

**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, 2022

☐ **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

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

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

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

Indicate by check mark whether the registrant 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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input checked="" type="checkbox"/>

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

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

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

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

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

As of June 30, 2022, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was approximately \$13,659,720 (based upon the closing sale price of the registrant’s common stock reported on that date). This calculation excludes shares held by the registrant’s current directors and executive officers and stockholders that the registrant has concluded are affiliates of the registrant.

Number of shares of common stock outstanding as of March 31, 2023 was 17,272,116.

Documents Incorporated by Reference: None.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

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

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

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

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

RISK FACTOR SUMMARY

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

Risk Related to our Financial Position and Need for Capital

- We have generated no revenue from commercial sales and our future profitability is uncertain.
- If we fail to obtain the capital necessary to fund our operations.
- Raising additional capital may cause dilution to our existing stockholders.
- There is substantial doubt about our ability to continue as a going concern.
- We have incurred net losses every year and expect to continue to incur increased expenses.

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

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

Risk Related to our Intellectual Property Rights

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

Risks Relating to Government Regulations

- Our failure to obtain and maintain FDA clearances or approvals on a timely basis, or at all, would prevent us from commercializing our products in the U.S., which could severely harm our business.
- Our promotional practices will be subject to extensive government scrutiny.
- Legislative or regulatory reform of the health care system in the U.S. may adversely impact our business.
- We are subject to stringent domestic and foreign medical device regulations.

- We will also be subject to stringent government regulation in foreign countries.
- Failure by us or our distributors to comply with foreign regulations applicable to the products we design, manufacture, install or distribute could expose us to enforcement actions or other adverse consequences.
- We will be subject to ongoing requirements and inspections.
- We could be subject to substantial fines or damages and possible exclusion from participation in federal or state health care programs if we fail to comply with the laws and regulations applicable to our business.
- If we fail to develop and successfully introduce new products our operating results may suffer.

Risks Related to Owning our Securities

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

PART I

ITEM 1. BUSINESS

Overview

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 early detection from use of two devices: (1) *Retinal Imaging Screening Device (RetinalGenixTM)*, being designed as a portable, high resolution retinal imaging Diabetic screening system providing a 200-degree field of view without requiring pupil dilation; and (2) *RetinalCamTM*, being designed as a high resolution home monitoring retinal imaging device and physician alert system offering real-time communication with physicians available 24/7. *RetinalCamTM*, is anticipated to have the capability to be used by patients in a variety of locations including at home, primary care centers, emergency rooms and telehealth centers and nursing homes, at a more efficient cost that is expected to be lower than that of a CT scan and an MRI. Initially, our primary focus was on designing the *RetinalGenixTM* high resolution retinal imaging system for Diabetic screening, however, due to the cost for such development, including the additional resources, personnel and equipment that will be required in order to obtain Food and Drug Administration (“FDA”) regulatory approval for commercialization of *RetinalGenixTM*, we have shifted our focus to development of the *RetinalcamTM* high resolution retinal imaging, home monitoring device and alert system. Currently, the majority of our design development team is focused on the development of the *RetinalcamTM* which does not require FDA approval for its commercialization. We have also recently acquired a pharmacogenetic mapping technology that is expected to have the ability to screen, monitor, and provide data to profile, trend and create diagnostic markers for systemic and retinal disorders i.e., cardiovascular, Alzheimers, Parkinsonism and other diseases. The markers and data analysis are expected to be rapid and cost effective and should eliminate expensive diagnostic equipment such as MRIs and CT scanning in many cases. The results are confidential to the patient and anonymous for any third party without permission of the patient.

To date, we have devoted substantially all of our resources to organizing, business planning, raising capital, designing and developing product candidates, and securing manufacturing partners. We do not have any products developed on a commercial scale or 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 \$12,000,000 to (i) complete product design and testing for the *RetinalGenixTM* and *RetinalCamTM* and submit *RetinalGenixTM* for U.S. Food and Drug Administration (“FDA”) clearance (we anticipate that the *RetinalCamTM* will not require FDA clearance); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS’ genetic mapping technology (which we anticipate will require approximately \$2,000,000); and (iii) build the infrastructure for our sustained growth. We intend to obtain such funds through the sales of our equity and debt securities and/or through potential strategic partnerships; however, no assurance can be provided that funds will be available to us on acceptable terms, if at all.

We do not expect to generate any revenues from product sales unless and until we either successfully complete development of *RetinalCamTM*, or we successfully obtain regulatory clearance for *RetinalGenixTM*. 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. An additional 60,500 shares were sold in January 2022 pursuant to this private placement. In October 2021, the registration statement on Form S-1 (the “Registration Statement”) that we filed with the Securities and Exchange Commission (“SEC”) pursuant to which we registered for resale shares of common stock, including shares of common stock sold in the offering and 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.

Our acquisition of DNA/GPS Inc.

On July 5, 2022, we entered into an exchange agreement (the “Exchange Agreement”) with Dr. Lawrence Perich pursuant to which we acquired all the outstanding shares of DNA/GPS Inc., a pharmacogenetics company based in Tampa, Florida (“DNA/GPS”), in exchange for the issuance of 2,000,000 shares of our common stock (the “Shares”). The acquisition of DNA/GPS allows us to combine DNA/GPS’ genetic mapping capabilities with our high resolution retinal imaging. The combined technology should have the ability to screen, monitor, and provide data to profile, trend and create diagnostic markers for systemic and retinal disorders i.e., cardiovascular, Alzheimer’s, Parkinsonism etc. The markers and data analysis are expected to be rapid and cost effective and should eliminate expensive diagnostic equipment such as MRI, CT scanning etc. in many cases. Dr. Perich joined our advisory board upon consummation of the acquisition. Upon acquiring DNA/GPS, we acquired the right to their platform technology that has the ability to screen, monitor, and provide data to profile, trend and create diagnostic markers for systemic and retinal disorders i.e., cardiovascular, Alzheimer’s, Parkinsonism and other diseases. This platform, if it received regulatory approval may offer an opportunity to bring testing away from laboratories and hospitals into primary care centers where it could be handled at reasonable prices. Since many manifestations of diseases are often seen in the eye, we believe it is possible to observe correlations between damage in the eye and kidney disease, high blood pressure and heart problems.

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.

