company in the amount of \$872,070 during the year ended December 31, 2021, of which we paid \$323,922 back to Sanovas, for a net of \$548,148. The cash flow used in operating activities in 2020 was driven by the net loss of \$2,077,993 offset in part by non-cash stock-based compensation expense of \$220,206 and costs and expenses paid and allocated to the Company by Sanovas of \$343,057 and an increase in accounts payable and other current liabilities/assets of \$77,358 for the years ended December 31, 2020. In each of 2019-2021, the Company has settled a portion of the amounts due to Sanovas through the issuance of common stock.

Investing Activities

There was no cash used in or provided by investing activities for the years ended December 31, 2021 and 2020.

Financing Activities

Net cash provided by financing activities was \$1,213,486 and \$1,370,141 during the years ended December 31, 2021 and 2020, respectively, attributable primarily to the sale of common stock in both periods, which yielded net proceeds of \$1,126,986 and \$1,395,141, respectively. During 2021, the Company also received \$73,000 from stockholders notes payable and \$13,500 from the exercise of warrants.

We anticipate that we will need \$5,000,000 in operating capital to complete product design and testing for RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for FDA approval as we anticipate that the RetinalCam™ will not require FDA approval. 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.

Critical Accounting Policies and 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 its 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 cost is recorded in the consolidated statements of operations based on the employees' respective function. The fair value of common stock was determined based upon the sale of common stock to third parties pursuant to the offering which commenced in 2019, which offering continued through December 2021.

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.

Allocated costs from Sanovas

A substantial portion of our expenses are costs and expenses paid by Sanovas and costs and expenses allocated to the Company 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 of 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.

Recently Issued and Adopted Accounting Standards

The following pronouncement may have an impact on the accounting policies of the Company:

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” (“ASU 2016-02”). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The FASB issued ASU No. 2018-10 “Codification Improvements to Topic 842, Leases” (“ASU 2018-10”), ASU No. 2018-11 “Leases (Topic 842) Targeted Improvements” (“ASU 2018-11”) in July 2018, and ASU No. 2018-20 “Leases (Topic 842) - Narrow Scope Improvements for Lessors” (“ASU 2018-20”) in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Pursuant to ASU 2019-10 the effective date for ASC 842 was deferred an additional year. The Company expects to recognize operating lease right-of-use assets and lease liabilities on the balance sheet upon adoption of this ASU for its 2022 financial period. The Company is currently evaluating these ASUs and their impact on its consolidated financial statements.

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 financial statements of the Company.

JOBS Act

We are an “emerging growth company,” as defined in Section 2(a) the Securities Act, as modified by the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.” For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other 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 \$1.07 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.

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

RetinalGenix Technologies Inc.
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 balance sheets of RetinalGenix Technologies Inc. (the “Company”) as of December 31, 2021 and 2020, and the related statements of operations, stockholders’ equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, 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 during 2023, it will not have sufficient capital. 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 audit committee 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 Goldberg & Hymowitz, LLP*

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

Garden City, New York
April 15, 2022
PCAOB ID No. 473

RETINALGENIX TECHNOLOGIES INC.
BALANCE SHEETS
DECEMBER 31,

	2021	2020
ASSETS		
Current Assets		
Cash	\$ 4,947	\$ 2,219
Due from Sanovas	-	15,069
Deferred offering costs	-	43,787
Total Current Assets	4,947	61,075
TOTAL ASSETS	\$ 4,947	\$ 61,075
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current Liabilities	\$	\$
Accounts payable and accrued liabilities	251,282	141,431
Due to Sanovas	142,721	-
Notes payable to stockholders	73,000	-
Accrued interest payable	2,619	-
Total Liabilities	469,622	141,431
Stockholders' Deficit:		
Preferred stock, \$0.0001 par value; 40,000,000 shares authorized; Series F preferred stock - 3,000,000 shares designated, 0 and 3,000,000 shares, issued and outstanding at December 31, 2021 and 2020, respectively	-	300
Common stock, \$0.0001 par value; 80,000,000 shares authorized; 14,221,814 shares issued and outstanding at December 31, 2021 and 40,678,323 shares issued and outstanding at December 31, 2020	1,423	4,067
Additional paid in capital	4,638,218	2,840,599
Preferred stock subscription receivable	-	(300)
Accumulated deficit	(5,104,316)	(2,925,022)
Total Stockholders' Deficit	(464,675)	(80,356)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 4,947	\$ 61,075

