

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549**

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2022

OR

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

For the transition period from _____ to _____

Commission file number: **001-41173**

NexGel, Inc.

(Exact name of registrant as specified in its charter)

Delaware <hr/> (State or other jurisdiction of incorporation or organization)	26-4042544 <hr/> (I.R.S. Employer Identification Number)
2150 Cabot Blvd West, Suite B Langhorne, PA <hr/> (Address of principal executive office)	19047 <hr/> (Zip Code)

Registrant's telephone number, including area code: **(215) 702-8550**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	NXGL	The Nasdaq Capital Market LLC
Warrants to Purchase Common Stock	NXGLW	The Nasdaq Capital Market LLC

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a nonaccelerated 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 by Rule 12b-2 of the Exchange Act).

Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2022, the last business day of the registrant's second fiscal quarter, was approximately \$7,524,481 based on the price at which the registrant last sold common equity.

As of March 27, 2023, the registrant had 5,611,282 shares of common stock outstanding.

Portions of the registrant's definitive proxy statement relating to its 2023 annual meeting of stockholders (the "2023 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2023 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the year to which this report relates.

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Basis of Presentation

On November 29, 2021, the Company effected a 1-for-35 reverse stock split of our issued and outstanding common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, each issued and outstanding share of our common stock, and the per share exercise price of and number of shares of the Company’s common stock underlying our outstanding equity awards and warrants, was automatically proportionally adjusted based on the 1-for-35 Reverse Stock Split ratio. No fractional shares of common stock were issued in connection with the reverse stock split, and all such fractional interests were rounded up to the nearest whole number.

Except as otherwise provided herein, all share and per-share amounts of our common stock, equity awards and warrants, including the shares of common stock and warrants being offered hereby, have been adjusted to give effect to the Reverse Stock Split for all years presented. The Reverse Stock Split did not alter the par value of the Company’s common stock, which remains at \$0.001 per share, modify any voting rights or other terms of our common stock, or impact the amount of preferred stock the Company is authorized to issue.

Forward-Looking Statements

This Annual Report on Form 10-K contains “forward-looking statements,” which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as “may,” “should,” “could,” “would,” “predict,” “potential,” “continue,” “expect,” “anticipate,” “future,” “intend,” “plan,” “believe,” “estimate,” and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management’s good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our ability to continue as a going concern;
- inadequate capital;
- inadequate or an inability to raise sufficient capital to execute our business plan;
- our ability to comply with current good manufacturing practices;
- loss or retirement of key executives;
- our plans to make significant additional outlays of working capital before we expect to generate significant revenues and the uncertainty regarding when we will begin to generate significant revenues, if we are able to do so;
- adverse economic and geopolitical conditions, including the current conflict in Ukraine, and/or intense competition;
- loss of a key customer or supplier;
- entry of new competitors;
- adverse federal, state and local government regulation;
- technological obsolescence of our manufacturing process and equipment;
- technical problems with our research and products;
- risks of mergers and acquisitions including the time and cost of implementing transactions and the potential failure to achieve expected gains, revenue growth or expense savings;
- price increases for supplies and components; and
- the inability to carry out our business plans.

For a discussion of these and other risks that relate to our business and investing in shares of our common stock, you should carefully review the risks and uncertainties described elsewhere in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

There may be other factors that may cause our actual results to differ materially from the forward-looking statements, including factors disclosed under the section titled and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this information statement. You should evaluate all forward-looking statements made in this information statement in the context of these risks and uncertainties.

No assurance can be given that any goal or plan set forth in any forward-looking statement can or will be achieved, and readers are cautioned not to place undue reliance on such statements which speak only as of the date they are made. We do not undertake any obligation to update or release any revisions to any forward-looking statement or to report any events or circumstances after the date of this information statement or to reflect the occurrence of unanticipated events, except as required by law.

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Our Company

We were incorporated in Delaware on January 13, 2009. We manufacture high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. We specialize in custom gels by capitalizing on proprietary manufacturing technologies. We have historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products and have recently began producing our own consumer products using our gels focused on proprietary branded products and white label opportunities. Both our gels and our consumer products are manufactured using proprietary and non-proprietary mixing, coating and cross-linking technologies. Together, these technologies enable us to produce gels that can satisfy rigid tolerance specifications with respect to a wide range of physical characteristics (e.g., thickness, water content, adherence, absorption, moisture vapor transmission rate (a measure of the passage of water vapor through a substance) and release rate) while maintaining product integrity. Additionally, we have the manufacturing ability to offer broad choices in the selection of liners onto which the gels are coated. Consequently, we and our customers are able to determine tolerances in moisture vapor transmission rate and active ingredient release rates while personalizing color and texture.

Contract Manufacturing Business

As described above, we have historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products. Our hydrogels are currently being marketed in the U.S. and abroad by our customers for the following applications:

- *Drug Delivery.* We believe delivering medication through hydrogel patches has important advantages over traditional methods of drug delivery. Hydrogel patches are less intrusive, painless, allow for pre-planned medication time periods, can potentially release medication in a manner consistent with the body's own glandular activity (by avoiding dosage spikes and/or digestive alteration), and minimize side effects related to the medication via injection or ingestion.
- *Other Medical Applications.* Hydrogel patches are being used for transdermal applications such as hormone replacement therapy and contraception, treatment of acne, shingles, diabetes, motion sickness, treatment of angina with nitroglycerin and treatment of smoking addiction using nicotine and palliatives (i.e., pain relievers).
- *Non-Prescription Therapeutic Applications.* Hydrogel patches are also used in the medical community and are also directly marketed to consumers for topical application of over the counter ("OTC") drugs such as non-prescription acne treatments, pain relievers, diet preparations, cough suppressants, treatment of warts, calluses and corns, and pain relief.
- *Moist Wound and Burn Dressings.* Hydrogel dressings have long been used for treating wounds and burns. Clinical trials have demonstrated the benefits of moist wound healing versus traditional dressings. Some of these benefits include immediate anti-inflammatory effects, allowing for freer cell flow and less scarring, increased absorption of exudate, and accelerated healing.
- *Components of Medical Devices.* Several medical devices utilize hydrogels as components. These devices include active drug delivery systems such as iontophoresis, warming and cooling devices, medical electrodes and various medical products for sensitive skin.
- *Cosmetic Applications.* Hydrogel patches and applications allow for delivery systems of cosmetic skin care products to consumers and skin care providers for uses that include moisturizers, face masks, cooling masks and applicators.

We believe our competitive advantage in each of the general hydrogel patch applications described above is that our hydrogel patches are gentler to the skin because we do not use chemical cross-linking agents which are incorporated into other hydrogel patches. In the past, we have not actively marketed our hydrogel or consumer products but recently hired two salespeople to focus on expanding our customer base and marketing efforts. Once the gels are manufactured according to a customer's specifications, the gels are generally shipped to the customer via a contract carrier (e.g., United Parcel Service, Inc.).

Our Facilities

We manufacture our hydrogels at what we believe to be one of only two facilities that can produce state-of-the-art hydrogel transdermal products and we have successfully used over two hundred active ingredients combinations in our hydrogels to date. Our facility consists of 13,500 square feet of manufacturing space, which we currently operate at only 5% capacity and can expand rapidly to meet increased demand, including for our healthcare and consumer product lines as described in more detail below. At full capacity, our facility should allow for us to produce approximately 1.4 billion square inches of product annually. Additionally, in 2021 we completed a \$650,000 facility accelerator upgrade which we believe will result in a more efficient manufacturing process. Our facility is subject to stringent FDA compliance requirements. We also believe our facility creates a high barrier to entry into our hydrogel and consumer product business.

