UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 333-258528

RETINALGENIX TECHNOLOGIES INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-3936890**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1450 North McDowell Boulevard, Suite 150 Petaluma, CA	**94954**
(Address of principal executive offices)	(Zip Code)

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

Not applicable
(Former name, former address and former fiscal year, if changed since last report

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

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

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

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

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

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

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

The number of shares of the issuer's common stock, $0.0001 par value per share, outstanding at November 17, 2021 was 42,155,654.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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, plans and objectives of management and markets for our common stock 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 our reports we file with the U.S. Securities and Exchange Commission (the "SEC"). You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed as exhibits to the reports we file with the SEC, 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 Quarterly Report on Form 10-Q is accurate as of the date hereof. Because the risk factors in our SEC reports 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 the information presented in this Quarterly Report on Form 10-Q, and particularly our forward-looking statements, by these cautionary statements.

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

RETINALGENIX TECHNOLOGIES INC.
BALANCE SHEETS

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current Assets		
Cash	**$ 36,578**	$ 2,219
Due from Sanovas	**-**	15,069
Deferred Offering Costs	**-**	43,787
Total Current Assets	**36,578**	**61,075**
TOTAL ASSETS	**$ 36,578**	**$ 61,075**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts Payable	**210,873**	141,431
Due to Sanovas	**164,233**	-
Shareholder's Loans	**73,000**	-
Accrued Interest	**1,180**	-
Total Liabilities	**449,286**	**141,431**
Stockholders' Deficit:		
Preferred stock, $0.0001 par value; 40,000,000 shares authorized; Series F preferred stock, 3,000,000 shares designated, issued and outstanding at September 30, 2021 and December 31, 2020	**300**	300
Common stock, $0.0001 par value; 80,000,000 shares authorized; 41,933,654 and 40,678,323 shares issued and outstanding at September 30, 2020 and December 31, 2020, respectively	**4,194**	4,067
Additional paid in capital	**4,277,676**	2,840,599
Preferred stock subscription receivable	**(300)**	(300)
Accumulated deficit	**(4,694,578)**	(2,925,022)
Total stockholders' deficit	**(412,708)**	**(80,356)**
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 36,578**	**$ 61,075**

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

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF OPERATIONS (Unaudited)

	For The Nine Months Ended September 30,	
	2021	**2020**
Revenue	**$ -**	**$ -**
Costs and expenses		
Administrative	**949,945**	1,077,450
Research and Development	**565,564**	222,193
Stock-based compensation	**252,867**	165,153
Total Operating Expenses	**1,768,376**	1,464,796
Interest expense	**1,180**	-
Net Loss	**$ (1,769,556)**	$ (1,464,796)
Net Loss per share - basic and diluted	**$ (0.04)**	$ (0.04)
Weighted average number of common shares outstanding during the period- basic and diluted	**41,303,545**	39,507,084

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

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF OPERATIONS (Unaudited)

	For The Three Months Ended September 30,	
	2021	**2020**
Revenue	**$ -**	**$ -**
Costs and expenses		
Administrative	**293,893**	413,151
Research and Development	**200,899**	98,896
Stock-based compensation	**55,051**	55,051
Total Operating Expenses	**549,843**	**567,098**
Interest expense	**1,180**	**-**
Net Loss	**$ (551,023)**	**$ (567,098)**
Net Loss per share - basic and diluted	**$ (0.01)**	**$ (0.01)**
Weighted average number of common shares outstanding during the period- basic and diluted	**41,825,154**	**39,996,806**

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

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
NINE MONTHS ENDED SEPTEMBER 30, 2021 (Unaudited)

	Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total
Balance as at December 31, 2020	40,678,323	$ 4,067	$ 2,840,599	$ (2,925,022)	$ (80,356)
Stock purchased by investors	398,097	40	398,057		398,097
Stock based compensation			111,487		111,487
Net loss				(683,681)	(683,681)
Balance as at March 31, 2021	**41,076,420**	**4,107**	**3,350,143**	**(3,608,703)**	**(254,453)**
Stock purchased by investors	263,376	27	263,349		263,376
Stock based compensation			86,329		86,329
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
Net loss				(534,852)	(534,852)
Balance as at June 30, 2021	**41,743,654**	**4,174**	**4,103,639**	**(4,143,555)**	**(35,742)**
Stock purchased by investors	190,000	20	189,980		190,000
Stock based compensation			55,051		55,051
Costs of stock sales			(70,994)		(70,994)
Net loss				(551,023)	(551,023)
Balance as at September 30, 2021	**41,933,654**	**$ 4,194**	**$ 4,277,676**	**$ (4,694,578)**	**$ (412,708)**