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

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31,

	<u>2021</u>	<u>2020</u>
Revenues	\$ -	\$ -
Operating expenses		
General and administrative expenses	1,188,464	1,426,230
Research and development	680,293	431,557
Stock-based compensation	<u>307,918</u>	<u>220,206</u>
Total operating expenses	2,176,675	2,077,993
Interest expense	<u>2,619</u>	<u>-</u>
Net Loss	\$ (2,179,294)	\$ (2,077,993)
Net Loss per share - basic and diluted	\$ (0.05)	\$ (0.05)
Weighted average number of common shares outstanding during the period- basic and diluted	<u>41,246,915</u>	<u>39,696,697</u>

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

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020

	<u>Common Stock</u>		<u>Preferred Stock Series F</u>		<u>Subscription Receivable</u>	<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Par Value</u>	<u>Shares</u>	<u>Par Value</u>	<u>Preferred Stock</u>			
Balance as at December 31, 2019	38,915,056	3,892	3,000,000	300	(300)	867,301	(847,029)	24,164
Stock purchased by investors	1,405,141	140	-	-	-	1,395,001	-	1,395,141
Stock-based compensation	-	-	-	-	-	220,206	-	220,206
Retirement of due to Sanovas through the issuance of shares of common stock to Sanovas Ophthalmology LLC	358,126	35	-	-	-	358,091	-	358,126
Net loss	-	-	-	-	-	-	(2,077,993)	(2,077,993)
Balance as at December 31, 2020	40,678,323	\$ 4,067	3,000,000	300	(300)	\$ 2,840,599	\$ (2,925,022)	\$ (80,356)
Stock purchased by investors, net of \$70,974 costs incurred.	1,154,173	117	-	-	-	1,083,082	-	1,083,199
Stock-based compensation	-	-	-	-	-	307,918	-	307,918
Retirement of due to Sanovas through the issuance of shares of common stock to Sanovas Ophthalmology LLC	390,358	39	-	-	-	390,319	-	390,358
Exercise of warrants	13,500	1	-	-	-	13,499	-	13,500
Exchange of shares owned by Sanovas Ophthalmology LLC for pre- funded warrants	(28,014,540)	(2,801)	-	-	-	2,801	-	-
Recission of preferred stock	-	-	(3,000,000)	(300)	300	-	-	-
Net loss	-	-	-	-	-	-	(2,179,294)	(2,179,294)
Balance as at December 31, 2021	14,221,814	\$ 1,423	-	-	-	\$ 4,638,218	\$ (5,104,316)	\$ (464,675)

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

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31,

	2021	2020
Cash Flows From Operating Activities		
Net Loss	\$ (2,179,294)	\$ (2,077,993)
Adjustments to reconcile net (loss) to net cash used in operating activities		
Stock-based compensation expense	307,918	220,206
Expenses paid by Sanovas on behalf of Company, net	548,148	343,057
Increase in accounts payable and accrued liabilities	109,851	136,214
(Increase) decrease in deferred offering costs	43,787	(43,787)
Increase in accrued interest payable	2,619	-
Total adjustments	1,012,323	655,690
Net cash used in operating activities	(1,166,971)	(1,422,303)
Cash Flows From Financing Activities		
Proceeds from the sale of common stock, net of costs	1,083,199	1,395,141
Proceeds from exercise of warrants	13,500	-
Proceeds from notes payable to stockholders	73,000	-
Decrease in stockholders' refund payable	-	(25,000)
Net cash provided by financing activities	1,169,699	1,370,141
Net increase (decrease) in cash	2,728	(52,162)
Cash at beginning of period	2,219	54,381
Cash at end of period	\$ 4,947	\$ 2,219
Supplemental information:		
Retirement of due to Sanovas through the issuance of common stock to Sanovas Ophthalmology LLC (Note C)	\$ 390,358	\$ 358,126
Exchange of common stock by Sanovas Ophthalmology LLC for pre-funded warrants	\$ 2,801	-

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

**RETINALGENIX TECHNOLOGIES INC.
NOTES TO FINANCIAL STATEMENTS**

December 31, 2021 and 2020

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. At December 31, 2021, Sanovas Ophthalmology owned a majority of the outstanding stock of the Company. During the years ended December 31, 2021 and 2020, substantially all 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 allocated to the Company for services performed on behalf of the Company.