Recent Developments

None

Market Opportunity

Our devices are being designed initially to detect the earliest stages of diabetic retinopathy to prevent blindness. Diabetic Retinopathy (“DR”) happens when too much blood sugar (glucose) associated with diabetes damages the blood vessels in the retina. As a result, the retina does not get enough oxygen and nutrients, and blood vessels can leak blood into the retina. According to the Mayo Clinic, DR is the leading cause of new cases of blindness in people 20 to 74 years of age in the United States. According to the Centers for Disease Control and Prevention (“CDC”) 2022 National Diabetes Statistics Report, more than 130 million adults are living with diabetes or prediabetes in the United States. The American Diabetes Association reports that diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in American adults. The number of individuals with diabetic retinopathy is predicted to increase by nearly 50% (it’s actually 47.7%) to over 11 million people by 2030. According to the CDC, 34.2 million patients in the U.S. have diabetic maculopathy with 26.9 million diagnosed and 7.3 million undiagnosed. In addition, 88 million adult Americans are pre-diabetics of which 84%, or 74 million, are undiagnosed. Diabetic maculopathy affects 500 million patients globally.

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

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

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

We believe RetinalGenixTM is a Class II medical device that will require 510(k) clearance from the FDA. In addition, we believe RetinalCamTM 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 RetinalGenixTM were to be classified as a Class II medical device, such classification would require us to submit a premarket notification submission to FDA prior to marketing. We anticipate the submission will require clinical evidence of safety and efficacy, generated through a regulated, randomized clinical trial or field evaluation. FDA clearance for ophthalmological devices usually require about 170 days.

We intend to launch RetinalCamTM in the fall of 2023 and we intend to apply for 510(k) clearance for RetinalGenixTM in 2024.

FDA Pre-Market Authorization and Notification

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

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

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

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

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

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

510(k) Premarket Notification Pathway

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

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

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

Post-market Requirements

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

Labeling and 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.

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

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

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

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

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

European Union Regulations

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

Other Healthcare Laws

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

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

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

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

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

Privacy and Data Protection Laws

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

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

Healthcare Reform

Healthcare reforms that have been adopted, and that may be adopted in the future, have been focused on cost containment in the healthcare system and could result in reductions in coverage and levels of reimbursement for healthcare products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The Department of Health and Human Services (“HHS”) plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act (“IRA”) in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct purchasers. The law will also, beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

Employees-Human Capital

As of March 31, 2023, we had no employees. We utilize certain Sanovas’ personnel for our business, and are allocated the proportion of payroll costs applicable to such usage from Sanovas.

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, California 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 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.

Risk Related to our Financial Position and Need for Capital

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

We were incorporated in November 2017 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, 2022 and December 31, 2021, were \$3,913,990 and \$2,179,294, respectively, and our accumulated deficit as of December 31, 2022 and December 31, 2021 was \$9,018,306 and \$5,104,316, respectively. There can be no assurance that the products under development by us will be cleared for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are cleared they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

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

We will need to continue to seek capital from time to time to continue development of our products and we cannot provide any assurances that any revenues they may generate in the future will be sufficient to fund our ongoing operations. We believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our products. We anticipate that we will need an additional \$12,000,000 to (i) complete product design and testing for the RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for FDA clearance (we anticipate that the RetinalCam™ will not require FDA clearance); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS' genetic mapping technology (which we anticipate will require approximately \$2,000,000); and (iii) build the infrastructure for our sustained growth.

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

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

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

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

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, or declaring dividends and may require us to grant security interests in our assets. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, or products or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may need to curtail or cease our operations.

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

As of December 31, 2022 and December 31, 2021, we had cash of \$38 and \$4,947, respectively. In addition, as of December 31, 2022 and December 31, 2021, we had current liabilities of \$1,069,357 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, 2022 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

We have incurred net losses every year since our inception and expect to continue to incur increased expenses and generate operating losses and experience negative cash flows and it is uncertain whether we will achieve profitability.

Our net losses for the year ended December 31, 2022 and December 31, 2021, were \$3,913,990 and \$2,179,294, respectively, and our accumulated deficit as of December 31, 2022 and December 31, 2021 was \$9,018,306 and \$5,104,316, respectively. We anticipate that we will need an additional \$12,000,000 to (i) complete product design and testing for the RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for FDA clearance (we anticipate that the RetinalCam™ will not require FDA clearance); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS' genetic mapping technology (which we anticipate will require approximately \$2,000,000); and (iii) build the infrastructure for our sustained growth. We intend to obtain such funds through the sales of our equity and debt securities and/or through potential strategic partnerships; however, no assurance can be provided that funds will be available to us on acceptable terms, if at all.

Risks Relating to Our Business

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

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

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

We rely on third-party suppliers to provide us with components that will be used in the products we are developing. For example, we rely on third-party suppliers to provide us with sensors which will be used in both RetinalGenix™ and RetinalCam™. Relying on third-party suppliers makes us vulnerable to component part failures or obsolescence and interruptions in supply including, but not limited to, as a result of 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.

Risk Related to our Intellectual Property Rights

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.

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

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

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

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

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

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

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

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.

Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years including the recent global economic uncertainty and financial market conditions. Russia's invasion and military attacks on Ukraine have triggered significant sanctions from U.S. and European leaders and financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a "trade war." Furthermore, if other countries, including the U.S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. 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. The COVID-19 outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. The future progression of the pandemic and its effects on our business and operations are uncertain. In addition, the outbreak of a pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. Pandemics could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

Further, due to increasing inflation, operating costs for many businesses including ours have increased and, in the future, could impact demand or pricing manufacturing of our devices, foreign exchange rates or employee wages. Inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we did not have any cash or cash equivalent balances on deposit with Silicon Valley Bank, uncertainty and liquidity concerns in the broader financial services industry remain and the failure of Silicon Valley Bank and its potential near- and long-term effects on the biotechnology industry and its participants such as our vendors, suppliers, and investors, may also adversely affect our operations and stock price.

We are actively monitoring the effects these disruptions and increasing inflation could have on our operations.

These conditions make it extremely difficult for us to accurately forecast and plan future business activities.

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

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

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

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

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

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 March 31, 2023, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 88% 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 \$1235 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, 2022 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

We do not own or lease any real property or office space. We are allocated a portion of Sanovas' office and laboratory space in Petaluma California based upon usage of such space for RetinGenix projects.

We believe this arrangement is adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

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

Not applicable.

PART II

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

Market Information

Our common stock is quoted on the OTC Pink tier of the OTC Markets Group, Inc. under the symbol "RTGN."