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
NINE MONTHS ENDED SEPTEMBER 30, 2020 (Unaudited)

	Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total
Balance as at December 31, 2019	38,915,056	$ 3,892	$ 867,301	$ (847,029)	$ 24,164
Stock purchased by investors	377,000	38	376,962		377,000
Stock based compensation			55,051		55,051
Net loss				(466,837)	(466,837)
Balance as at March 31, 2020	**39,292,056**	**3,930**	**1,299,314**	**(1,313,866)**	**(10,622)**
Stock purchased by investors	257,670	26	257,644		257,670
Stock based compensation			55,051		55,051
Net loss				(430,861)	(430,861)
Balance as at June 30, 2020	**39,549,726**	**3,956**	**1,612,009**	**(1,744,727)**	**(128,762)**
Stock purchased by investors	416,658	42	416,616		416,658
Stock based compensation			55,051		55,051
Retirement of due to Sanovas through the issuance of shares of common stock to Sanovas Ophthalmology LLC	358,126	36	358,090		358,126
Net loss				(567,098)	(567,098)
Balance as at September 30, 2020	**40,324,510**	**$ 4,034**	**$ 2,441,766**	**$ (2,311,825)**	**$ 133,975**

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

RETINALGENIX TECHNOLOGIES INC.
STATEMENTS OF CASH FLOWS (Unaudited)

	For The Nine Months Ended September 30,	
	2021	**2020**
Cash Flows From Operating Activities		
Net Loss	**$ (1,769,556)**	$ (1,464,796)
Stock based compensation expense	**252,867**	165,153
Costs and expenses paid on behalf of Company by Sanovas, net	**569,657**	236,739
Increase in accounts payable	**69,446**	12,282
Increase in accrued interest	**1,180**	-
Total Adjustments	**893,150**	414,174
Net cash used in operating activities	**(876,406)**	(1,050,622)
Cash Flows From Financing Activities		
Proceeds from common stock sold, net of costs	**824,265**	1,051,331
Proceeds from exercise of warrants	**13,500**	-
Proceeds from shareholder loans	**73,000**	-
Change in stockholders refund payable, net	**-**	(25,000)
Net cash provided by financing activities	**910,765**	1,026,331
Net increase (decrease) in cash	**34,359**	(24,291)
Cash at beginning of period	**2,219**	54,381
Cash at end of period	**$ 36,578**	$ 30,090
Supplemental information:		
Retirement of due to Sanovas to capital through the issuance of common stock to Sanovas Ophthalmology LLC (Note C)	**$ 390,358**	**$ 358,126**

The accompanying notes are an integral part of these 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. At September 30, 2021 and December 31, 2020, Sanovas Ophthalmology owns a majority of the outstanding stock of the Company. During the nine months ended September 30, 2021 and 2020, substantially all of the operations of the Company were conducted by Sanovas, who invoices the Company for reimbursement for services and costs performed on behalf of the Company.

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

In October 2021, the Company filed a registration 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 from 2019 through September 30, 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.

Liquidity and Going Concern

The Company expects that operating losses and negative cash flows from operations will occur for at least the next several years, and the Company will need to access additional funds to achieve its strategic goals with respect to the sublicensed technology. Sanovas has paid most of the Company's operating expenses through September 2021.

The Company commenced private offerings of shares of its common stock raising gross proceeds of approximately $1,395,000 in the year ended December 31, 2020, and $851,000 for the nine months ended September 30, 2021 - See Note D. The Company also issued shares of its common stock to offset amounts due to Sanovas for payment of bills on behalf of the Company of $390,358 in June 2021 and $358,126 in July 2020, respectively.

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

The Company will seek to raise substantial funds through the sale of common stock, through debt financing and/or through establishing strategic collaboration agreements. In February 2020, the Company entered into an agreement with an investment banker to support fundraising or strategic transactions. This agreement was terminated in March 2021. In February 2021, the Company entered into a new agreement with an investment banker to raise funds for the Company. The Company does not know whether additional financing will be available when needed, whether it will be available on favorable terms, or if it will be available at all. As of the date of this report, the Company does not have adequate resources to fund its operations through September 2022 without considering any potential future milestone payments that it may receive under any new collaborations that it may enter into in the future or any future capital raising transactions. These factors raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE B - SIGNIFICANT ACCOUNTING POLICIES

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

1. Basis of Presentation

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

2. Cash Equivalents

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

3. Deferred Offering Costs

Deferred offering costs are expenses directly related to an expected financing. These costs consisted of legal fees that the Company capitalized which will be offset against the proceeds upon completion of such future financing. During the quarter ended September 30, 2021, all such costs were charged against additional paid in capital for the funds raised during 2021.