The Company was formed to develop technologies to diagnose and treat optical disorders. The Company sublicensed certain technology initially developed by Sanovas from Sanovas Ophthalmology – See Note C. Since 2018, the Company has been developing its screening device and home monitoring and physician alert system.

In October 2021, the Company filed a registration statement on Form S-1 (the “Registration Statement”) with the Securities and Exchange Commission pursuant to which it registered for resale shares of common stock, including shares of common stock issuable upon exercise of outstanding options and warrants. The Company did not raise any cash from the resale of the securities offered by the Registration Statement, and accordingly, the previously deferred offering costs were applied against the proceeds of the shares of common stock sold in 2021 pursuant to the Company’s previous private offering of securities.

On October 8, 2019, the Company entered into an option exchange agreement (the “Option Exchange Agreement”) with Diopsys, Inc. (“Diopsys”) pursuant to which the Company shall issue Diopsys an option to purchase up to 10% of its issued and outstanding shares of common stock and Diopsys shall grant the Company an option to purchase up to 10% of the issued and outstanding shares of common stock of Diopsys on the Closing Date (the “Option Exchange”). “Closing Date” means a date that is within 30 days of the date that all of the contingencies set forth in the Option Exchange Agreement are satisfied including, but not limited to, approval of a product by the U.S. Food and Drug Administration. In addition, pursuant to the Option Exchange Agreement, upon the closing of the Option Exchange, the Company shall enter into an exclusive distribution agreement with Diopsys pursuant to which Diopsys shall act as the Company’s exclusive distributor of such product. On February 14, 2022, the Company entered into a Termination of Option Exchange Agreement (the “Termination Agreement”) with Diopsys pursuant to which the prior Option Exchange Agreement between the Company and Diopsys dated October 8, 2019 (the “Option Exchange Agreement”) was terminated effective immediately and of no further force and effect, and neither party has any past, current or future obligations or liabilities to the other (or any other person or entity) with respect to any rights, obligations or any of the transactions contemplated in the Agreement. At the time of such termination, none of the conditions in the Option Exchange Agreement were satisfied and no options thereunder had been issued to either the Company or Diopsys. In addition, the Exclusive Distribution Agreement to be entered into between the Company and Diopsys and referred to in the Option Exchange Agreement has not been negotiated and does not currently exist. However, the Company and Diopsys are continuing their discussions regarding the aforementioned Exclusive Distribution Agreement and working in good faith towards negotiation and execution of a definitive agreement with respect thereto.

On December 27, 2021, RetinalGenix Technologies Inc. entered into an exchange agreement (the “Exchange Agreement”) with Sanovas Ophthalmology pursuant to which the Company exchanged 28,014,540 shares of common stock 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.

Liquidity and Going Concern

The Company has had net losses since inception and has an accumulated deficit of approximately \$5.1 million at December 31, 2021. The Company has minimal cash at December 31, 2021 and remains dependent on Sanovas for much of its operations. 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. Sanovas has paid most of the Company's operating expenses through December 2021.

The Company commenced private offerings of shares of its common stock raising net proceeds of approximately \$1,395,000 in the year ended December 31, 2020, and \$1,127,000 in the year ended December 31, 2021 - See Note D. The Company also issued shares of its common stock to offset amounts due to Sanovas for payment of expenses on behalf of the Company of \$390,358 in June 2021 and \$358,126 in July 2020.

In February 2020, the Company entered into an agreement with an investment banker to support fundraising or strategic transactions. This agreement was terminated in March 2021. In February 2021, the Company entered into a new agreement with an investment banker to raise funds for the Company which lead to the private offering of shares mentioned above. 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.

As of the date of this report, the Company does not have adequate resources to fund its operations through April 2023 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. These factors raise substantial doubt about the Company's ability to continue as a going concern. The 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 financial statements is as follows:

1. Basis of Presentation

The Company's financial statements were prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

2. Cash Equivalents

For purpose of the 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. Deferred Offering Costs

Deferred offering costs are expenses directly related to an expected financing. These costs consisted of legal fees that the Company capitalized. During the year ended December 31, 2021, all such costs were charged against additional paid in capital for the funds raised during 2021.

4. Use of Estimates

In preparing the Company's 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 financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

5. 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.

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, 2021 or December 31, 2020. The Company’s policy is to expense any penalties and interest associated with this topic. At December 31, 2021 and December 31, 2020, there were no amounts accrued for penalties and interest.