Shareholders

As of March 31, 2023, there were 109 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Equity Compensation Plan Information

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

Recent Sales of Unregistered Securities

We did not sell any equity securities during the year ended December 31, 2022 and 2021 in transactions that were not registered under the Securities Act other than as disclosed in our prior filings with the SEC and as set forth below.

In August 2022, the Company issued stock options to purchase up to 500,000 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 three-year period.

ITEM 6. RESERVED

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 early detection from use of two devices: (1) *Retinal Imaging Screening Device (RetinalGenixTM)*, being designed as a portable, high resolution retinal imaging Diabetic screening system providing a 200-degree field of view without requiring pupil dilation; and (2) *RetinalCamTM*, being designed as a high resolution home monitoring retinal imaging device and physician alert system offering real-time communication with physicians available 24/7. *RetinalCamTM*, is anticipated to have the capability to be used by patients in a variety of locations including at home, primary care centers, emergency rooms and telehealth centers and nursing homes, at a more efficient cost that is expected to be lower than that of a CT scan and an MRI. Initially, our primary focus was on designing the *RetinalGenixTM* high resolution retinal imaging system for Diabetic screening, however, due to the cost for such development, including the additional resources, personnel and equipment that will be required in order to obtain FDA regulatory approval for commercialization of *RetinalGenixTM* we have shifted our focus to development of the *RetinalcamTM* high resolution retinal imaging, home monitoring device and alert system. Currently, the majority of our design development team is focused on the development of the *RetinalcamTM* which does not require FDA approval for its commercialization. We have also recently acquired a pharmacogenetic mapping technology that is expected to have the ability to screen, monitor, and provide data to profile, trend and create diagnostic markers for systemic and retinal disorders i.e., cardiovascular, Alzheimers, Parkinsonism and other diseases. The markers and data analysis are expected to be rapid and cost effective and should eliminate expensive diagnostic equipment such as MRIs and CT scanning in many cases. The results are confidential to the patient and anonymous for any third party without permission of the patient.

To date, we have devoted substantially all of our resources to organizing, business planning, raising capital, designing and developing product candidates, and securing manufacturing 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 \$12,000,000 to (i) complete product design and testing for the RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for U.S. Food and Drug Administration (“FDA”) clearance (we anticipate that the RetinalCam™ will not require FDA clearance); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS’ genetic mapping technology (which we anticipate will require approximately \$2,000,000); and (iii) build the infrastructure for our sustained growth. We intend to obtain such funds through the sales of our equity and debt securities and/or through potential strategic partnerships; however, no assurance can be provided that funds will be available to us on acceptable terms, if at all.

We do not expect to generate any revenues from product sales unless and until we either successfully complete development of RetinalCam™, or 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.

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. An additional 60,500 shares were sold in January 2022 pursuant to this private placement. 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.

On July 5, 2022, RetinalGenix Technologies Inc. (the “Company”) entered into the Exchange Agreement with Dr. Lawrence Perich pursuant to which it acquired all the outstanding shares of DNA/GPS Inc., a pharmacogenetics company based in Tampa, Florida (“DNA/GPS”), in exchange for the issuance of 2,000,000 shares of our common stock. The acquisition of DNA/GPS combines DNA/GPS’ genetic mapping capabilities with the Company’s high resolution retinal imaging capabilities. The combined technology is expected to have the ability to provide diagnoses of systemic and retinal diseases.

Trends and Uncertainties—COVID-19

Increasing inflation, operating costs for many businesses including ours have increased and, in the future, could impact demand or pricing manufacturing of our devices, foreign exchange rates or employee wages. Inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks.

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, 2022 and 2021

The following table sets forth key components of our results of operations for the year ended December 31, 2022 and 2021.

	For The Years Ended December 31,		Change	% Change
	2022	2021		
Revenues	\$ -	\$ -	\$	
Expenses				
General and Administrative Expenses	807,406	1,120,949	(313,543)	(28)%
Research and Development	809,255	747,808	61,447	8%
Acquired In-process research and development	2,032,889	-	2,032,889	100%
Stock-based compensation	259,300	307,918	(48,618)	(16)%
Total Expenses	3,908,850	2,176,675	1,732,175	80%
Interest expense	5,140	2,619	2,521	96%
Net Loss	\$ (3,913,990)	\$ (2,179,294)	(1,734,696)	80%

Revenues

We did not recognize revenues for the years ended December 31, 2022 and 2021.

Research and Development Expenses

	For the years ended December 31,	
	2022	2021
Direct costs	\$ 713,801	\$ 635,108
Allocated costs from Sanovas	95,454	112,700
Total Research and Development expenses	\$ 809,255	\$ 747,808

Research and development expenses increased by \$61,447, or 8%, to \$809,255 for the year ended December 31, 2022 from \$747,808 for the year ended December 31, 2021. The increase was primarily the result of an increase in prototype related expense, engineering and technology consultants, and pilot manufacturing costs.

Stock Based Compensation Expenses

Stock-based compensation expenses decreased by \$48,618, or 16%, to \$259,300 for the year ended December 31, 2022 from \$307,918 for the year ended December 31, 2021. The decrease was primarily due to the recognition of expense for fully vested warrants issued in the first quarter of 2021, which did not re-occur in 2022.

General and Administrative Expenses

	For the years ended December 31,	
	2022	2021
Direct costs	\$ 370,523	\$ 361,580
Allocated costs from Sanovas	436,883	759,369
Total general and administrative expenses	\$ 807,406	\$ 1,120,949

Administrative expenses decreased by \$313,543 or 28%, to \$807,406 for the year ended December 31, 2022 from \$1,120,949 for the year ended December 31, 2021. We have no full-time employees. The decrease in administrative expenses was primarily due to a decrease in compensation allocated to us from Sanovas from \$654,000 to \$360,000 during the year ended December 31, 2022 and 2021, respectively due to a total lower quantity of Sanovas employees in total and an increase in Sanovas staff working on other projects. 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. Other administrative expenses were lower due to a lack of funding. This decrease was offset by increases corporate travel and entertainment of approximately \$22,000 during the year ended December 31, 2022 as compared to the year ended December 31, 2021 primarily related to investor meetings.

Acquired in-process research and development

Acquired in-process research and development presents the estimated fair value of the acquired technology held by DNA/GPS, Inc. when we acquired that company in July 2022. The estimated fair value of the transaction was \$2,000,000 plus legal fees associated with the transaction of \$32,889 is recorded as acquired in-process research and development costs in the associated consolidated statement of operations.