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Consumer Products

Beginning in the third quarter of 2020, we began selling our own branded products using our hydrogel technology on the Amazon marketplace. In 2022 we expanded access to our products by launching our own direct to consumer website, Medagel.com. We currently have fourteen different product offerings, including multiple packaging configurations of the same product, which we market under the brand names MedaGel and LumaGel Beauty and intend to offer additional products in 2023 and beyond. The products we sell under our MedaGel brand primarily relate to over-the-counter (“OTC”) remedy solutions, such as blister and pain applications; while the products we sell under our LumaGel Beauty brand primarily relate to beauty and cosmetic solutions, such as wrinkle and skin cream applications.

Additionally, we have several more products in our development pipeline. We intend for these products to address various market opportunities including the OTC pharmaceutical drug delivery market, pain management, beauty and cosmetics, sports related applications, cannabinoids (CBD/THC) and general podiatry.

Custom and White Label Opportunities

We are also implementing a new strategy to leverage our hydrogel products and technologies by allowing other OTC brands to incorporate them into their products. We believe our hydrogels, which do not use chemical cross-linking agents or parabens but rather use electronic beam energy, will be attractive to other OTC brands, especially in the beauty and cosmetics industry, and their customers. We believe these white labeling opportunities will increase the markets’ awareness of us as a consumer-friendly and reliable supplier of customizable patches. Additionally, we created a process where customers have the ability to create their own custom hydrogel products. Customers pay a development fee, eliminating our financial risk in the success or failure of the custom product. As opposed to our contract manufacturing business, where we provide bulk sale of roll stock hydrogel to our customers who then use it as one component in their products which they themselves then manufacture, test, market and sell, our custom and white label business will provide customers with a finished product which they will then brand and re-sell.

Medical Devices

We have recently entered into the medical device development sector which a focus on analyzing, creating and developing devices and solutions that reduce skin pain and irritation, improve and maintain skin integrity and provide greater comfort and safety for patients at the site of which a medical device interfaces with the human body.

We conducted proof of concept studies for the development of our first medical device, which we call NEXDrape and have filed for a patent on this device under the Patent Cooperation Treaty which provides patent protection in the nations who are members of the treaty. The NEXDrape device is an incise surgical drape designed for patients with impaired skin. The elderly, diabetics, trauma patients and those with an adhesive sensitivity can have adverse events from the removal of adhesive drapes. Additionally, patients taking certain medications, such as ELIQUIS® and steroids, may experience impaired skin as well. These groups represent a sizable percentage of the incise surgical drape market, a market we believe to be significant and growing. The incise surgical drape market is currently fragmented with 3M Healthcare being the market leader. Skin tears, infections, rashes, and post-surgical site pain are some of the problems that can occur as a result of the removal of adhesive drapes, and have been reported with other currently available surgical drapes.

We have conducted one animal and two human cadaver proof of concept studies with respect to NEXDrape. As a result of these studies, we believe NEXDrape will represent a gentle to the skin alternative to the current adhesive based standard of care and will provide a unique solution for patients with fragile or compromised skin. Additionally, we believe NEXDrape offers the following benefits over the current incise surgical drape products: (i) no skin irritation; (ii) able to deliver a wide range of antiseptic and antibiotic agents; (iii) eliminates air bubbles; and (iv) prevents dermis removal post-surgery, which reduces the risk of patient infection and discomfort. We intend to file a 510(k) premarket submission with the Food and Drug Administration (FDA), which is an application to demonstrate that NEXDrape is as safe and effective (or substantially equivalent to) a legally marketed surgical drape device. There can be no guarantee that the FDA approves our application, if submitted.

We are also in the process of developing a product we call NEXDerm which will be an adhesive tape designed to secure central lines and intravenous tubes and devices to patients before, during and after medical treatment. We believe NEXDerm will be an attractive alternative to Tegaderm™, a 3M Healthcare product. Based on our discussion with medical professionals, Tegaderm™ is often difficult and painful to remove after adhesion, particularly for comprised skin patients. NEXDerm, which will incorporate exclusively licensed technology owned by Noble Fiber, is designed to create a gentle to skin surgical tape impregnated with antimicrobial X-Static® silver fiber. We believe NEXDerm, if successfully developed, will offer the following advantages over Tegaderm™: (i) ability to easily reposition the adhesive tape; (ii) pain-free removal; (iii) gentle to the skin; and (iv) increased infection prevention. As with NEXDrape, we intend to file a 510(k) premarket submission with the FDA to demonstrate that NEXDrape is as safe and effective (or substantially equivalent to) a legally marketed surgical drape device. There can be no guarantee that the FDA approves our application, if submitted.

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We are also in the early stages of exploring opportunities to develop a number of other potential medical devices. Our current intent with any medical devices will not be to commercialize due to the expense required but to potentially prepare them to go to market and to identify and pursue licensing and partnering arrangements with third parties possessing the necessary resources and capabilities to bring the devices to market.

Sales and Marketing

Contract Manufacturing, Consumer Products and Customer and White Label Offerings. We continue to focus on sales and marketing efforts in the United States. The Company has expanded their sales effort throughout 2022, including hiring a dedicated employee and contracting with individuals for business development exploration and sales effort. These individuals have been and will continue to focus on expanding contract manufacturing, consumer products and white label offering businesses.

Medical Devices. We do not intend to spend efforts or resources on selling or marketing our medical device business. Our current intent with any medical devices will not be to commercialize due to the expense required but to identify and pursue licensing arrangements with third parties possessing the necessary resources and capabilities to bring the devices to market.

Competition

Contract Manufacturing. To our knowledge, NexGel is one of three manufacturers using electron beam technology for high performance hydrogels for the wound care, cosmetic and drug delivery industries.

Consumer Products and Medical Devices. As we expand our consumer products and medical device business, we will face a number of competitors. Our competitors include numerous manufacturers; distributors; marketers; online, specialty, mass, and other retailers; and physicians that actively compete for the business of consumers both in the United States and abroad, including companies such as Johnson & Johnson, Pfizer Consumer Healthcare and Procter & Gamble. Most of our competitors have longer operating histories, significantly greater resources, better developed and more innovative sales and distribution channels and platforms, greater name recognition, and larger established customer bases than we do. Therefore, a strategic partnership will be critical to our success in the medical device business. We also face similar challenges with our own consumer branded products and may pursue similar strategic partnerships, though direct to consumer marketing and selling is more feasible.

Custom and White Label Offerings. As our custom and white label offering business will provide customers with a finished product which they will then brand and resell, the competition will depend, to a great deal, on the type of product the customer request and will not result in direct competition to us.

Sources and Availability of Raw Materials; Principal Suppliers

In general, raw materials essential to our business are readily available from multiple sources. For reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. The principal suppliers for our raw materials are Berry Global, Inc., DeWolf Chemical, Inc., and Univar, Inc. Our policy is to maintain sufficient inventory of components and raw materials so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time.