6. 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 loss during the years ended December 31, 2021 and 2020, 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, 2021, include stock options to purchase 1,882,500 shares of common stock, Pre-funded Warrant to purchase 28,014,540 shares of common stock, and warrants to purchase 199,000 shares of common stock. Potentially dilutive securities not included in the computation of loss per share for the year ended December 31, 2020 included 3,000,000 shares of Series F preferred stock, stock options to purchase 1,800,000 shares of common stock, and warrants to purchase 62,500 shares of common stock. The shares of common stock potentially issuable to Diopsys upon the resolution of specified contingencies and exercise of stock options are also excluded from the loss per share calculation for the year ended December 31, 2020.

7. 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.

8. Research and Development Costs:

Research and development costs are expensed as incurred.

9. Recent Accounting Pronouncements:

The following pronouncement may have an impact on the accounting policies of the Company:

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," ("ASU 2016-02"). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" ("ASU 2018-10"), ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" ("ASU 2018-11") in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" ("ASU 2018-20") in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Pursuant to ASU 2019-10 the effective date for ASC 842 was deferred an additional year. The Company expects to recognize operating lease right-of-use assets and lease liabilities on the balance sheet upon adoption of this ASU for its 2022 financial period. The Company is currently evaluating these ASUs and their impact on its financial statements.

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 financial statements of the Company.

NOTE C - RELATED PARTY TRANSACTIONS

The Company is related to Sanovas through common ownership and management. Commencing in 2019, Sanovas began paying expenses on behalf of the Company, and began allocating a portion of salaries and infrastructure costs to the Company and other entities where Sanovas was performing shared services. Included in such allocated costs is approximately \$621,000 and \$360,000 in costs related to an officer and consultant to the Company in the years ended December 31, 2021 and 2020, respectively. The Company and Sanovas did not have specific terms of repayment. In June 2021 and July 2020, the Company issued 390,358 and 358,126 shares of common stock, respectively, to Sanovas Ophthalmology to retire the then estimated debt due from the Company.

The following summarizes the transactions between the Company and Sanovas for the years ended December 31, 2021 and 2020:

	For The Years Ended December 31,	
	2021	2020
Balance due from Sanovas – beginning of year	\$ (15,069)	\$ -
Costs and expenses paid by Sanovas on behalf of the Company	68,073	127,967
Costs allocated to the Company by Sanovas	803,997	1,301,246
Repayment of amounts charged by Sanovas, net	(323,922)	(1,086,156)
Subtotal	548,148	343,057
Retirement of due to Sanovas through the issuance of 390,358 and 358,126 shares of common stock in 2021 and 2020, respectively, to Sanovas Ophthalmology	(390,358)	(358,126)
Balance due to (from) Sanovas - end of year	\$ 142,721	\$ (15,069)

Sublicense

On June 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 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.

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.

Pursuant to the terms of an employment agreement dated January 1, 2012 (the “Effective Date”) by and between Sanovas and Lawrence Gerrans, the then President and Chief Executive Officer of Sanovas (the “Original Employment Agreement”), in consideration for Mr. Gerrans’ services, Mr. Gerrans was to receive, among other consideration, the following equity securities: (i) 441,177 shares of restricted common stock of each of the wholly-owned subsidiaries of Sanovas, as of the Effective Date (the “Affiliate Subsidiaries”), representing 7.5% of the total equity capital of each such subsidiary issued and outstanding as of the date of grant; and (ii) 5,000 shares of Series F preferred stock of Sanovas and each of the Affiliate Subsidiaries. The Company was incorporated in Delaware on November 17, 2017, subsequent to the Effective Date, and as such these shares were never issued by the Company because the Company was not an Affiliate Subsidiary of Sanovas. Thereafter, in May 2015, Mr. Gerrans’ Original Employment Agreement was amended and restated with an effective date of January 1, 2012 (the “Amended and Restated Employment Agreement”), the same as the Effective Date of the Original Employment Agreement. Pursuant to the Amended and Restated Employment Agreement, in consideration for Mr. Gerrans’ services, Mr. Gerrans was to receive, among other consideration, the following equity securities: (i) 7.5% of the total equity capital of each of Sanovas’ Affiliate Subsidiaries as of the Effective Date or thereafter formed (collectively, the “New Subsidiaries”); and (ii) 5,000 shares of Series F preferred stock of Sanovas, each of the Affiliate Subsidiaries and each of the New Subsidiaries, including the Company. Subsequently, pursuant to a board resolution dated December 1, 2017 approved by Lawrence Gerrans, the Company’s then Chief Executive Officer, President and sole director, in 2018 the Company issued 27,000,000 shares of its common stock to Sanovas Ophthalmology LLC, and issued 3,000,000 shares of its Series F preferred stock to Halo Management LLC (“Halo”), an entity owned by Mr. Gerrans, for certain enumerated consideration that was purported to have been provided. Thereafter, and in part based upon the evidence and testimony presented, and verdict and conviction rendered, in the Criminal Action (discussed below), including, but not limited to, the fact that Mr. Gerrans misled and coerced the board of Sanovas regarding the terms and need for approval of the Amended and Restated Employment Agreement, the Company’s board of directors, acting in concert with the board of directors of Sanovas, carried out an investigation with respect to actions taken by Mr. Gerrans and have determined that Halo did not provide us with valid consideration for the Series F preferred stock, and the Company disputes whether any of the shares of the Company issued to Halo were validly issued.