Liquidity and Capital Resources

To date, we have devoted substantially all of our resources to organizing, business planning, raising capital, designing and developing product candidates, and securing manufacturing partners. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily from the sale of common stock, loans and advances from related parties and by utilizing Sanovas personnel and facilities. During the year ended December 31, 2022, we received \$1,225,014 of cash advances and allocated services from Sanovas. We have settled a portion of the amounts due to Sanovas through the periodic issuance of shares of common stock, including 353,432 shares of common stock issued in May 2022 in settlement of the amounts due to Sanovas of \$353,432 and 586,370 shares of common stock issued in November 2022 in settlement of the amounts due to Sanovas of \$586,370.

We anticipate that we will need \$12,000,000 in operating capital to (i) complete product design and testing for RetinalGenixTM and RetinalCamTM and submit RetinalGenixTM for FDA approval (we anticipate that the RetinalCamTM will not require FDA approval); (ii) complete the development and expansion of the software tools around the recently acquired DNA/GPS' genetic mapping technology; and (iii) build the infrastructure for our sustained growth. We do not expect to generate any revenues from product sales unless and until we successfully complete development of RetinalGenixTM and RetinalCamTM and obtain regulatory approval for RetinalGenixTM. We will also require additional operating capital as a result of us operating as a public company, including for legal, accounting, investor relations, compliance and other expenses.

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

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

Cash Flow Activities for the year ended December 31, 2022 and 2021

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

	For The Year Ended December 31,	
	2022	2021
Net cash used in operating activities	\$ (199,287)	\$ (1,166,971)
Net cash used in investing activities	(307)	-
Net cash provided by financing activities	194,685	1,169,699
Net (decrease) increase in cash	(4,909)	2,728
Cash at beginning of the period	4,947	2,219
Cash at end of the period	\$ 38	\$ 4,947

Operating Activities

Net cash used in operating activities was \$199,287 for the year ended December 31, 2022 and \$1,166,971 for the year ended December 31, 2021, the decrease driven by a reduction in salaries allocated from Sanovas to the Company and expenditures by third-party consultants and engineers on the prototype development due to a lack of funding. The cash flow used in operating activities in 2022 was driven by the net loss of \$3,913,990 offset in part by non-cash expenses of \$2,259,351 and an increase in accounts payable and accrued interest payable of \$230,338. In addition, Sanovas billed us for allocated costs and expenses paid on behalf of and allocated to us in the amount of \$532,337 during the year ended December 31, 2022, and we received \$692,677 of net advances from Sanovas, for a net change in cash of \$1,225,014.

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 and other current liabilities/assets of \$156,257 for the year ended December 31, 2021. In addition, Sanovas billed us for allocated costs and expenses paid on behalf of and allocated to us in the amount of \$872,069 during the year ended December 31, 2021, and we paid \$323,922 of net advances from Sanovas, for a net change in cash of \$548,148.

In each of the years, 2019-2022, the Company has settled a portion of the amounts due to Sanovas through the issuance of common stock. The Company issued 939,802 and 390,358 shares of its common stock to offset amounts due to Sanovas for payment of expenses on behalf of the Company of \$939,802 and \$390,358 during the years ended December 31, 2022 and 2021, respectively.

Investing Activities

There was no cash used in or provided by investing activities for the year ended December 31, 2022 and 2021, except an equipment purchase in the third quarter of 2022.

Financing Activities

Net cash provided by financing activities was \$194,685 and \$1,169,699 during the year ended December 31, 2022 and 2021, respectively, attributable primarily to proceeds from the sale of common stock of \$60,500 and proceeds from advances from related parties of \$109,185 in the year ended December 31, 2022, and proceeds from the exercise of options and warrants and the sale of common stock of \$1,096,699 and shareholder loans of \$73,000 in the year ended December 31, 2021.

Critical Accounting Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and related disclosures in the financial statements and accompanying notes. Management bases 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 January 2022.

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 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, but does not expect it to have a significant 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.

JOBS Act

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

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.
Consolidated Financial Statements
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of RetinalGenix Technologies Inc. (the “Company”) as of December 31, 2022 and 2021, and the related consolidated statements of operations, stockholders’ deficit, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, 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
March 31, 2023
PCAOB ID No. 473

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

**RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED BALANCE SHEETS**

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash	\$ 38	\$ 4,947
Total Current Assets	<u>38</u>	<u>4,947</u>
Equipment, net of accumulated depreciation of \$52	256	-
TOTAL ASSETS	<u>\$ 294</u>	<u>\$ 4,947</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current Liabilities		
Accounts payable and accrued liabilities	475,480	251,282
Due to Sanovas	427,933	142,721
Due to related parties	109,185	-
Shareholders' notes payable	49,000	73,000
Accrued interest payable	7,759	2,619
Total Liabilities	<u>1,069,357</u>	<u>469,622</u>
Stockholders' Deficit:		
Preferred stock, \$0.0001 par value; 40,000,000 shares authorized; Series F preferred stock - 3,000,000 shares designated, 0 issued and outstanding at December 31, 2022 and December 31, 2021	-	-
Common stock, \$0.0001 par value; 80,000,000 shares authorized; 17,272,116 shares issued and outstanding at December 31, 2022 and 14,221,814 shares issued and outstanding at December 31, 2021	1,783	1,423
Additional paid in capital	7,947,460	4,638,218
Accumulated deficit	(9,018,306)	(5,104,316)
Total Stockholders' Deficit	<u>(1,069,063)</u>	<u>(464,675)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 294</u>	<u>\$ 4,947</u>

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

RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For The Year Ended	
	December 31,	
	2022	2021
Revenues	\$ -	\$ -
Operating expenses:		
General and administrative expenses	807,406	1,120,949
Research and development	809,255	747,808
Acquired in-process research and development	2,032,889	-
Stock-based compensation	259,300	307,918
Total Operating expenses	3,908,850	2,176,675
Interest expense	5,140	2,619
Net loss	\$ (3,913,990)	\$ (2,179,294)
Net loss per share - basic and diluted	\$ (0.25)	\$ (0.05)
Weighted average number of common shares outstanding during the period- basic and diluted	15,584,346	41,246,915