4. Use of Estimates

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

NOTE B - SIGNIFICANT ACCOUNTING POLICIES - continued

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 September 30, 2021 or December 31, 2020. The Company's policy is to expense any penalties and interest associated with this topic. At September 30, 2021 and December 31, 2020, there were no amounts accrued for penalties and interest.

6. Income (Loss) Per Common Share

The Company computes net income (loss) per share in accordance with ASC 260, *Earnings Per Share* ("EPS"). Under the provisions of ASC 260, basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted-average number of common and common equivalent shares outstanding during the period. However, common shares that are considered anti-dilutive are excluded from the computation of diluted EPS. Since the Company had a loss during the nine months ended September 30, 2021 and 2020, the basic and diluted net loss per share are the same.

Potentially dilutive securities not included in the computation of loss per share for the nine months ended September 30, 2021 included 3,000,000 shares of Series F preferred stock, stock options to purchase 1,820,000 shares of common stock, and warrants to purchase 199,000 shares of common stock. Potentially dilutive securities not included in the computation of loss per share for the nine months ended September 30, 2020 included 3,000,000 shares of Series F preferred stock, stock options to purchase 1,800,000 shares of common stock, and warrants to purchase 62,500 shares of common stock. The shares of common stock potentially issuable to Diopsys upon the resolution of specified contingencies and exercise of stock options (which as of September 30, 2021 would have been approximately 4,193,000 shares) are also excluded from the loss per share calculation.

NOTE B - SIGNIFICANT ACCOUNTING POLICIES - continued

7. Stock-based compensation:

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

8. Research and Development costs:

Research and development costs are expensed as incurred.

9. Recent Accounting Pronouncements:

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

In August 2016, the FASB issued Accounting Standards Update ("ASU") 2016-15, *Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 is intended to reduce diversity in practice on how certain cash receipts and payments are presented and classified in the statement of cash flows. The standard provides guidance in a number of situations including, among others, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, and distributions received from equity method investees. ASU 2016-15 also provides guidance for classifying cash receipts and payments that have aspects of more than one class of cash flows. ASU 2016-15 is effective for the Company's fiscal year beginning January 1, 2019. The standard requires application using a retrospective transition method. The impact of adoption on the Company's financial statements was not significant.

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

NOTE C - RELATED PARTY TRANSACTIONS

The Company is related to Sanovas through common ownership and management. Commencing in 2019, Sanovas began paying invoices on behalf of the Company, and began allocating a portion of salaries and infrastructure costs to the Company and other entities where Sanovas was performing shared services. Included in such allocated costs is approximately $360,000 in costs related to an officer and consultant to the Company in both the nine months ended September 30, 2021 and 2020. The Company and Sanovas did not have specific terms of repayment. In June 2021 and July 2020, the Company issued 390,358 and 358,126 shares of common stock, respectively, to Sanovas Ophthalmology to retire the then estimated debt due from the Company.

NOTE C - RELATED PARTY TRANSACTIONS, continued

The following summarizes the transactions between the Company and Sanovas for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
Balance due from Sanovas – beginning of period	$ (15,069)	$ -
Costs paid by Sanovas on the Company's behalf	34,510	87,785
Costs of Sanovas allocated to the Company	750,639	1,248,154
Repayment of costs charged by Sanovas to the Company	(215,489)	(1,099,200)
Subtotal	554,591	236,739
Retirement of due to Sanovas through the issuance of 390,358 and 358,126 shares of common stock to Sanovas Ophthalmology, respectively	(390,358)	(358,126)
Balance due to Sanovas at September 30,	$ 164,233	$ (121,387)