Because we have no direct control over these suppliers, interruptions or delays in the products and services provided by these parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary components or raw materials, we may be unable to redesign or adapt our technology to work without such components or raw materials or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs, quality control problems, and/or be unable to sell the applicable products, all of which could have a significant adverse impact on our revenue.

Other than as discussed above, we believe that, due to the size and scale of production of our suppliers, there should be an adequate supply of components and raw materials from our other suppliers.

Customers

During the year ended December 31, 2022 one major customer accounted for approximately 29% and during the year ended December 31, 2021, three major customers accounted for approximately 42% of our revenue. We cannot be certain as to this customer's intentions to use our services during and beyond the fiscal year ended December 31, 2022 since we do not currently have a contract with this customer. However, we have been supplying this customer for more than 15 years and have no reason to anticipate any change. Our contract manufacturing business, including with respect to this customer, operates on a purchase order basis.

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Patents, Proprietary Rights and Trademarks

We own or license trademarks covering our company and our products. We filed for a patent on NEXDrape under the Patent Cooperation Treaty which provides patent protection in the nations who are members of the treaty. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position. We also hold certain intellectual property that is not material to our current business and prospects, including patent rights to one patent in Europe, which covers the use of lignin for inhibiting restenosis and thrombosis formation, and coated medical devices where the coating includes lignin. This patent is set to expire in the near future, however we believe the expiration of these patents will not have an adverse impact on our overall business. In addition, in connection with our Spin-Off, we received an exclusive license with right to sub-license from Specialty Pharmaceutical Products, L.L.C. (which was held by Adynxx) to two issued patents, one in the U.S. and one in Europe, which cover technology relating to a transdermal patch containing transcutol. The transdermal patch is effective to deliver lidocaine to a patient. Neither of these patent rights are material to our current business and prospects. These licensed patent rights are expected to expire in April 2032.

Government Regulation

Product Regulation. Under the Federal Food, Drug and Cosmetic Act, medical devices are classified by the FDA into one of three classes - Class I, Class II or Class III - depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. While some applications of hydrogels fall under the jurisdiction of the FDA, hydrogels are generally classified as Class I exempt devices and the majority of the hydrogel products that we manufacture are thereby exempt from the FDA filing of any regulatory submissions and/or pre-market notification requirements. To the extent that any FDA regulatory submissions are required, we will be required to file these submissions and maintain all appropriate documentation. With respect to registering the manufacturing facility with the FDA under the Code of Federal Regulations, 21 CFR 820.1, Scope: Part A, it is stated that the regulation does not apply to manufacturers of component parts of finished devices. Currently, hydrogels are sold as component parts to various medical device/cosmetic manufacturers.

Quality Assurance Requirements. The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs and medical devices conform with current good manufacturing practice (CGMP). The CGMP regulations enforced by the FDA are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality and purity characteristics required of them. The CGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the Federal Food, Drug and Cosmetic Act. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA also conducts periodic inspections of drug and device registered facilities to assess their current CGMP status. If the FDA were to find serious non-compliant manufacturing or processing practices during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations, financial condition and cash flows. With respect to domestic establishments, the FDA could initiate product seizures or in some instances require product recalls and seek to enjoin a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with CGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an "unacceptable supplier", thereby disqualifying that company from selling products to federal agencies.

We conduct audits of our outside manufacturers and believe that we and our suppliers and outside manufacturers are currently in compliance with CGMP requirements. We are currently registered as a device manufacturer and distributor with the FDA and we intend to register as a drug facility with the FDA when we are required to do so.

Environmental Regulation. We are subject to various laws and governmental regulations concerning environmental matters and employee safety and health in the U.S. and other countries. We have made, and continue to make, significant investments to comply with these laws and regulations. We cannot predict the future capital expenditures or operating costs required to comply with environmental laws and regulations. We believe that we are currently compliant with applicable environmental, health and safety requirements in all material respects. However, we cannot assure you that current or future regulatory, governmental, or private action will not have a material adverse effect on our performance, results or financial condition.

In the future, if a loss contingency related to environmental matters, employee safety, health or conditional asset retirement obligations is recognized, we would record a liability for the obligation and it may result in a material impact on net income for the annual or interim period during which the liability is recorded. The investigation and remediation of environmental obligations generally occur over an extended period of time, and therefore we do not know if these events would have a material adverse effect on our financial condition, liquidity, or cash flow, nor can we assure you that such liabilities would not have a material adverse effect on our performance, results or financial condition.

Federal and State Anti-kickback, Self-referral, False Claims and Similar Laws. Our relationships with physicians, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. Certain states have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations. We believe that we are currently compliant with applicable anti-kickback, self-referral, false claims in all material respects.

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Research and Development Costs

For the years ended December 31, 2022 and 2021, we incurred approximately \$367 thousand and \$31 thousand, respectively, in research and development costs. We expect to incur increased costs in the future for our medical device business. Research and development will be an important component in the growth of our business.

Employees

As of December 31, 2022, we had 12 full-time employees. Of these employees, three are involved with finance, sales, marketing, and administration and nine are involved with manufacturing and regulatory matters. Our employees are not represented by a labor union or other collective bargaining groups, and we consider relations with our employees to be good. We currently plan to retain and utilize the services of outside consultants for additional research, testing, regulatory, accounting and tax services, legal compliance, and other services on an as needed basis.

Properties

We maintain a combined corporate office and manufacturing facility in Langhorne, Pennsylvania, where we lease approximately 16,500 square feet of office and manufacturing space. Our lease expires on January 31, 2031. We believe that our facility is well maintained and are suitable and adequate for our current needs.

Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholder of more than 5% of our common stock is an adverse party or has a material interest adverse to our interest.

Contractual Obligations

The Company is a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and is not required to provide the information under this item.

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Item 1A. Risk Factors

You should carefully consider the risks described below and elsewhere in this Annual Report on Form 10-K before making an investment decision. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Our common stock is considered speculative and the trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. The following risk factors are not the only risk factors facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business.

Risks Relating to Our Business

Our future success depends upon market acceptance of our existing and future products.

We believe that our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals and physicians and other health care providers, third-party payers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

Our suppliers may fail to deliver components and raw materials and parts according to schedules, prices, quality and volumes that are acceptable to us, or we may be unable to manage these components and raw materials effectively.

Our products contain materials and parts purchased globally from many suppliers, including single-source direct suppliers, which exposes us to potential component shortages or delays. Unexpected changes in business conditions, materials pricing, labor issues, wars such as the current conflict in Ukraine, trade policies, natural disasters, health epidemics, trade and shipping disruptions, port congestions and other factors beyond our or our suppliers' control could also affect these suppliers' ability to deliver components to us or to remain solvent and operational. Additionally, if our suppliers do not accurately forecast and effectively allocate production or if they are not willing to allocate sufficient production to us, it may reduce our access to components and raw materials, thus requiring us to search for new suppliers. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities, product design changes and loss of access to important technology and tools for producing and supporting our products. Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. While we believe that we will be able to secure additional or alternate sources for most of our components, there is no assurance that we will be able to do so quickly or at all.

As the scale of production of our products, we will also need to accurately forecast, purchase, warehouse and transport components at high volumes to our manufacturing facilities. If we are unable to accurately match the timing and quantities of component purchases to our actual needs or successfully implement automation, inventory management and other systems to accommodate the increased complexity in our supply chain and parts management, we may incur unexpected production disruption, storage, transportation and write-off costs, which may harm our business and operating results.