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

RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	<u>Common Stock</u>		<u>Preferred Stock Series F</u>		<u>Subscription Receivable</u>	<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Par Value</u>	<u>Shares</u>	<u>Par Value</u>	<u>Preferred Stock</u>	<u>Paid-in Capital</u>	<u>Deficit</u>	
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	1,154,173	117				1,083,082		1,083,199
Stock based compensation						307,918		307,918
Exercise of warrants	13,500	1				13,499		13,500
Retirement of due to Sanovas through the issuance of shares of common stock to Sanovas Ophthalmology LLC	390,358	39				390,319		390,358
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)
Stock based compensation	-	-	-	-	-	259,300	-	259,300
Stock purchased by investors	60,500	61	-	-	-	60,439	-	60,500
Retirement of due to Sanovas through the issuance of shares of common stock to Sanovas Ophthalmology LLC	939,802	94	-	-	-	939,708	-	939,802
Exercise of warrants and options	50,000	5				49,995		50,000
Issuance of shares upon acquisition of in process research and development	2,000,000	200				1,999,800		2,000,000
Net loss	-	-	-	-	-	-	(3,913,990)	(3,913,990)
Balance as at December 31, 2022	17,272,116	\$ 1,783	-	-	-	\$ 7,947,460	\$ (9,018,306)	\$ (1,069,063)

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

RETINALGENIX TECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For The Years Ended December 31,	
	2022	2021
Cash Flows From (Used In) Operating Activities		
Net loss	\$ (3,913,990)	\$ (2,179,294)
Adjustments to reconcile net loss to net cash used in operating activities		
Non-cash items:		
Stock based compensation expense	259,300	307,918
Acquired In-process research and development through issuance of common stock	2,000,000	-
Depreciation expense	51	-
Expenses paid by Sanovas on behalf of Company, net	1,225,014	548,148
Changes in operating assets and liabilities:		
Increase (decrease) in accounts payable and accrued liabilities	225,198	109,851
(Increase) decrease in deferred offering costs	-	43,787
Increase in accrued interest	5,140	2,619
Total Adjustments	3,714,703	1,012,323
Net cash used in operating activities	(199,287)	(1,166,971)
Cash Flows (Used In) Investing Activities		
Equipment purchase	(307)	-
Cash Flows From (Used In) Financing Activities		
Proceeds from common stock sold, net of costs	60,500	1,083,199
Proceeds from exercise of warrants and options	25,000	13,500
Proceeds from shareholders' notes payable	-	73,000
Advances from related parties	109,185	-
Net cash provided by financing activities	194,685	1,169,699
Net (decrease) increase in cash	(4,909)	2,728
Cash at beginning of year	4,947	2,219
Cash at end of year	\$ 38	\$ 4,947
Supplemental information:		
Retirement of due to Sanovas through the issuance of common stock to Sanovas Ophthalmology LLC (Note C)	\$ 939,802	\$ 390,358
Exchange of common stock by Sanovas Ophthalmology LLC for pre-funded warrants	-	2,801
Repayment of shareholders' note payable through the exercise of warrants	25,000	-

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

RETINALGENIX TECHNOLOGIES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

RetinalGenix Technologies Inc. (the “Company”), a Delaware corporation, was formed in November 2017 by Sanovas Ophthalmology, LLC (“Sanovas Ophthalmology”), a majority owned subsidiary of Sanovas Inc. (“Sanovas”), a privately held research and development incubator. During the years ended December 31, 2022 and December 31, 2021, a substantial portion of the operations of the Company were conducted by Sanovas, who invoices the Company for costs and expenses paid for on behalf of the Company and costs and expenses allocated to the Company for services performed on behalf of the Company.

The Company was formed to develop technologies to diagnose and treat ophthalmic 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 Option Exchange 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 as of the second quarter of 2022, there are no plans to move forward with Diopsys.

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 and terminates when exercised in full.

On July 5, 2022, RetinalGenix Technologies Inc. entered into an Exchange Agreement (the “Exchange Agreement”) with Dr. Lawrence Perich pursuant to which it acquired all the outstanding shares of DNA/GPS Inc., a pharmacogenetics company based in Tampa, Florida (“DNA/GPS”), in exchange for the issuance of 2,000,000 shares of the Company’s common stock. The acquisition of DNA/GPS combines DNA/GPS’ genetic mapping capabilities with the Company’s retinal imaging capabilities. The combined technology is expected to have the ability to screen, monitor and provide data to profile trends and create diagnostic markers for systemic and retinal disorders in the cardiovascular, Alzheimer’s, Parkinson and other diseases. The markers and data analysis are rapid and cost effective, thereby eliminating expensive diagnostic equipment such as MRI or CT scanning. The results are to be confidential to the patient and anonymous for any third party without permission of the patient. The Company accounted for this transaction as an asset acquisition in 2022. The estimated fair value of the transaction was \$2,000,000 plus legal fees associated with the transaction of \$32,889 is recorded as acquired in-process research and development costs in the associated consolidated statement of operations.

Liquidity and Going Concern

The Company has had net losses since inception and has an accumulated deficit of approximately \$9,018,000 at December 31, 2022. In addition, as of December 31, 2022 and December 31 2021, the Company had liabilities of approximately \$1,069,000 and \$470,000, respectively, the majority of which is with related parties. The Company has minimal cash at December 31, 2022 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. The Company commenced private offerings of shares of its common stock raising net proceeds of approximately \$1,083,000 in the year ended December 31, 2021, and \$60,500 in the year ended December 31, 2022 - See Note D. In February 2021, the Company entered into an agreement with an investment banker to raise funds for the Company which led to the private offering of shares mentioned above. The Company is in discussions with investment bankers and individual investors with respect to raising additional capital for the Company and potentially up-listing to the NASDAQ exchange.

Sanovas has paid a significant portion of the Company's operating expenses through December 2022, and was owed approximately \$428,000 as of December 31, 2022 by the Company. 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 \$353,432 in May 2022 and \$586,370 in November 2022 (see Note C).

As of the date of this report, the Company does not have adequate resources to fund its operations through April 2024 without considering any potential future milestone payments that it may receive under any new collaborations that it may enter into in the future or any future capital raising transactions. The Company will need to raise additional funding to complete the development of its products and commence the market launch, assuming regulatory approval is obtained. The Company does not know whether additional financing will be available when needed, whether it will be available on favorable terms, or if it will be available at all. These factors raise substantial doubt about the Company's ability to continue as a going concern. The 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"). As of December 31, 2022, there have been no material changes in the Company's significant accounting policies from those that were disclosed in the 2021 Annual Report. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, DNA/GPS, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

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. Offering Costs

Deferred offering costs are expenses directly related to an expected financing. These costs consisted of legal fees that the Company capitalized. These costs are offset against the resultant capital raised.