In January 2020, a jury in the United States District Court for the Northern District of California found Mr. Gerrans guilty, in a criminal proceeding (the “Criminal Action”), on 12 felony counts of wire fraud, money laundering, perjury, contempt of court, witness tampering, and obstruction of justice in connection with his activities as an officer and director of Sanovas. Thereafter, in November 2020, Sanovas commenced an action in the Court of Chancery of the State of Delaware (the “Delaware Action”) against Halo and 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. The Delaware Action is currently still pending.

On November 21, 2021, the Company’s Board of Directors resolved to rescind the 3,000,000 shares of Series F preferred stock purported to be issued to Halo Management Group LLC for lack of contract consideration. The Company is aware that the management/ownership of Halo Management Group LLC may dispute this decision however, the Company is prepared to defend its decision in this case. In addition, the Company reserves the right to void the shares and adjust its filings accordingly if necessary.

Common Stock

During 2019, the Company commenced a private offering of its shares of common stock at a purchase price of \$1.00 per share. For the years ended December 31, 2021 and 2020, the Company sold an aggregate of 1,154,173 and 1,405,141 shares of its common stock, respectively.

The common stockholders, voting as a separate class, are entitled to elect one member of the Board of Directors.

Preferred Stock

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.

For so long as at least 25,000 shares of Series F preferred stock remain outstanding, the vote or written consent of the holders of the majority of the outstanding shares of Series F preferred stock is 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.

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, 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.

In November 2019, the Company issued stock options to purchase up to 1,800,000 shares of common stock at an exercise price of \$1.00 per share to members of the Company’s medical advisory board and consultants pursuant to the Plan. The options vest over a five year period and were unexercised at December 31, 2020 and December 31, 2021. The estimated aggregate fair value of the stock options was determined to be \$1,101,028 using a Black Scholes model.

In the year ended December 31, 2021, the Company issued stock options to purchase up to 82,500 shares of common stock at an exercise price of \$1.00 per share to members of the Company’s medical advisory board and consultants pursuant to the Plan. The options vest immediately and were unexercised at December 31, 2021. The estimated aggregate fair value of the stock options was determined to be approximately \$63,900 using a Black Scholes model.

The Company recognized \$307,918 and \$220,206 of stock-based compensation expense during the years ended December 31, 2021 and 2020, respectively, related to all stock options and warrants (see Note F) which is included in the accompanying statements of operations. As of December 31, 2021, there was approximately \$633,000 of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of approximately 2.9 years.

At December 31, 2021, there were 5,617,500 shares available to be issued under the Plan. The following table summarizes stock option activity of the Plan during 2021 and 2020:

	<u>Options Issued</u>	<u>Weighted-Average Exercise Price</u>
Options outstanding – December 31, 2019	1,800,000	\$ 1.00
Granted	-	-
Canceled	-	-
Exercised	-	-
Options outstanding – December 31, 2020	1,800,000	1.00
Granted	82,500	1.00
Canceled	-	-
Exercised	-	-
Options outstanding – December 31, 2021	<u>1,882,500</u>	<u>\$ 1.00</u>

Additional information regarding the exercisable options and average remaining contractual life of the options outstanding as of December 31, 2021 is as follows:

<u>Exercise Price</u>	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Number Exercisable at December 31, 2020</u>	<u>Number Exercisable at December 31, 2021</u>
\$ 1.00	1,882,500	3.5 Years	405,000	525,000

The fair value of each option grant was estimated on the date of grant to be \$0.53 per share using the Black-Scholes option-pricing model with the following assumption weighted-averages in 2021:

Risk-free interest rates	1.2% - 2.42%
Expected life in years	5.0
Expected volatility	73.1%
Expected dividend yield	0%
Fair value common stock	\$ 1.00

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.