Sublicense

On June 24, 2021, the Company entered into a sublicense agreement ("Sublicense Agreement") with Sanovas Ophthalmology pursuant to which Sanovas Ophthalmology granted the Company an exclusive worldwide ("Territory") license to certain intellectual property licensed to Sanovas Ophthalmology by Sanovas Intellectual Property LLC relating to certain technologies for eye and ocular visualization and monitoring ("Licensed IP") for uses related to the screening, examination, diagnosis, prevention and/or treatment of any eye disease, medical condition or disorder, or any disease, medical condition or disorder affecting the eye. Pursuant to the Sublicense Agreement, commencing on the date of the first commercial sale of a Licensed Product (as defined in the Sublicense Agreement), in each country in the Territory and continuing on a country by country basis until the expiration or termination of the last Valid Claim (as defined in the Sublicense Agreement) of a licensed patent in such country (the "Royalty End Date"), the Company shall pay Sanovas Ophthalmology a royalty equal to a mid-single digit percentage of any Net Sales (as defined in the Sublicense Agreement) of any Licensed Product. The Sublicense Agreement shall continue until the Royalty End Date, unless earlier terminated pursuant to its terms. The Sublicense Agreement may be terminated by either party if the other party materially breaches the Sublicense Agreement in a manner that cannot be cured, or materially breaches the Sublicense Agreement in a manner that can be cured and such breach remains uncured for more than 30 days after the receipt by the breaching party of notice specifying the breach. Furthermore, the Company may terminate the Sublicense Agreement at any time upon 90 days written notice to Sanovas Ophthalmology.

NOTE D - COMMON AND PREFERRED STOCK

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

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

In January 2020, a jury in the United States District Court for the Northern District of California found Mr. Gerrans guilty, in a criminal proceeding (the "Criminal Action"), on 12 felony counts of wire fraud, money laundering, perjury, contempt of court, witness tampering, and obstruction of justice in connection with his activities as an officer and director of Sanovas. Thereafter, in November 2020, Sanovas commenced an action in the Court of Chancery of the State of Delaware (the "Delaware Action") against Halo and Mr. Gerrans seeking an order declaring that any rights that Halo and/or Mr. Gerrans may have with respect to any equity securities in Sanovas and each of its affiliated subsidiaries (including, but not limited to, the Company) are void or voidable and may be cancelled. The Delaware Action is currently still pending. The Company intends 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. See Note H.

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, pursuant to which the Company sold an aggregate of 1,405,141 shares of its common stock during the year ended December 31, 2020. For the nine months ended September 30, 2021 and 2020, the Company sold and aggregate of approximately 851,000 and 1,051,000 shares of its common stock, respectively.

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

Preferred Stock

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

Voting Privileges and Protective Features:

Each holder of outstanding shares of Series F preferred stock is entitled to cast the number of votes equal to the number of whole shares of common stock into which the Series F preferred stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. The holders of record of a majority of outstanding Series F preferred stock shall be entitled to elect two of the members of the Board of Directors of the Company. The right to elect two directors shall terminate on the date upon which there are less than 25,000 shares of Series F preferred stock issued and outstanding.

For so long as at least 25,000 shares of Series F preferred stock remain outstanding, the vote or written consent of the holders of the majority of the outstanding shares of Series F preferred stock is necessary for the Company to conduct certain corporate actions, including, but not limited to, merger, consolidation or dissolution of the Company; certain amendments to the Certificate of Incorporation or bylaws of the Company; authorization or issuance of shares of any additional class or series of capital stock unless the same ranks on parity or junior to the Series F preferred stock with respect to voting rights.

Redemption:

The Series F preferred stock does not have redemption features.

Dividends:

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

Conversion:

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

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

NOTE E - STOCK PLAN

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

In November 2019, the Company issued stock options to purchase up to 1,800,000 shares of common stock at an exercise price of $1.00 per share to members of the Company's medical advisory board and consultants pursuant to the Plan. The options vest over a five year period and were unexercised at December 31, 2020 and September 30, 2021. The estimated aggregate fair value of the stock options was determined to be $1,101,028 using a Black Scholes model.

In the nine months ended September 30, 2021, the Company issued stock options to purchase up to 20,000 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 immediately and were unexercised at September 30, 2021. The estimated aggregate fair value of the stock options was determined to be approximately $12,200 using a Black Scholes model.

The Company recognized $252,867 and $165,153 of compensation expense during the nine months ended September 30, 2021 and 2020, respectively, related to all stock options and warrants (see Note F) which is included in the accompanying statements of operations. As of September 30, 2021, there was approximately $688,000 of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of approximately 2.9 years.