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, 2022 or December 31, 2021. The Company's policy is to expense any penalties and interest associated with this topic. At December 31, 2022 and December 31, 2021, 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 year ended December 31, 2022 and 2021, 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, 2022, include stock options to purchase 2,360,000 shares of common stock, pre-funded warrant to purchase 28,014,540 shares of common stock, and warrants to purchase 161,500 shares of common stock. Potentially dilutive securities not included in the computation of loss per share for the year ended December 31, 2021 included 3,000,000 shares of Series F preferred stock, stock options to purchase 1,882,500 shares of common stock, and warrants to purchase 212,500 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, 2021.

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

9. Property and Equipment:

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

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

10. 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 when it obtains a lease. The Company is currently evaluating these ASUs and their impact on its financial statements, but does not expect it will have a material effect on the 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.

11. Reclassification:

The Company reclassified approximately \$68,000 of costs incurred during the year ended December 31, 2021 from general and administrative expense to research and development costs to conform to the current presentation.

NOTE C - RELATED PARTY TRANSACTIONS

Sanovas

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

Commencing in 2019, Sanovas began paying expenses on behalf of the Company, and began allocating a portion of expenses and infrastructure costs to the Company and other entities where Sanovas was performing shared services. Included in such allocated costs is approximately \$344,000 and \$391,000 in costs related to an officer of the Company in the year ending December 31, 2022 and 2021, respectively.

The following summarizes the transactions between the Company and Sanovas for the year ended December 31, 2022 and December 31, 2021:

	Years Ended	
	December 31, 2022	December 31, 2021
Balance due to (from) Sanovas – beginning of year	\$ 142,721	\$ (15,069)
Costs paid by Sanovas on the Company's behalf	79,290	68,073
Costs of Sanovas allocated to the Company	453,047	803,997
Proceeds from (repayment of) costs charged by Sanovas to the Company, net	692,677	(323,922)
Retirement of due to Sanovas through the issuance of common stock to Sanovas Ophthalmology	(939,802)	(390,358)
Balance due to Sanovas - end of year	\$ 427,933	\$ 142,721

The Company issued 390,358, 353,432 and 586,370 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 \$353,432 in May 2022 and \$586,370 in November 2022, respectively.

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. No royalties have been paid through December 31, 2022 under this Sublicense Agreement.

Due to affiliates

From time to time, an officer of the Company, a shareholder of the Company and affiliates of Sanovas advances funds or paid expenses on behalf of the Company. There is no formal notes or repayment plan for such advances. At December 31, 2022, the Company had received \$109,185 pursuant to such advances.

Shareholders' notes payable – See Note G

NOTE D - COMMON AND PREFERRED STOCK

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

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 the Company 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, 2022 and 2021, the Company sold an aggregate of 60,500 and 398,057 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

As of December 31, 2022 and 2021, there were 3,000,000 shares of preferred stock designated as Series F preferred stock, none of which were outstanding.

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, 2022 and December 31, 2021. The estimated aggregate fair value of the stock options at the date of grant 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 vested immediately. The estimated aggregate fair value of the stock options at the date of grant was determined to be approximately \$63,900 using a Black Scholes model.

In August 2022, the Company issued stock options to purchase up to 500,000 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 three-year period. The estimated aggregate fair value of the stock options at the date of grant was determined to be \$287,487 using a Black Scholes model.

The Company recognized approximately \$259,000 and \$232,000 of stock-based compensation expense during the year ended December 31, 2022 and 2021, respectively, related to stock options which is included in the accompanying statements of operations. As of December 31, 2022, there was approximately \$655,000 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 2.0 years.

At December 31, 2022, there were 5,115,000 shares available to be issued under the Plan. The following table summarizes stock option activity of the Plan through December 31, 2022:

	<u>Options Issued</u>	<u>Weighted-Average Exercise Price</u>
Options outstanding – December 31, 2020	1,800,000	\$ 1.00
Granted	82,500	1.00
Canceled	-	-
Exercised	-	-
Options outstanding – December 31, 2021	1,882,500	\$ 1.00
Granted	502,500	1.00
Canceled	-	-
Exercised	(25,000)	1.00
Options outstanding – December 31, 2022	<u>2,360,000</u>	<u>\$ 1.00</u>

Additional information regarding the exercisable options and average remaining contractual life of the options outstanding as of December 31, 2022 is as follows:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable at December 31, 2022	Number Exercisable at December 31, 2021
\$ 1.00	2,360,000	7.2 Years	1,204,444	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 fair value of each option grant was estimated on the date of grant to be \$0.56 per share using the Black-Scholes option-pricing model with the following assumption weighted-averages in 2022:

Risk-free interest rates	2.19%
Expected life in years	3.5
Expected volatility	80%
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 \$75,000 and \$0 in the year ended December 31, 2021 and 2022, respectively. At December 31, 2022, there is no remaining compensation expense to be recognized.

The following table summarizes warrant activity through December 31, 2022:

	Warrants Issued	Weighted-Average Exercise Price
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
Granted	-	-
Canceled	(12,500)	1.00
Exercised	(25,000)	1.00
Warrants outstanding – December 31, 2022	161,500	\$ 1.09

Additional information regarding the warrants outstanding as of December 31, 2022 is as follows:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable
\$ 1.00	11,500	.7 Years	11,500
\$ 1.10	150,000	5.7 Years	150,000
	161,500		161,500

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 – SHAREHOLDERS’ 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 has informally extended the maturity date to December 31, 2023 under the same terms. During the year ended December 31, 2022, one of the noteholders exercised outstanding warrants with an aggregate exercise price of \$25,000 through the offset of the note payable due to them from the Company, such that \$48,000 remain outstanding at December 31, 2022. Interest expense amounted to \$5,140 and \$2,619 for the years ended December 31, 2022 and 2021, respectively. The accrued interest payable at December 31, 2022 and 2021 was \$7,759 and \$2,619, respectively.

NOTE H – INCOME TAXES

The Company had no current income tax expense for the years ended December 31, 2022 and 2021 due to operating losses. The effective income tax rate for the years ended December 31, 2022 and 2021 is zero, as the deferred tax benefits are fully offset by the valuation allowance against such deferred income tax assets.