NOTE F - WARRANTS

In 2021, the Company finalized the issuance of warrants to purchase 150,000 shares of common stock at \$1.10 per share which are fully vested as of December 31, 2021, and exercisable over 7 years, to a consulting firm. The fair value of such warrants was estimated on the date of grant to be \$0.61 per share using the Black-Scholes option-pricing model with the following assumption weighted-averages in 2021:

Risk-free interest rates	2.42%
Expected life in years	3.5
Expected volatility	73.1%
Expected dividend yield	0%
Fair value common stock	\$ 1.00

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 approximately \$75,500 and \$0 in the years ended December 31, 2021 and 2020, respectively. At December 31, 2021, there is no remaining compensation expense to be recognized.

The following table summarizes warrant activity during 2021 and 2020:

	Warrants Issued	Weighted-Average Exercise Price
Warrants outstanding – December 31, 2019	62,500	\$ 1.00
Granted	-	-
Canceled	-	-
Exercised	-	-
Warrants outstanding – December 31, 2020	62,500	\$ 1.00
Granted	150,000	\$ 1.10
Canceled	-	-
Exercised	(13,500)	\$ 1.00
Warrants outstanding – December 31, 2021	199,000	\$ 1.07

Additional information regarding the warrants outstanding as of December 31, 2021 is as follows:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable
\$ 1.00	49,000	1.7 Years	49,000
\$ 1.10	150,000	6.2 Years	150,000

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.

NOTE G – NOTES PAYABLE

During 2021, the Company borrowed an aggregate of \$73,000 from several stockholders pursuant to note agreements bearing interest at 8% per annum and maturing December 31, 2022. The Company accrued interest of \$2,619 for the year ended December 31, 2021.

NOTE H – INCOME TAXES

The Company had no current income tax expense for the years ended December 31, 2021 and 2020 due to operating losses. The effective income tax rate for the years ended December 31, 2021 and 2020 is zero, as the deferred tax benefits are fully offset by the valuation allowance against such deferred income tax assets.

At December 31, 2021, the Company had net operating loss carryforwards (“NOL”) of approximately \$3,305,000 for federal income tax purposes of which \$2,530,000 has no expiration date, \$775,000 which begins to expire in 2034, and approximately \$3,487,000 for state income tax purposes which begins to expire in 2030.

The resulting net deferred tax assets of approximately \$1,178,000 (\$992,000 applicable to net operating loss carryforwards and \$186,000 applicable to accruals) and \$789,000 (\$618,000 applicable to net operating loss carryforwards and \$171,000 applicable to accruals) at December 31, 2021 and December 31, 2020, respectively, has been fully reserved due to the uncertainty of future realization. The valuation allowance increased by approximately \$389,000 and \$556,000 at December 31, 2021 and 2020, 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.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. The open years for tax examination are 2017 and thereafter.

NOTE I - SUBSEQUENT EVENTS

Subsequent events were reviewed through April 14, 2022, the date these financial statements were available for issuance.

During January 2022, the Company received \$60,000 in proceeds from the sale of 60,000 shares of common stock pursuant to the private placement described in Note D.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls

We are required to maintain disclosure controls and procedures (as defined in Rules 13a-15e 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.

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, 2021.

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 first half of 2022, 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 testing in the fourth quarters of 2021, and we hope to complete the implementation, remediation and test of the new procedures by the end of the year.

Changes in Internal Control Over Financial Reporting

As of the December 31, 2021, 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

None.

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	68	Chief Executive Officer, President and Director
Herbert Gould	93	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 Vision 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.

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.

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 Jack M. Dodick, M.D., Marguerite B. McDonald, M.D., Lawrence A. Yannuzzi, M.D. and Ahmed Mohiuddin, M.D.

ITEM 11. EXECUTIVE COMPENSATION

During the year ended December 31, 2021, our executive officers did not receive any compensation

Outstanding Equity Awards at December 31, 2021

As of December 31, 2021, there were no outstanding equity awards held by any of our executive officers.

Non-Employee Director Compensation

During the year ended December 31, 2021, our non-employee directors did not receive any compensation.

Employment Agreements

During the year ended December 31, 2021, we were not a party to any employment agreement.