At September 30, 2021, there were 5,680,000 shares available to be issued under the Plan. The following table summarizes stock option activity of the Plan during 2021 and 2020:

	Options Issued	Weighted-Average Exercise Price
Options outstanding – December 31, 2019	1,800,000	$ 1.00
Granted	-	-
Canceled	-	-
Exercised	-	-
Options outstanding – December 31, 2020	1,800,000	1.00
Granted	20,000	1.00
Canceled	-	-
Exercised	-	-
Options outstanding – September 30, 2021	1,820,000	$ 1.00

NOTE E - STOCK PLAN (continued)

Additional information regarding the exercisable options and average remaining contractual life of the options outstanding as of September 30, 2021 is as follows:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable at December 31, 2020	Number Exercisable at September 30, 2021
$ 1.00	1,820,000	3.5 Years	405,000	605,000

The fair value of each option grant 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 2020:

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

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

NOTE F - WARRANTS

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

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

The risk-free interest rate assumption is determined using the yield currently available on U.S. Treasury zero-coupon issues with a remaining term commensurate with the expected term of the award. Management has estimated expected volatility based on similar comparable industry sector averages. Expected life of the option represents the period of time options are expected to be outstanding. The estimate for dividend yield is 0% because the Company has not historically paid, and does not intend to pay a dividend on its common stock in the foreseeable future. The Company recognized stock-based compensation expense of approximately $75,500 in the nine months ended September 30, 2021. At September 30, 2021, there is no remaining compensation expense to be recognized.

The following table summarizes warrant activity during 2021 and 2020:

	Warrants Issued	Weighted-Average Exercise Price
Warrants outstanding – December 31, 2019	62,500	$ 1.00
Granted	-	-
Canceled	-	-
Exercised	-	-
Warrants outstanding – December 31, 2020	62,500	$ 1.00
Granted	150,000	$ 1.10
Canceled	-	-
Exercised	(13,500)	$ 1.00
Warrants outstanding – September 30, 2021	199,000	$ 1.07

Additional information regarding the warrants outstanding as of September 30, 2021 is as follows:

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

NOTE G – INCOME TAXES

At December 31, 2020, the Company had net operating loss carryforwards ("NOL") of approximately $2,058,000 for federal income tax purposes of which $1,283,000 has no expiration date, $775,000 which begins to expire in 2034, and approximately $2,058,000 for state income tax purposes which begins to expire in 2030.

The resulting net deferred tax assets of approximately $788,000 and $232,000 at December 31, 2020 and December 31, 2019, respectively, has been fully reserved due to the uncertainty of future realization. The valuation allowance increased by approximately $556,000 and $232,000 at December 31, 2020 and 2019, 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 open years for tax examination are 2017 and thereafter.

NOTE H - SUBSEQUENT EVENTS

Subsequent events were reviewed through November 22, 2021, the date these financial statements were available for issuance.

From October 2021 through November 19, 2021, the Company sold 170,000 shares of its common stock at $1.00 per share pursuant to the offering described in Note D.

On November 21,2021, the Company's Board of Directors resolved to rescind the 3,000,000 shares of Series F preferred stock purported issued to Halo Management Group LLC for lack of contract consideration. The Company expects to record this action into the accounts of the Company in the fourth quarter of 2021.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 ab initio and adjust its filings accordingly if necessary.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. 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 included in our reports we file with the SEC. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

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

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

We anticipate that we will need an additional $5,000,000 to complete product design and testing for RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for U.S. Food and Drug Administration ("FDA") clearance as we anticipate that the RetinalCam™ will not require FDA clearance. We intend to obtain such funds through the sales of our equity and debt securities and/or through potential strategic partnerships; however, no assurance can be provided that funds will be available to us on acceptable terms, if at all.

We do not expect to generate any revenues from product sales unless and until we successfully complete development of RetinalCam™, and we do not expect to generate any revenues from product sales unless and until we successfully obtain regulatory clearance for RetinalGenix™. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses.

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

We have been issuing shares of our common stock pursuant to a private placement raising approximately $2.4 million from the sale of 2,441,000 shares of common stock from 2019 through September 30, 2021. In October 2021, the registration statement on Form S-1 (the "Registration Statement") that we filed with the U.S. Securities and Exchange Commission 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 pursuant to the Registration Statement.

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

Trends and Uncertainties—COVID-19

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

Basis of presentation:

These accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("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 shareholders.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table sets forth key components of our results of operations for the three months ended September 30, 2021 and 2020. Our activities to date have been limited based upon the availability of cash flow and availability of personnel/resources from Sanovas.

	Three Months Ended September 30,		
	2021	2020	Change
Revenue	**$ -**	**$ -**	
Expenses			
Administrative	293,893	413,151	(119,258)
Research and Development	200,899	98,896	102,003
Stock-based compensation	55,051	55,051	-
Total Operating Expenses	**549,843**	**567,098**	**17,255**
Loss from operations	**(549,843)**	**(567,098)**	**17,255**
Interest expense	**1,180**	**-**	**1,180**
Net Loss	**$ (551,023)**	**$ (567,098)**	**$ 16,075**

Revenues

We did not recognize revenues for the three months ended September 30, 2021 and September 30, 2020.