We are dependent on significant customers.

Our hydrogel manufacturing business is currently our sole source of revenue, and much of this revenue is generated from a limited number of clients, who account for a substantial percentage of our total revenues. For the year ended December 31, 2022, one major customer accounted for approximately 29% of our revenue. The loss of any of our significant customers would have a significantly negative effect on our overall operations.

We rely heavily on the Amazon marketplace for the sales and distribution of our consumer products, and if we are unable to maintain a good relationship with Amazon or if Amazon experiences disruptions, our business will suffer.

We rely heavily on the Amazon marketplace for the sales and distribution of our consumer products to our end consumers. We believe that we have good relationships with Amazon. However, if we or any of our partners, (or if Amazon believes we or any of our partners have violated) its terms of service, Amazon could limit or terminate its relationship with us. Any limitation or termination of our relationship with Amazon could materially adversely affect our business, financial condition and or results of operations. Additionally, any prolonged disruption of Amazon's website or its delivery and distribution of our consumer products could materially adversely impact our business.

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We have no contracts in place with our customers in either our contract manufacturing or consumer products business. The absence of such contracts could result in periods during which we must continue to pay costs without revenues.

Our sales are made on a purchase order basis, we do not have contracts with our customers in either our contract manufacturing or consumer products business. Accordingly, our customers are not required to purchase a minimum amount of our products, and we therefore could have periods during which we have no or limited orders for our products, which will make it difficult for us to operate as we will have to continue paying our expenses. We cannot provide assurance that we will be able to timely locate new customers, if at all, when our existing customers are not placing orders. The periods in which we have no or limited purchase orders for our products would have a material adverse effect on our business and financial condition.

We operate in a highly competitive industry.

Competition from other hydrogel manufacturers is intense. There can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete.

Our competitors enjoy several competitive advantages over us, including some or all of the following:

- large and established distribution networks in the U.S. and/or in international markets;
- greater financial, managerial and other resources for products, research and development, sales and marketing efforts and protecting and enforcing intellectual property rights;
- significantly greater name recognition;
- more expansive portfolios of intellectual property rights; and
- greater experience in obtaining and maintaining regulatory approvals and/or clearances from the FDA and other regulatory agencies.

Our competitors' products will compete directly with our products. In addition, our competitors, as well as new market entrants, may develop or acquire new products that will compete directly or indirectly with our products. The presence of this competition in our market may lead to pricing pressure which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

As we enter the consumer product business sector to a larger extent, our failure to compete successfully could materially harm our business, financial condition, and operating results.

The business of developing and marketing consumer and personal care products is highly competitive and sensitive to the introduction of new, competitive products, which may rapidly capture a significant share of the applicable market. Our competitors include numerous manufacturers; distributors; marketers; online, specialty, mass, and other retailers; and physicians that actively compete for the business of consumers both in the United States and abroad. Most of our competitors have longer operating histories, significantly greater resources, better-developed and more innovative sales and distribution channels and platforms, greater name recognition, and larger established customer bases than we do. Our present and future competitors may be able to better withstand reductions in prices or other adverse economic or market conditions than we can; develop products that are comparable or superior to those we offer; adapt more quickly or effectively to new technologies, changing regulatory requirements, evolving industry trends and standards, and customer requirements than we can; and/or devote greater resources to the development, promotion, and sale of their products than we do. In addition, because the industry in which we operate is not particularly capital intensive or otherwise subject to high barriers to entry, it is relatively easy for new competitors to emerge that will compete with us. Accordingly, competition may intensify, and we may not be able to compete effectively in our markets. If we are not able to compete successfully in the consumer products sector, our business, financial condition, and operating results would be materially adversely affected.

Our failure to appropriately respond to changing consumer trends, preferences, and demand for new products and product enhancements could materially harm our business, financial condition, and operating results.

Our consumer products business is subject to rapidly changing consumer trends and preferences and product introductions. Our success will depend in part on our ability to anticipate and respond to these changes and introductions, and we may not respond or develop new products or product enhancements in a cost-effective, timely, or commercially appropriate manner. The success of our new product offerings and enhancements depends on a number of factors, including our ability to:

- accurately anticipate consumer needs;
- innovate and develop new products and product enhancements that meet these needs;
- successfully commercialize new products and product enhancements;
- price our products competitively;
- manufacture and deliver our products in sufficient volumes and in a cost-effective and timely manner; and
- differentiate our product offerings from those of our competitors and successfully respond to other competitive pressures, including technological advancements, evolving industry standards, and changing regulatory requirements.

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Our failure to accurately predict changes in consumer demand and technological advancements could negatively impact consumer opinion of our products or our business. In addition, if we do not introduce new products or make enhancements to meet the changing needs of our customers in a cost-effective, timely, and commercially appropriate manner, or if our competitors release new products or product enhancements before we do, some of our product offerings could be rendered obsolete, which could cause our market share to decline and negatively impact our business, financial condition, and operating results.

If we fail to further penetrate existing markets, the sales of our consumer products, along with our operating results, could be negatively impacted.

The success of our consumer product business will be to a large extent contingent on our ability to penetrate existing markets, which is subject to numerous factors, many of which are out of our control. Moreover, our growth in existing markets will depend upon our ability to achieve brand awareness. Therefore, we cannot assure you that our general efforts to achieve market penetration in existing markets will be successful. If we are unable to further penetrate existing markets, our business, financial condition, and operating results could materially suffer.

We are subject to governmental regulations in all aspects of our business.

Like other companies in the healthcare industry, we are subject to extensive regulation, investigations and legal action, by national, state and local government agencies in the U.S. Regulatory issues regarding compliance with current Good Manufacturing Practices (cGMP) by manufacturers of medical devices and consumer products can lead to fines and penalties, product recalls, product shortages, interruptions in production, delays in new product approvals and litigation. In addition, the marketing, pricing and sale of our products are subject to regulation, investigations and legal actions including under the Federal Food, Drug, and Cosmetic Act, federal and state false claims acts, state unfair trade practices acts and consumer protection laws. Scrutiny of health care industry business practices by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties.

As we continue to develop our medical devices, if we fail to protect our intellectual property in the future, our ability to compete could be negatively affected, which could materially harm our financial condition and operating results.

As we continue to develop our medical devices, such as NEXDrape, our future success and the market for our products will depend to a significant extent upon the goodwill associated with our trademark and tradenames and our ability to protect our proprietary rights in our innovative products and product enhancements. We own, or have licenses to use, the material trademark and trade name rights used in connection with the packaging, marketing, and distribution of our products in the markets where those products are sold. Therefore, trademark and trade name protection are important to our business. Although most of our trademarks are filed in the United States, we may not be successful in asserting trademark or trade name protection or obtaining new trademark registrations.