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 (“NSOs”) 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 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 of 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.

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 April 14, 2022 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 named 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.

Beneficial Owner ⁽¹⁾	Shares of Common Stock Beneficially Owned	Percentage ⁽²⁾
Directors and Named Executive Officers:		
Jerry Katzman	34,001,540(3)	80.18%
Herbert Gould	350,000	2.45%
All Officers and Directors as a Group	34,261,540	81.00%
5% or Greater Shareholders:		
Sanovas Ophthalmology, LLC (4)	28,014,540(5)	66.23%
Bayern Capital, LLC (6)	5,067,000	35.48%
Capital Funding Partners, LLC (7)	5,897,000	41.29%

- (1) The address of each person is c/o RetinalGenix Technologies Inc., 1450 North McDowell Boulevard, Suite 150, Petaluma, CA 94954 unless otherwise indicated herein.
- (2) The calculation in this column is based upon 14,282,314 shares of common stock outstanding on April 14, 2022. 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 April 14, 2022 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.
- (3) Represents (i) 5,987,000 shares of common stock held by Capital Funding Partners, LLC and (ii) pre-funded warrants to purchase up to 28,014,540 shares of common stock held by Sanovas Ophthalmology. 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 and in such capacity has the right to vote and dispose of the securities held by such entity.
- (5) Represents pre-funded warrants to purchase up to 28,014,540 shares of the Company's common stock.
- (6) 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.
- (7) 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, 2021.

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)) (c)
Equity compensation plans approved by security holders (1)	1,825,500(2)	\$ 1.00	8,174,500
Equity compensation plans not approved by security holders	-	-	-
Total		\$	

- (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.
- (2) In the year ended December 31, 2021, the Company issued stock options to purchase up to 82,500 shares of common stock at an exercise price of \$1.00 per share to members of the Company's medical advisory board and consultants pursuant to the Plan. The options vest immediately and were unexercised at December 31, 2021. The estimated aggregate fair value of the stock options was determined to be approximately \$63,900 using a Black Scholes model.

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 during our fiscal years ended December 31, 2021 and December 31, 2020 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.

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, 2021 and 2020, Sanovas allocated an aggregate of \$872,070 and \$1,429,207, respectively to the Company. As of December 31, 2021, the Company owed Sanovas \$142,721. For the years ended December 31, 2020 and December 31, 2019, the Company paid Sanovas \$323,922 and \$1,086,156, respectively, to discharge a portion of the payments due to Sanovas. A portion of the balance of the payments due to Sanovas were discharged pursuant to the issuance by the Company of shares of its common stock. Specifically, at December 31, 2019, Sanovas retired the debt due from the Company through the issuance of 266,056 shares of the Company's common stock to Sanovas Ophthalmology LLC. In June 2021 and July 2020, the Company issued 390,358 and 358,126 shares of common stock to Sanovas Ophthalmology LLC to retire the then estimated debt due from the Company, respectively. The Company is related to Sanovas through common ownership and management.

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 Herbert Gould 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 Goldberg & Hymowitz, LLP as described below:

	2021	2020
Audit Fees	\$ 22,500	\$ 20,000
Audit Related Fees	0	0
Tax Fees	0	0
All Other Fees	0	0
Total	\$ 22,500	\$ 20,000

Audit Fees: Audit fees consist of fees billed for professional services performed by Liebman Goldberg & 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 \$22,500 and \$20,000 of such fees incurred by the Company in the fiscal years ended December 31, 2021 and 2020, 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, 2021 and 2020.

Tax Fees: Tax fees may consist of fees for professional services, including tax compliance performed by Liebman Goldberg & Hymowitz, LLP. There were no such fees incurred by the Company in the fiscal years ended December 31, 2021 and 2020, respectively.

All Other Fees: There were no such fees incurred by the Company in the fiscal years ended December 31, 2021 and 2020.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements:

Report of Independent Registered Public Accounting Firm	F-1
Balance Sheets	F-2
Statements of Operations and Comprehensive Loss	F-3
Statements of Changes in Stockholders' Equity	F-4
Statements of Cash Flows	F-5
Notes to Financial Statements	F-6

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 the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021)
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)
4.1	Description of Registrant's Securities
10.1	Option Exchange Agreement by and between the Company and Diopsys, Inc. dated October 8, 2019 (Incorporated by reference to Exhibit 10.1 the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021)
10.2+	RetinalGenix Technologies Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.2 the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021)
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 the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021)
10.4#	Sublicense Agreement by and between the Company and Sanovas Ophthalmology LLC dated June 24, 2021 (Incorporated by reference to Exhibit 10.4 the Company's Registration Statement on Form S-1 filed with the SEC on August 5, 2021)
31.1*	Certification of the Chief Executive Officer and 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 and 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.