Research and Development Expenses

	Three Months Ended September 30,	
	2021	**2020**
Direct costs	$ 200,899	$ 71,986
Allocated costs from Sanovas	-	26,910
Total Research and Development expenses	$ 200,899	$ 98,896

Research and development expenses increased by $102,003, or 103%, to $200,899 for the three months ended September 30, 2021 from $98,896 for the three months ended September 30, 2020. The increase was primarily the result of an increase in prototype related expense, engineering and technology consultants, and pilot manufacturing.

Stock Based Compensation Expenses

Stock based compensation expenses remained constant in the three months ended September 30, 2021 and September 30, 2020. There were no stock options or warrants issued in the three months ended September 30, 2021 or September 30, 2020.

Administrative Expenses

	Three Months Ended September 30,	
	2021	**2020**
Direct costs	$ 64,902	$ 240,651
Allocated costs from Sanovas	228,991	172,500
Total Administrative expenses	$ 293,893	$ 413,151

Administrative expenses decreased by $119,258, or 29%, to $293,893 for the three months ended September 30, 2021 from $413,151 for the three months ended September 30, 2020. Executive salaries were $120,000 during the three months ended September 30, 2021 and 2020. Professional fees were approximately $47,000 during the three months ended September 30, 2021 as compared to $70,000 during the three months ended September 30, 2020, the decrease resulting from accounting and auditing services and legal services. The decrease in administrative expenses was primarily due to decrease in other salaries and operating costs allocated from Sanovas and reduced marketing costs. 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.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table sets forth key components of our results of operations for the nine months ended September 30, 2021 and 2020. Our activities to date have been limited based upon the availability of cash flow and availability of personnel/resources from Sanovas.

	Nine Months Ended September 30,		
	2021	2020	Change
Revenue	**$ -**	**$ -**	
Expenses			
Administrative	949,945	1,077,450	(127,505)
Research and Development	565,564	222,193	343,371
Stock-based compensation	252,867	165,153	87,714
Total Operating Expenses	**1,768,376**	**1,464,796**	**303,580**
Loss from operations	**(1,768,376)**	**(1,464,796)**	**(303,580)**
Interest expense	**1,180**	**-**	**1,180**
Net Loss	**$ (1,769,556)**	**$ (1,464,796)**	**$ (304,760)**

Revenues

We did not recognize revenues for the nine months ended September 30, 2021 and September 30, 2020.

Research and Development Expenses

	Nine Months Ended September 30,	
	2021	**2020**
Direct costs	$ 547,734	$ 136,051
Allocated costs from Sanovas	17,830	86,142
Total Research and Development expenses	$ 565,564	$ 222,193

Research and development expenses increased by $343,371, or 155%, to $565,564 for the nine months ended September 30, 2021 from $222,193 for the nine months ended September 30, 2020. The increase was primarily the result of an increase in prototype related expense, engineering and technology consultants, and pilot manufacturing.

Stock Based Compensation Expenses

Stock based compensation expenses increased by $87,714, or 53%, to $252,867 for the nine months ended September 30, 2021 from $165,153 for the nine month ended September 30, 2020. The increase was primarily due to the recognition of expense related to stock options issued in late 2020.

Administrative Expenses

	For The Nine Months Ended September 30,	
	2021	**2020**
Direct costs	$ 217,135	$ 528,038
Allocated costs from Sanovas	732,810	549,412
Total Administrative expenses	$ 949,945	$ 1,077,450

Administrative expenses decreased by $127,505, or 12%, to $949,945 for the nine months ended September 30, 2021 from $1,077,450 for the nine months ended September 30, 2020. The decrease in administrative expenses was primarily due to decreases of marketing and corporate legal, accounting and auditing expenses. Executive salaries were $360,000 during the nine months ended September 30, 2021 and 2020. Professional fees were approximately $127,000 during the nine months ended September 31, 2021 as compared to $80,000 during the nine months ended September 30, 2002, the increase resulting from additional accounting and auditing services and legal services. The decrease in administrative expenses was primarily due to decrease in other salaries and operating costs allocated from Sanovas and reduced marketing costs. Administrative costs consisting of costs related to executives and employees from Sanovas were allocated based upon the amount of effort spent by such personnel on our business.