We will attempt to protect our innovative products and product enhancements under a combination of patents, trademarks, and trade secret laws, confidentiality procedures, and contractual provisions. However, monitoring infringement or misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect every infringement or misappropriation of our proprietary rights or to prevent third parties from infringing upon or misappropriating our proprietary rights or from independently developing non-infringing products that are competitive with, equivalent to, or superior to our products. Even if we do detect infringement or misappropriation of our proprietary rights, litigation to enforce these rights could cause us to divert financial and other resources away from our business operations and may result in the impairment or loss of all or portions of our proprietary rights. As a result, we cannot assure you that we will be able to adequately protect our intellectual property in any jurisdictions. The loss or infringement of our trademarks or tradenames or other proprietary rights could impair the goodwill associated with our brands and harm our reputation, which could materially harm our business, financial condition, and operating results.

We have limited sales, marketing and distribution capabilities.

We currently have limited sales, marketing and distribution capabilities. We must either develop our own sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services for us. If we enter into third party arrangements, the third parties may not be capable of successfully selling any of our products. If we decide to market any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, our business and financial condition will be adversely affected.

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Our products risk exposure to product liability claims.

We are exposed to potential product liability risks, which are inherent in the testing, manufacturing and marketing of our products. We may incur significant expense investigating and defending any product liability claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

We are reliant upon two manufacturers for key ingredients of the manufacture of our hydrogels.

The Dow Chemical Company and the BASF Corporation are the principal manufacturers of the two polymers, polyethylene oxide and polyvinylpyrrolidone, respectively, that we primarily use in the manufacture of hydrogels. Although we have not experienced significant production delays attributable to supply changes, we believe that developing alternative sources of supply for the polymers used to make our current hydrogels would be difficult over a short period of time. Because we have no direct control over its third-party suppliers, interruptions or delays in the products and services provided by these third parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary raw materials or products, we may be unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs or quality control problems, which would have a material and adverse effect on our business, results of operations and financial condition.

There can be no assurance that our internal controls over financial reporting will be able to detect fraud or other issues.

We will be required under the Sarbanes-Oxley Act of 2002 to include a report of management on our internal controls that contains an assessment by management of the effectiveness of our internal control over financial reporting. Because and so long as we are an emerging growth company, our public accounting firm auditing our financial statements will not be required to report on the effectiveness of internal control over financial reporting, and our stockholders will not have the benefit thereof. Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. However, a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. There can be no assurance that all control issues or fraud will be detected. In connection with the Merger, and as we continue to grow our business, our internal controls continue to become more complex and require more resources.

Our ability to provide customers with competitive services is dependent on our ability to attract and retain qualified personnel, including our senior management team.

Our ability to grow and provide our customers with competitive services is partially dependent on our ability to attract and retain highly motivated people with the skills necessary to serve our customers. Personnel with the requisite skills or qualifications may be in short supply or generally unavailable. The loss of personnel could impair our ability to perform under certain contracts, which could have a material adverse effect on our consolidated financial position, results of operations, prospects and cash flows.

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial results or financial condition.

GAAP and related accounting pronouncements, implementation guidelines and interpretations with regard to a wide range of matters that are relevant to our business, including but not limited to revenue recognition, business combinations, impairment of goodwill, indefinite-lived intangible assets and long-lived assets, inventory and equity-based compensation, are highly complex and involve many subjective assumptions, estimates and judgments. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments could significantly change our reported or expected financial performance or financial condition.

Our ability to pursue strategic partnerships may impact our ability to compete in the markets we serve or desire to enter.

We have entered into, and expect to seek to enter into, additional strategic partnerships with other industry participants as part of an effort to expand our business. However, we may be unable to identify attractive strategic partnership candidates or complete such partnerships on terms favorable to us. In addition, if we are unable to successfully implement our partnership strategies or our strategic partners do not fulfill their obligations or otherwise do not prove advantageous to our business, our investments in such partnerships and our anticipated business expansion could be adversely affected.

Achieving our growth objectives may prove unsuccessful. We may be unable to identify future attractive strategic partnerships, which may adversely affect our growth. In addition, our ability to consummate or implement our strategic partnerships may be materially and adversely affected.

Risks Relating to our Common Stock and Capital Structure

An active trading market may not develop or be sustained, and our stock price may fluctuate significantly once we do trade.

Our common stock and certain of our warrants trade on The Nasdaq Capital Market under the symbols “NXGL” and “NXGLW,” respectively. However, prior to December, 2021 there has historically been no public market for our common stock and an active trading market for our common stock may not develop or may not be sustained in the future. The lack of an active market may make it more difficult for stockholders to sell our shares and could lead to our share price being depressed or volatile.

We cannot predict the prices at which our common stock may trade. The market price of our common stock may fluctuate widely, depending on many factors, some of which may be beyond our control, including:

- actual or anticipated fluctuations in our operating results due to factors related to our business;
- success or failure of our business strategies;
- our quarterly or annual earnings, or those of other companies in our industry;
- our ability to obtain financing as needed;
- announcements by us or our competitors of significant acquisitions or dispositions;
- changes in accounting standards, policies, guidance, interpretations or principles;
- the failure of securities analysts to cover our common stock after we commence trading;
- changes in earnings estimates by securities analysts or our ability to meet those estimates;
- the operating and stock price performance of other comparable companies;
- overall market fluctuations;
- results from any material litigation or government investigation;
- changes in laws and regulations (including tax laws and regulations) affecting our business;
- changes in capital gains taxes and taxes on dividends affecting stockholders; and
- general economic conditions and other external factors, including wars such as the current conflict in Ukraine and other geopolitical risks.

Furthermore, our business profile and market capitalization may not fit the investment objectives of some of our stockholders and, as a result, these stockholders may sell their shares of our common stock if we are able to list our common stock on The Nasdaq Capital Market. Substantial sales of our common stock may occur, which could cause our stock price to decline. Low trading volume for our stock, which may occur if an active trading market does not develop, among other reasons, would amplify the effect of the above factors on our stock price volatility.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock and warrants.

If we fail to continue to satisfy the continued listing requirements of The Nasdaq Stock Market, LLC such as the corporate governance requirements, the stockholder’s equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock and warrants. Such a delisting or even notification of failure to comply with such requirements would likely have a negative effect on the price of our common stock and warrants and would impair your ability to sell or purchase our common stock and warrants when you wish to do so. In the event of a delisting, we expect that we would take actions to restore our compliance with Nasdaq’s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock and warrants to become listed again, stabilize the market price or improve the liquidity of our common stock and warrants, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq’s listing requirements.

We cannot assure you that we will pay dividends on our common stock, and our indebtedness may limit our ability to pay dividends on our common stock.

The timing, declaration, amount and payment of future dividends to stockholders will fall within the discretion of our Board of Directors. Our Board of Directors’ decisions regarding the payment of future dividends will depend on many factors, including our financial condition, earnings, capital requirements of our business and covenants associated with debt obligations, as well as legal requirements, regulatory constraints, industry practice and other factors that our Board of Directors deems relevant. There can be no assurance that we will pay a dividend in the future or continue to pay any dividend if we do commence paying dividends.

The interests of our principal stockholders, officers and directors, who collectively beneficially own approximately 27% of our stock, may not coincide with yours and such stockholders will have the ability to control decisions with which you may disagree.

As of March 27, 2023, our principal stockholders, officers and directors beneficially owned approximately 27% of our common stock. As a result, our principal stockholders, officers and directors will have the ability to substantially influence matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company and make some future transactions more difficult or impossible without the support of our controlling stockholders. The interests of such stockholders may not coincide with your interests or the interests of other stockholders.