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 15th day of April, 2022.

RETINALGENIX TECHNOLOGIES INC.

/s/ Jerry Katzman

Jerry Katzman
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jerry Katzman</u>	Chief Executive Officer, President and Director (Principal Executive Office and Principal Financial and Accounting Officer)	April 15, 2022
Jerry Katzman		
<u>/s/ Herbert Gould</u>	Director	April 15, 2022
Herbert Gould		

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 80,000,000 shares of common stock, \$0.0001 par value and 40,000,000 shares of preferred stock, \$0.0001 par value. We have designated 3,000,000 shares of preferred stock as Series F preferred stock. As of December 31, 2021, there were 14,282,314 shares of our common stock outstanding that were held of record by approximately 104 stockholders of record.

The following description is only a summary. You should also refer to our amended and restated certificate of incorporation and bylaws, both of which have been filed with the SEC as exhibits to the Annual Report on Form 10-K of which this exhibit forms a part.

Common Stock

We are authorized to issue up to a total of 80,000,000 shares of common stock, par value \$0.0001 per share. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. Holders of our common stock have no cumulative voting rights, preemptive or conversion rights or other subscription rights. Upon our liquidation, dissolution or winding-up, holders of our common stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of our assets which are legally available.

The holders of a majority of the shares of our capital stock, represented in person or by proxy, are necessary to constitute a quorum for the transaction of business at any meeting. If a quorum is present, an action by stockholders entitled to vote on a matter is approved if the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, with the exception of the election of directors, which requires a plurality of the votes cast.

Preferred Stock

Our board of directors will have the authority, without further action by the stockholders, to issue up to 40,000,000 shares of preferred stock in one or more series and to fix the designations, powers, preferences, privileges, and relative participating, optional, or special rights as well as the qualifications, limitations, or restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the common stock. Our board of directors, without stockholder approval, will be able to issue preferred stock with voting, conversion, or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms calculated to delay or prevent a change of control or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock, and may adversely affect the voting and other rights of the holders of common stock.

Options

Our 2017 Equity Incentive Plan provides for us to issue up to 10,000,000 shares of common stock as restricted shares, incentive stock options, nonqualified stock options, stock appreciation rights or restricted stock unit awards to our and our subsidiaries' employees, members of the board of directors and consultants. As of December 31, 2021, 1,820,000 options to purchase common stock pursuant to our 2017 Equity Incentive Plan were outstanding.

Warrants

As of December 31, 2021, warrants to purchase up to 199,000 shares of our common stock were outstanding and pre-funded warrants to purchase up to 28,014,540 shares of our common stock were outstanding.

Effect of Certain Provisions of our Amended and Restated Articles of Incorporation and Bylaws and the Delaware Anti-Takeover Provisions

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly traded Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An interested stockholder is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of the corporation's voting stock, subject to certain exceptions. The statute could have the effect of delaying, deferring or preventing a change in control of our Company.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to our secretary at our Company's principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder must be delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the 90th day prior to such annual meeting or the 10th day following the day on which a public announcement of the date of such meeting is first made by the Company. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval and may be utilized for a variety of corporate purposes, including future private or public offerings to raise capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Transfer Agent and Registrar

We have engaged the services of Continental Stock Transfer & Trust Company, as our transfer agent and registrar

**Certification of Chief Executive Officer and Principal Financial and Accounting Officer of RetinalGenix Technologies Inc.
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 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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, 2022

/s/ Jerry Katzman

Jerry Katzman

Chief Executive Officer and President

(Principal Executive Officer and Principal Financial and Accounting Officer)

**Statement of Chief Executive Officer and Chief Financial Officer
Pursuant to Section 1350 of Title 18 of the United States Code**

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Jerry Katzman, the Chief Executive Officer and Principal Financial and Accounting Officer, respectively, of RetinalGenix Technologies Inc. (the “Company”), hereby certify that based on the undersigned’s knowledge:

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2021 (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, 2022

/s/ Jerry Katzman

Jerry Katzman

Chief Executive Officer and President

(Principal Executive Officer and Principal Financial and Accounting Officer)