Liquidity and Capital Resources

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

Cash Flow Activities for the Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30,	
	2021	**2020**
Net cash used in operating activities	$ (876,406)	$ (1,050,622)
Net cash used in/provided by investing activities	-	-
Net cash provided by financing activities	910,765	1,026,331
Net increase (decrease) in cash	**34,359**	**(24,291)**
Cash at beginning of period	**2,219**	**54,381**
Cash at end of period	**$ 36,578**	**$ 30,090**

Operating Activities

Net cash used in operating activities was $876,406 for the nine months ended September 30, 2021 and $1,050,622 for the nine months ended September 30, 2020. The cash flow used in operating activities was driven by the net loss of $1,769,556 offset in part by non-cash stock based compensation expense of $252,867 for the nine months ended September 30, 2021. The cash flow used in operating activities was driven by the net loss of $1,464,796 offset in part by non-cash stock based compensation expense of $165,153 for the nine months ended September 30, 2020. The net cash used in operating activities also driven by an increase in accounts payable and amounts due to Sanovas to fund the losses from operations in both periods.

Investing Activities

There was no cash used in or provided by investing activities for the nine months ended September 30, 2021 and 2020.

Financing Activities

Net cash provided by financing activities was $910,765 and $1,026,331 during the nine months ended September 30, 2021 and 2020, respectively, attributable primarily to the sale of common stock in both the 2021 and 2020 periods; and proceeds from the exercise of warrants and shareholder loans during the nine months ended September 30, 2021.

We anticipate that we will need $5,000,000 in operating capital to complete product design and testing for RetinalGenix™ and RetinalCam™ and submit RetinalGenix™ for FDA approval as we anticipate that the RetinalCam™ will not require FDA approval. We do not expect to generate any revenues from product sales unless and until we successfully complete development of RetinalGenix™ and RetinalCam™ and obtain regulatory approval for RetinalGenix™. We will also require additional operating capital as a result of us operating as a public company, including for legal, accounting, investor relations, compliance and other expenses.

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

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

Off-Balance Sheet Arrangements; Commitments and Contractual Obligations

As of September 30, 2021, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues, expenses, results of operations, liquidity, capital expenditures or capital resources, nor did we have any commitments or contractual obligations.

Critical Accounting Policies and Estimates

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

Stock Based Compensation

Stock based compensation represents the cost related to stock based awards granted to employees. We measure stock based compensation costs at the grant date, based on the estimated fair value of the award and recognize the cost (net of estimated forfeitures) over the vesting period. Forfeitures are estimated on the date of grant and revised if actual or expected forfeiture activity differs materially from the original estimates. We estimate the fair value of stock options using a Black-Scholes valuation model. The 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 continues through September 2021.

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

In August 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-15, *Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 is intended to reduce diversity in practice on how certain cash receipts and payments are presented and classified in the statement of cash flows. The standard provides guidance in a number of situations including, among others, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, and distributions received from equity method investees. ASU 2016-15 also provides guidance for classifying cash receipts and payments that have aspects of more than one class of cash flows. ASU 2016-15 is effective for our fiscal year beginning January 1, 2019. Early adoption is permitted. The standard requires application using a retrospective transition method. The impact of adoption on our financial statements was not significant.

See Note B of notes to the financial statements included in this Quarterly Report on Form 10-Q for details about other pronouncements not yet implemented.

JOBS Act

We are an "emerging growth company," as defined in Section 2(a) the Securities Act, as modified by the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies." For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1.07 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We are required to maintain disclosure controls and procedures (as defined in Rules 13a-15€ and 15d-15(e) of the Exchange Act) that are designed to be effective in providing reasonable assurance that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

In connection with the preparation of this Quarterly Report on Form 10-Q, 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 September 30, 2021.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We are considering various remediation measures, including hiring internal accounting resources or using outside providers to provide additional resources and capabilities as well as implementing a more formal accounting and financial reporting system to mitigate such material weakness, but have not yet adopted or implemented any such measures. When we have sufficient business activity and funding available, we intend to begin to implement remediation measures to address our material weakness and improve our internal control over financial reporting and disclosure controls and procedures. We hope to complete the implementation, remediation and test of the new procedures in the first half of 2022, as resources permit us to spend time and money on building finance infrastructure.

Management is actively engaged in the planning for, and implementation of, remediation efforts to address our material weakness and improve our internal control over financial reporting and disclosure controls and procedures. We are developing new procedures that we are implementing and testing in the fourth quarters of 2021, and we hope to complete the implementation, remediation and test of the new procedures by the end of the year.

Changes in Internal Controls over Financial Reporting

As of the September 30, 2021, there have been no changes in our internal controls over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

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

PART II – OTHER INFORMATION

ITEM 1. 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 expect to record 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 1A. RISK FACTORS.