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If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results or prevent fraud and our business may be harmed and our stock price may be adversely impacted.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and to effectively prevent fraud. Any inability to provide reliable financial reports or to prevent fraud could harm our business. The Sarbanes-Oxley Act requires management to evaluate and assess the effectiveness of our internal control over financial reporting. In order to continue to comply with the requirements of the Sarbanes-Oxley Act, we are required to continuously evaluate and, where appropriate, enhance our policies, procedures and internal controls. If we fail to maintain the adequacy of our internal controls over financial reporting, we could be subject to litigation or regulatory scrutiny and investors could lose confidence in the accuracy and completeness of our financial reports. We cannot assure you that in the future we will be able to fully comply with the requirements of the Sarbanes-Oxley Act or that management will conclude that our internal control over financial reporting is effective. If we fail to fully comply with the requirements of the Sarbanes-Oxley Act, our business may be harmed and our stock price may decline.

If securities or industry analysts do not publish research about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock, to some extent, may at some point depend on the research and reports that securities or industry analysts publish about our business. We do not have any control over these analysts. If one or more of the analysts elect to cover us and downgrade our shares or lower their opinion of our shares, our share price would likely decline. If one or more of these analysts elect to cover us and subsequently cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Future sales or potential sales of our common stock in the public market could cause our share price to decline.

If the existing holders of our common stock, particularly our directors and officers, sell a large number of shares, they could adversely affect the market price for our common stock. Sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, could cause the market price of our common stock to decline.

We may issue additional securities in the future upon conversion or exercise of outstanding securities which would result in dilution to our stockholders.

As described elsewhere in this Form 10-K, we have previously issued warrants, restricted stock units, and stock options to fund our operations, pay for services rendered and incentivize our employees and directors. The conversion or exercise of these securities would result in substantial dilution to our stockholders. As of the date of the filing of this Form 10-K, we may be required to issue:

- 524,937 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$2.351416 per share;
- 3,637,190 shares of common stock issuable upon the exercise of warrants at a weighted average exercise price of approximately \$5.16281; and
- 90,432 shares of restricted common stock issuable upon vesting.

We are an “emerging growth company” and a “smaller reporting company” and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, and are subject to lesser public company reporting requirements applicable to smaller reporting 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 may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including 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 shareholder approval of any golden parachute payments not previously approved. 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 fifth anniversary of the Distribution; (iii) the date on which we have issued more than \$1.0 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 Exchange Act. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. In addition, we are a “smaller reporting company” and accordingly are required to provide less public disclosure than larger public companies. 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.

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

As a public reporting company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act and rules subsequently implemented by the SEC, have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will entail significant legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept low policy limits and coverage.

Provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and of Delaware law may prevent or delay an acquisition of our company, which could decrease the trading price of our common stock.

Several provisions of our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware law may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable. These include provisions that:

- permit us to issue blank check preferred stock as more fully described under “Description of Our Capital Stock Anti-Takeover Effects of Various Provisions of Delaware Law and Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws”;
- require stockholders to follow certain advance notice and disclosure requirements in order to propose business or nominate directors at an annual or special meeting; and
- limit our ability to enter into business combination transactions with certain stockholders.

These and other provisions of our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware law may discourage, delay or prevent certain types of transactions involving an actual or a threatened acquisition or change in control of us, including unsolicited takeover attempts, even though the transaction may offer our stockholders the opportunity to sell their shares of our common stock at a price above the prevailing market price. See “Description of Our Capital Stock Anti-Takeover Effects of Various Provisions of Delaware Law and Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws” for more information.

Our Amended and Restated Bylaws include a forum selection clause, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us.

Our Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any internal corporate claims within the meaning of the Delaware General Corporation Law (“DGCL”), (ii) any derivative action or proceeding brought on our behalf, (iii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or employees to us or to our stockholders, or (iv) any action asserting a claim arising pursuant to any provision of the DGCL, will be a state court located within the State of Delaware (or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware). Specifically, the sole and exclusive forum for such legal actions shall be (i) first, the Court of Chancery of the State of Delaware, (ii) second, if the Court of Chancery of the State of Delaware lacks jurisdiction, the Superior Court of the State of Delaware, or (iii) third, if the Superior Court of the State of Delaware lacks jurisdiction, the United States District Court for the District of Delaware, in all cases subject to the court’s having personal jurisdiction over the indispensable parties named as defendants. This exclusive forum provision will apply to state and federal law claims, including claims under the federal securities laws (including actions arising under the Exchange Act or the Securities Act), although our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act, however, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under federal securities laws. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing provisions. This forum selection provision in our bylaws may limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us. It is also possible that, notwithstanding the forum selection clause included in our bylaws, a court could rule that such a provision is inapplicable or unenforceable.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We maintain a combined corporate office and manufacturing facility in Langhorne, Pennsylvania, where we lease approximately 16,500 square feet of office and manufacturing space. Our lease expires on January 31, 2031. We believe that our facility is well maintained and are suitable and adequate for our current needs.

Item 3. Legal Proceedings

From time to time, we may become involved in lawsuits, investigations and claims that arise in the ordinary course of business. As of the date of this information statement, we are not a party to any litigation whereby the outcome of such litigation, if determined adversely to us, would materially affect our financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosure

Not applicable.

Part II

Item 5. Market for the Registrants Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on NASDAQ Capital Markets under the symbol “NXGL” and certain warrants to purchase our common stock issued on December 27, 2021 are traded on NASDAQ Capital Markets under the symbol “NXGLW.”

Holders

As of March 27, 2023, there were over 1,109 shareholders of record and 5,611,282 shares of common stock outstanding.

On November 29, 2021, we effected a 1-for-35 reverse stock split of our issued and outstanding common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, each issued and outstanding share of our common stock, and the per share exercise price of and number of shares of our common stock underlying our outstanding equity awards and warrants, was automatically proportionally adjusted based on the 1-for-35 Reverse Stock Split ratio. No fractional shares of common stock were issued in connection with the reverse stock split, and all such fractional interests were rounded up to the nearest whole number.

Sales of Unregistered Securities during the Fiscal Year Ended December 31, 2022

The Company did not sell any unregistered securities during the fiscal year ended December 31, 2022.

Issuer Repurchases of Securities during the Fiscal Year Ended December 31, 2022

The Company did not repurchase any of its securities during the fiscal year ended December 31, 2022.

Item 6. [Reserved]

The Company is a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and is not required to provide the information under this item.

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

The following discussion and analysis are intended to help prospective investors understand our business, financial condition, results of operations, liquidity and capital resources. You should read this discussion in conjunction with our financial statements and related notes thereto included elsewhere in this information statement.

The statements in this discussion regarding industry outlook, expectations regarding our future performance, liquidity and capital resources and other non-historical statements are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in “Special Note Regarding Forward-Looking Statements.” Actual results may differ materially from those contained in any forward-looking statements.

The NexGel Financial Statements, discussed below, reflect the NexGel financial condition, results of operations, and cash flows. The financial information discussed below and included in this information statement, however, may not necessarily reflect what the NexGel financial condition, results of operations, or cash flows would have been had NexGel been operated as a separate, independent entity during the years presented, or what the NexGel financial condition, results of operations, and cash flows may be in the future.