At December 31, 2022, the Company had net operating loss carryforwards (“NOL”) of approximately \$4,499,000 for federal income tax purposes of which \$3,724,000 has no expiration date, \$775,000 which begins to expire in 2034, and approximately \$4,499,000 for state income tax purposes which begins to expire in 2030.

The resulting net deferred tax assets of approximately \$1,714,000 (\$1,350,000 applicable to net operating loss carryforwards, \$236,000 applicable to stock-based compensation and \$128,000 applicable to accruals) and \$1,193,000 (\$992,000 applicable to net operating loss carryforwards, \$158,000 applicable to stock based compensation and \$43,000 applicable to accruals) at December 31, 2022 and December 31, 2021, respectively, has been fully reserved due to the uncertainty of future realization. The valuation allowance increased by approximately \$521,000 and \$389,000 at December 31, 2022 and 2021, 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 - CONTINGENCY

The Company received a claim against it relating to a former indirect vendor. The Company believes the claim is without merit and intends to vigorously defend itself. The Company does not believe the claim would have a material impact on the financial condition of the Company.

NOTE J - SUBSEQUENT EVENTS

The Company has evaluated the effect of events and transactions subsequent to December 31, 2022 through the date of issuance of the consolidated financial statements, and determined that no subsequent events have occurred that require recognition in the consolidated financial statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls

Our management, with the participation of our Chief Executive Officer who also serves as our Chief financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. We are required to maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are designed to be effective in providing reasonable assurance that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report, is collected, recorded, processed, summarized, and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer who is also our Chief Financial Officer concluded that, as of such a date, our disclosure controls and procedures were not effective due to the material weaknesses in our internal control over financial reporting, described below.

Management's Report on Internal Control over Financial Reporting

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, 2022.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We are considering various remediation measures, including hiring internal accounting resources or using outside providers to provide additional resources and capabilities as well as implementing a more formal accounting and financial reporting system to mitigate such material weakness, but have not yet adopted or implemented any such measures. When we have sufficient business activity and funding available, we intend to begin to implement remediation measures to address our material weakness and improve our internal control over financial reporting and disclosure controls and procedures. We hope to complete the implementation, remediation and test of the new procedures in the second half of 2023, 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

During the quarter ended December 31, 2022, 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
Vinay Mehindru	55	Director

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

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

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

Herbert Gould. Herbert Gould has served as a member of the Company's board of directors since April 2019. Since 2007, he has served as a Medical Director of Nutraceutical Delivery Corporation, a drug delivery system company. He previously served in various capacities including Medical Director of Diamond 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.

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

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

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

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

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

Larry Perich, D.O.

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

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

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

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

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

Jack M. Dodick, M.D.

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

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

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

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

Marguerite B. McDonald, M.D.

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

Lawrence A. Yannuzzi, M.D.

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

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

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

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

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

Ahmed Mohiuddin, M.D.

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

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

ITEM 11. EXECUTIVE COMPENSATION

During the year ended December 31, 2022, our executive officers did not receive any compensation.

Outstanding Equity Awards at December 31, 2022

As of December 31, 2022, there were no outstanding equity awards held by any of our executive officers.

Non-Employee Director Compensation

The following table sets forth information regarding all forms of compensation that were both earned by and paid to our non-employee directors during the year ended December 31, 2022.

Name	Fees Earned or Paid in Cash (\$)	Option Awards ⁽¹⁾	All Other Compensation (\$)	Total
Herbert Gould	\$ —	\$ —	\$ —	\$ —
Vinay Mehindru	\$ —	\$ 287,487	\$ —	\$ 287,487

(1) This column indicates the aggregate grant date fair value, as determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation — Stock Compensation (“FASB ASC Topic 718”), of option awards granted as of their respective grant date. See “Note B, paragraph 7 — Stock-based compensation” of the Notes to Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended December 31, 2022 for an explanation of the assumptions made in valuing these awards.

The aggregate number of option and stock awards outstanding as of December 31, 2022 for each non-employee director was as follows:

Name	Option Awards (#)	Stock Awards (#)
Herbert Gould	—	—
Vinay Mehindru	500,000	—

Employment Agreements

During the year ended December 31, 2022, we were not a party to any employment agreement.

2017 Equity Incentive PlanSummary

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 March 31, 2023 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.

As of March 31, 2023, we had 17,272,116 shares of common stock outstanding. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the subject securities. Shares of common stock that are currently exercisable or convertible within 60 days of March 31, 2023 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage beneficial ownership of such person, but are not treated as outstanding for the purpose of computing the percentage beneficial ownership of any other person.

Beneficial Owner ⁽¹⁾	Shares of Common Stock Beneficially Owned	Percentage
Directors and Named Executive Officers:		
Jerry Katzman	34,851,342 ⁽³⁾⁽⁴⁾	76.96% ⁽²⁾
Herbert Gould	350,000	2.0%
Vinay Mehindru	500,000 ⁽⁵⁾	2.8%
All Officers and Directors as a Group	35,201,342	77.97%
5% or Greater Shareholders:		
Sanovas Ophthalmology, LLC ⁽⁴⁾	28,954,342 ⁽⁶⁾	63.94% ⁽²⁾
Bayern Capital, LLC ⁽⁷⁾	5,067,000	29.34%
Capital Funding Partners, LLC ⁽⁸⁾	5,897,000	34.14%

(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 is based upon 17,272,116 shares of common stock outstanding on March 31, 2023 and the buy-back warrant to purchase 28,014,540 shares of common stock held by Sanovas Ophthalmology LLC.

(3) Represents (i) 5,897,000 shares of common stock held by Capital Funding Partners, LLC; (ii) 939,802 shares of common stock held by Sanovas Ophthalmology LLC and (iii) 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 LLC and in such capacity has the right to vote and dispose of the securities held by such entity.

(5) Vinay Mehindru holds fully-vested options to purchase 500,000 shares of common stock at \$1.00 per share.

(6) Represents 939,802 shares of common stock held by Sanovas Ophthalmology LLC and pre-funded warrants held by Sanovas Ophthalmology LLC to purchase up to 28,014,540 shares of the Company's common stock.

(7) 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.

(8) 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, 2022.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (c))
Equity compensation plans approved by security holders (1)	2,360,000 ⁽²⁾	\$ 1.00	5,115,000
Equity compensation plans not approved by security holders	-	-	-
Total	2,360,000	\$	5,115,000

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

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

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

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

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

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

The following includes a summary of transactions since January 1, 2021 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this Annual Report on Form 10-K. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

Transactions with Sanovas, Inc.