Risks Relating to Our Business

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

We were incorporated in November 2017 and have a limited operating history, and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with development and expansion of a new business enterprise. Since inception, we have incurred losses and expect to continue to operate at a net loss for at least the next several years. Our net losses for the year ended December 31, 2020 and nine months ended September 30, 2021, were $2,077,993 and $1,769,556, respectively, and our accumulated deficit as of December 31, 2020 and September 30, 2021 was $2,925,022 and $4,694,578, respectively. There can be no assurance that the products under development by us will be cleared for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are cleared they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

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

We will need to continue to seek capital from time to time to continue development of our products and we cannot provide any assurances that any revenues they may generate in the future will be sufficient to fund our ongoing operations. We believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our products.

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

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

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

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

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

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

As of December 31, 2020 and September 30, 2021, we had cash of $2,219 and $36,578, respectively. In addition, as of December 31, 2020 and September 30, 2021, we had current liabilities of $141,432 and $449,286, 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, 2020 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

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

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

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

We rely on third-party suppliers to provide us with components that will be used in the products we are developing. For example, we rely on third-party suppliers to provide us with sensors which will be used in both RetinalGeniX^{TM} and RetinalCam^{TM}. Relying on third-party suppliers makes us vulnerable to component part failures or obsolescence and interruptions in supply including, but not limited to, as a result of COVID-19, either of which could impair our ability to develop our products in a timely manner. Vendor lead times to supply us with ordered components vary significantly and as a result of COVID-19 can exceed three months or more. We cannot be sure that our suppliers will furnish us required components when we need them or be able to provide us with sufficient components to support the development and manufacture of our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our future operations and successes depend in large part upon the strength of our management team. We rely heavily on the continued service of Jerry Katzman, our President and Chief Executive Officer. Accordingly, if Dr. Katzman terminates his employment with us, such a departure may have a material adverse effect on our business. Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified financial, managerial, technical and regulatory personnel. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Government Regulations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, which may include clinical trials that lead to the development of new products and new applications using our products. Our research and development process is expensive, prolonged, and entails considerable uncertainty. Due to the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully. In addition, our research and development process has been slowed by the impact of COVID-19, and should the COVID-19 economic restrictions worsen, it could delay and disrupt our research and development processes even further.

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

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

Risks Related to Owning our Securities

Our shares of common stock are not publicly traded and there can be no assurance that there will be an active market for our shares of common stock in the future.

Our shares of common stock are not currently publicly traded and timing for the commencement of trading is uncertain. An active trading market for shares of our common stock may never develop or be sustained if developed. If an active trading market does not develop, you may have difficulty selling your shares of common stock at an attractive price, or at all. An inactive market may also impair our ability to raise capital by selling our common stock, and it may impair our ability to attract and motivate our employees through equity incentive awards and our ability to acquire other companies, products or technologies by using our common stock as consideration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended ("Securities Act"), for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

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

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

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

As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and 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 the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act") 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 the quarter ended September 30, 2021 as a result of a material weakness in our internal controls due to the lack of segregation of duties. While management is working to remediate the material weakness, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

From July 1, 2021 to September 27, 2021, the Company issued an aggregate of 190,000 shares of its common stock for a purchase price of $1.00 per share.
The foregoing offers, sales and issuances were exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File - the cover page from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 is formatted in Inline XBRL

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

RETINALGENIX TECHNOLOGIES INC.

Date: November 22, 2021

By: */s/ Jerry Katzman*
Jerry Katzman,
Chief Executive Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Chief Executive Officer of RetinalGenix Technologies Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jerry Katzman, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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 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 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: November 22, 2021

/s/ Jerry Katzman

Jerry Katzman,
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer of RetinalGenix Technologies Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jerry Katzman, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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 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 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: November 22, 2021

/s/ Jerry Katzman

Jerry Katzman,
Principal Financial and Accounting Officer

Exhibit 32.1

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

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Jerry Katzman, Chief Executive Officer of RetinalGenix Technologies Inc. (the "Company"), hereby certifies that based on the undersigned's knowledge:

1. The Company's quarterly report on Form 10-Q for the period ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 22, 2021

/s/ Jerry Katzman

Jerry Katzman,
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Statement of Principal Financial Officer
Pursuant to Section 1350 of Title 18 of the United States Code

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

1. The Company's quarterly report on Form 10-Q for the period ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 22, 2021

/s/ Jerry Katzman

Jerry Katzman,
Principal Financial and Accounting Officer