Overview

We manufacture high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. We specialize in custom gels by capitalizing on proprietary manufacturing technologies. We have historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products and have recently begun producing our own consumer products using our gels focused on proprietary branded products and white label opportunities. Both our gels and our consumer products are manufactured using proprietary and non-proprietary mixing, coating and cross-linking technologies. Together, these technologies enable us to produce gels that can satisfy rigid tolerance specifications with respect to a wide range of physical characteristics (e.g., thickness, water content, adherence, absorption, moisture vapor transmission rate [a measure of the passage of water vapor through a substance] and release rate) while maintaining product integrity. Additionally, we have the manufacturing ability to offer broad choices in the selection of liners onto which the gels are coated. Consequently, we and our customers are able to determine tolerances in moisture vapor transmission rate and active ingredient release rates while personalizing color and texture.

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2021 Initial Public Offering

On December 27, 2021, the Company sold an aggregate of 2,585,000 units at a price to the public of \$5.50 per unit (the “Offering”), each unit consisting of one share of the Company’s common stock and a warrant to purchase one share of common stock at an exercise price of \$5.50 per share.

Pursuant to the Offering, the Company received gross proceeds of approximately \$14.2 million, before deducting underwriting discounts and commissions of seven percent (7%) of the gross proceeds and estimated Offering expenses.

Results of Operations

The following sections discuss and analyze the changes in the significant line items in our statements of operations for the comparison years identified.

Year Ended December 31, 2022 Compared to the Year Ended December 31, 2021

Revenues, net

For the year ended December 31, 2022 revenues were \$2.05 million and increased by \$497 thousand, or 32.0%, when compared to \$1.55 million for the year ended December 31, 2021. The increase in our overall revenues was primarily due to sales growth in both our contract manufacturing and branded products.

The Company has four distinct lines of business; Contract Manufacturing, Custom & White Label, Consumer Branded Products, and Medical Devices.

Contract Manufacturing

Customers order rolls of gel (“rollstock”). The rollstock is shipped to our customers, which they package into finished goods. Historically, this has been the Company’s primary source of revenue.

Custom & White Label

These products often infuse various ingredients into our base gel to develop unique product offerings to satisfy market demand (e.g. aloe infused into the gel for a beauty mask). The rollstock is converted and packaged into salable units. The finished goods are shipped to the customer, who is ultimately responsible for product distribution. Frequently these products started as development deals, in which the customer paid the company a small fee to develop a specific product. Once completed, the customer places a large order for newly developed product.

Consumer Branded Products

These products are finished goods marketed and sold directly to the customer by the Company through online and retail channels. The Company is responsible for sales, marketing, and distribution. These products carry the Company’s brand names.

Medical Devices

Medical Devices are a hybrid business, combining elements of Custom & White Label and Consumer Branded Products. Medical Devices, which are not yet marketed, are expected to be distributed through strategic partnerships. The Company will manufacture and possibly convert/package the device while the strategic partner brings the product to market. Small market Medical Devices could be launched by the Company, but also be offered to a distributor to reach the full scale of the market.

Gross profit (loss) Our gross profit was \$256 thousand for the year ended December 31, 2022 compared to a gross profit of \$8 thousand for the year ended December 31, 2021. The increase in the profit recorded for the year ended December 31, 2022, as compared to December 31, 2021, was primarily due to the higher volume of contract manufacturing sales against fixed costs and lower manufacturing labor costs. Gross profit was approximately 12.5% for the year ended December 31, 2022 compared to a gross profit of 0.5% for the year ended December 31, 2021. The Company anticipates continued improvement in gross margins due to both increased revenue against fixed facility expenses and larger production runs on commercially proven products.

The components of cost of revenues are as follows for the years ended December 31, 2022 and 2021 (\$ in thousands):

	Year Ended December 31,	
	2022	2021
Cost of revenues		
Materials and finished products	\$ 541	\$ 520
Compensation and benefits	702	569
Depreciation and amortization	83	86
Equipment, production and other expenses	466	368
Total cost of revenues	\$ 1,792	\$ 1,543

Cost of revenues increased by \$249 thousand, or 16.14%, to \$1.8 million for the year ended December 31, 2022, as compared to \$1.5 million for the year ended December 31, 2021. The increase in cost of revenues is primarily aligned with the revenue growth in the current year.

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Selling, general and administrative expenses. The following table highlights selling, general and administrative expenses by type for the years ended December 31, 2022 and 2021 (\$ in thousands):

	Year Ended December 31,	
	2022	2021
Selling, general and administrative expenses		
Compensation and benefits	\$ 526	\$ 381
Share-based compensation	282	285
Depreciation and amortization	16	13
Advertising, marketing, & Amazon fees	436	320
Investor & shareholder services	567	429
Franchise taxes & corporate insurance	405	129
Professional and consulting fees	643	488
Other expenses and professional fees	362	502
Total selling, general and administrative expenses	\$ 3,237	\$ 2,547

Selling, general and administrative expenses increased by \$690 thousand, or 27.09%, to \$3.24 million for the year ended December 31, 2022, as compared to \$2.55 million for the year ended December 31, 2021. The increase in selling, general and administrative expenses is primarily attributable to an increase of franchise tax expense, increased research and development investment, and the costs for professional fees and other administrative expenses in the current year associated with public company governance requirements.

Compensation and benefits increased by \$145 thousand, or 38.06%, to \$526 thousand for the year ended December 31, 2022, as compared to \$381 thousand for the year ended December 31, 2021. The number of employees increased compared to the prior year and officer compensation increased in conjunction with contract renewals.

Share-based compensation decreased by \$3 thousand, or 1.1%, to \$282 thousand for the year ended December 31, 2022, as compared to \$285 thousand for the year ended December 31, 2021. The share-based compensation related to the issuance of restricted stock awards and options to our CEO, restricted stock awards to all employees and options to board members, employees, and advisors.

Advertising, marketing, Amazon fees increased by \$116 thousand, or 36.3%, to \$436 thousand for the year ended December 31, 2022, as compared to \$320 thousand for the year ended December 31, 2021. The increase is due to the increased Amazon selling fees as well as an increase in advertising and marketing.

Investor and shareholder services increased by \$138 thousand, or 32.2%, to \$567 thousand for the year ended December 31, 2022, as compared to \$429 thousand for the year ended December 31, 2021. The increase is due to the increase shareholder requirements in 2022 upon the IPO occurring on December 27, 2021.

Franchise taxes and corporate insurance increased by \$276 thousand, or 214.0%, to \$405 thousand for the year ended December 31, 2022, as compared to \$129 thousand for the year ended December 31, 2021. The exceptionally high franchise tax was due to the Company's IPO and the associated increase in gross assets. In August of 2022, the Company reduced its authorized shares at its annual meeting. The result of this reduction, assuming a similar asset base as the Company currently has, will reduce the 2023 franchise tax liability to approximately \$24 thousand.

Professional and consulting fees increased by \$155 thousand, or 31.8%, to \$643 thousand for the year ended December 31, 2022, as compared to \$488 thousand for the year ended December 31, 2021. We continued to incur accounting and consulting fees associated with public company governance requirements. However, the increase in professional fees compared to the prior year was in connection with our NASDAQ up-listing on December 27, 2021.