On June 24, 2021, we entered into a sublicense agreement (“Sublicense Agreement”) with Sanovas Ophthalmology pursuant to which Sanovas Ophthalmology granted us an exclusive worldwide (“Territory”) license to certain intellectual property licensed to Sanovas Ophthalmology by Sanovas Intellectual Property LLC relating to certain technologies for eye and ocular visualization and monitoring (“Licensed IP”) for uses related to the screening, examination, diagnosis, prevention and/or treatment of any eye disease, medical condition or disorder, or any disease, medical condition or disorder affecting the eye. Pursuant to the Sublicense Agreement, commencing on the date of the first commercial sale of a Licensed Product (as defined in the Sublicense Agreement), in each country in the Territory and continuing on a country by country basis until the expiration or termination of the last Valid Claim (as defined in the Sublicense Agreement) of a licensed patent in such country (the “Royalty End Date”), the Company shall pay Sanovas Ophthalmology a royalty equal to a mid-single digit percentage of any Net Sales (as defined in the Sublicense Agreement) of any Licensed Product. The Sublicense Agreement shall continue until the Royalty End Date, unless earlier terminated pursuant to its terms. The Sublicense Agreement may be terminated by either party if the other party materially breaches the Sublicense Agreement in a manner that cannot be cured, or materially breaches the Sublicense Agreement in a manner that can be cured and such breach remains uncured for more than 30 days after the receipt by the breaching party of notice specifying the breach. Furthermore, the Company may terminate the Sublicense Agreement at any time upon 90 days written notice to Sanovas Ophthalmology. No royalties have been paid through December 31, 2022 under this Sublicense Agreement.

Commencing in 2019, Sanovas began paying invoices on behalf of the Company, and began allocating a portion of salaries and infrastructure costs to the Company. There were no specific terms of repayment. For the years ended December 31, 2022 and 2021, Sanovas allocated an aggregate of \$532,337 and \$872,070, respectively to the Company. As of December 31, 2022, the Company owed Sanovas \$427,933. For the years ended December 31, 2022 and 2021, the Company received (paid) \$692,677 and (\$323,922) from (to) Sanovas, respectively. A portion of the balance of the payments due to Sanovas have been discharged pursuant to the issuance by the Company of shares of its common stock since 2019. Specifically, in June 2021, the Company issued 390,358 shares of common stock to Sanovas Ophthalmology LLC to retire the then estimated debt due from the Company. In May 2022 and November 2022, we issued 353,432 and 586,370 shares of common stock to discharge \$353,432 and \$586,370 of debt owed to Sanovas Ophthalmology LLC at a purchase price of \$1.00 per share, respectively. The Company is related to Sanovas through common ownership and management.

On December 23, 2018, Sanovas entered into an employment agreement with Dr. Katzman pursuant to which Dr. Katzman serves as the President and Chief Executive Officer of Sanovas.

Due to affiliates

From time to time, an officer of the Company, a shareholder of the Company and affiliates of Sanovas advances funds or paid expenses on behalf of the Company. There is no formal notes or repayment plan for such advances. At December 31, 2022, the Company had received \$109,185 pursuant to such advances.

Stockholders' loans 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. Company has informally extended the maturity date to December 31, 2023. During the year ended December 31, 2022, one of the noteholders exercised outstanding warrants with an aggregate exercise price of \$25,000 through the offset of the note payable due to them from the Company, such that \$48,000 remain outstanding at December 31, 2022.

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 and Vinay Mehindru 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:

	2022	2021
Audit Fees	\$ 39,750	\$ 22,500
Audit Related Fees	0	0
Tax Fees	0	0
All Other Fees	0	0
Total	<u>\$ 39,750</u>	<u>\$ 22,500</u>

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 \$39,750 and \$22,500 of such fees incurred by the Company in the fiscal years ended December 31, 2022 and 2021, 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, 2022 and 2021.

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, 2022 and 2021, respectively.

All Other Fees: There were no such fees incurred by the Company in the fiscal years ended December 31, 2022 and 2021.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

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

(1) Consolidated Financial Statements:

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations and Comprehensive Loss	F-4
Consolidated Statements of Changes in Stockholders' Equity	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

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)
10.5	Termination of Option Exchange Agreement, by and between the Company and Diopsys, Inc., dated February 17, 2022 (Incorporated by reference to Exhibit 10.1 the Company's Form 8-K filed with the SEC on February 17, 2022)
10.6+	Exchange Agreement, by and between the Company and Sanovas Ophthalmology, LLC, dated May 9, 2022 (Incorporated by reference to Exhibit 10.1 the Company's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2022)
10.7	Exchange Agreement, by and between the Company and Lawrence Perich, dated July 5, 2022, (Incorporated by reference to Exhibit 10.1 the Company's Form 8-K filed with the SEC on July 7, 2022)
21.1*	List of Subsidiaries
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

* Filed herewith.

+ Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.

Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (iii) would be competitively harmful if publicly disclosed.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 31st day of March, 2023.

RETINALGENIX TECHNOLOGIES INC.

/s/ Jerry Katzman

Jerry Katzman
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

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

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

Signature	Title	Date
<u>/s/ Jerry Katzman</u> Jerry Katzman	Chief Executive Officer, President and Director (Principal Executive Office and Principal Financial and Accounting Officer)	March 31, 2023
<u>/s/ Herbert Gould</u> Herbert Gould	Director	March 31, 2023
<u>/s/ Vinay Mehindru</u> Vinay Mehindru	Director	March 31, 2023
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DESCRIPTION OF SECURITIES

RetinalGenix Technologies Inc. (the “Company,” “we,” “us,” and “our”) has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, which is our common stock, \$0.0001 par value (the “common stock”).

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.

Description of 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.

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 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.

Subsidiaries of the Registrant

None

**Certification of Chief Executive Officer and Principal Financial and Accounting Officer of RetinalGenix Technologies Inc.
Pursuant to Rule 13a-14 or Rule 15d-14 of the Securities Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Jerry Katzman, certify that:

1. I have reviewed this Annual Report on Form 10-K of RetinalGenix Technologies Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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: March 31, 2023

/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
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

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, 2022 (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: March 31, 2023

/s/ Jerry Katzman

Jerry Katzman

Chief Executive Officer and President

(Principal Executive Officer and Principal Financial and Accounting Officer)