Other expenses decreased by \$140 thousand, or 27.9%, to \$362 thousand for the year ended December 31, 2022 from \$502 thousand for the year ended December 31, 2021. Other selling, general and administrative expenses generally consist of costs associated with our selling efforts and general management, including information technology, travel, training and recruiting.

Research and development expenses

Research and development expenses increased by \$336 thousand to \$367 thousand for the year ended December 31, 2022 from \$31 thousand for the year ended December 31, 2021. The increase is due to the initiation of two proof of concept studies for drug delivery candidates utilizing our hydrogel technology.

Liquidity and Capital Resources

Cash Flow (in thousands)

	Years Ended December 31,	
	2022	2021
Net cash used in operating activities	\$ (2,992)	\$ (2,753)
Net cash used in investing activities	(5,595)	(269)
Net cash provided by (used in) financing activities	(3,662)	16,340
Net increase (decrease) in cash and cash equivalents	(12,249)	13,318
Cash and cash equivalents at beginning of year	13,350	32
Cash and cash equivalent at end of year	\$ 1,101	\$ 13,350

As of December 31, 2022, we had \$1.1 million of cash and cash equivalents and \$5.5 million of marketable securities, compared to \$13.4 million of cash at December 31, 2021. Net cash used in operating activities was \$3.0 million and \$2.80 million for the years ended December 31, 2022 and 2021, respectively. See Notes 2 and 3 of our financial statements above for a more detailed discussion of our marketable securities.

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Net cash used in investing activities was \$5,595 thousand and \$269 thousand for the years ended December 31, 2022 and 2021, respectively, consisting of purchases of marketable securities of \$6,999 thousand, the sales of marketable securities of \$1,500 thousand, and purchases of capital equipment of \$96 thousand for year ended December 31, 2022 and purchases of capital equipment of \$269 thousand in the prior year.

Net cash used by financing activities for year ended December 31, 2022 was \$3.7 million which is attributable to the principal payments of convertible notes of \$3.5 million and payments of \$151 thousand made on the operating lease liability. Net cash provided by financing activities for the year ended December 31, 2021 was \$16.3 million which is primarily attributable to the issuance of common stock of \$13.5 million, proceeds from notes payable of \$142 thousand, proceeds from convertible notes of \$3.0 million offset by principal payments on convertible notes of \$100 thousand.

At December 31, 2022, current assets totaled \$7.5 million and current liabilities totaled \$859 thousand, as compared to current assets totaling \$13.9 million and current liabilities totaling \$2.9 million at December 31, 2021. As a result, we had working capital of \$6.6 million at December 31, 2022, compared to a working capital of \$11.0 million at December 31, 2021. The decrease in the working capital as of December 31, 2022 is primarily attributable to the repayment of convertible notes payable of \$3.5 million in the current year.

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, we anticipate that all available funds and any earnings generated in our business will be used to finance the growth of our business and will not be paid out as dividends to our shareholders. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our Board of Directors may deem relevant.

Management is exploring new product channel sales in consumer products, such as cosmetics, athletic products, and proprietary medical devices. The Company has increased its focus on sales and developing a sales pipeline for potential customers. This customer base expansion will enable us to provide financial stability for the foreseeable future, expand our current processes, and position us for long-term shareholder value creation.

We have sufficient capital to maintain as a going concern due to the capital raise that occurred on December 27, 2021 and we believe we have sufficient cash and marketable securities to operate our business plan through 2025. We intend to maintain and attempt to grow our existing contract manufacturing business. We also plan to continue building and developing our catalog of consumer products for sale to branding partners and to use our in-house capabilities to create and test market additional branded products. These products will be target marketed and sold online through social media, television and online marketplaces. Furthermore, the Company plans to develop its own proprietary medical devices and explore drug delivery programs for its technology. Additionally, the Company continues to evaluate strategic initiatives (e.g., acquisitions) and additional capital raises through debt or equity may be necessary to achieve these objectives.

We expect to continue incurring losses for the near-term future. Our ability to continue to operate as a going concern in the long term is dependent upon our ability to manage and grow our current products and to ultimately achieve profitable operations. Management may consider various options to raise capital to fund potential acquisitions through equity or debt offerings. There can be no assurances, however, that management will be able to obtain sufficient additional funds, if needed, or that such funds, if available, will be obtained on terms satisfactory to us. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should we be unable to continue as a going concern. Additionally, it is reasonably possible that estimates made in the financial statements have been, or will be, materially and adversely impacted in the near term as a result of these conditions, including the recoverability of long-lived assets.

Additionally, it is reasonably possible that estimates made in the financial statements have been, or will be, materially and adversely impacted in the near term as a result of these conditions, including the recoverability of long-lived assets.

Off Balance Sheet Arrangements

As of December 31, 2022, we had no off-balance sheet arrangements in the nature of guarantee contracts, retained or contingent interests in assets transferred to entities (or similar arrangements serving as credit, liquidity or market risk support to entities for any such assets), or obligations (including contingent obligations) arising out of variable interests in entities providing financing, liquidity, market risk or credit risk support to us, or that engage in leasing, hedging or research and development services with us.

Critical Accounting Policies and Estimates

The preparation of our Financial Statements in accordance with generally accepted accounting principles is based on the selection and application of accounting policies that require us to make significant estimates and assumptions about the effects of matters that are inherently uncertain. We consider the accounting policies discussed below to be critical to the understanding of our Financial Statements. Actual results could differ from our estimates and assumptions, and any such differences could be material to our Financial Statements.

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Share-based compensation – We utilize share-based compensation in the form of incentive stock options. The fair values of incentive stock option award grants are estimated as of the date of grant using a Black-Scholes option valuation model. Compensation expense is recognized in the statements of operations on a straight-line basis over the requisite service period, which is generally the vesting period required to obtain full vesting. The expected term of the awards granted is estimated using the simplified method which computes the expected term as the sum of the award's vesting term plus the original contractual term divided by two.

Warrant Liability – Warrants to purchase common stock were issued in connection with equity financing raises which occurred during 2019 through 2021. The fair values of the warrants are estimated as of the date of issuance and again at each year end using a Black-Scholes option valuation model. At issuance, the fair value of the warrant is recognized as an equity issuance cost within additional paid-in-capital. Fair value adjustments to the warrant liability are recognized in other income (expense) in the statements of operations. The expected term of the awards granted are based on either the three-year or five-year contractual expiration date.

Black Scholes Inputs - The fair value of each stock option award and warrant issued was estimated on the date of grant using a Black-Scholes option-valuation model, which requires management to make certain assumptions regarding: (i) fair value of the common stock that underlies the stock option; (ii) the expected volatility in the market price of our common stock; (iii) dividend yield; (iv) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected term). Under the Black-Scholes option-valuation model, entities typically estimate the expected volatility based on historical volatilities of the entity's own common stock. Based on the lack of historical data of volatility for the Company's common stock, the Company based its estimate of expected volatility on a weighted average of the historical volatility of comparable public companies that manufacture similar products and are similar in size, stage of life cycle, and financial leverage. The fair value of the common stock that underlies the stock option is estimated by the Company considering the price of the most recent issuance of the Company's common stock. The dividend yield is based upon the assumption that the Company will not declare a dividend over the life of the options. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for bonds with maturities consistent with the expected term of the related award.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

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Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders of
NexGel, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of NexGel, Inc. (the “Company”) as of December 31, 2022 and 2021, and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 and 2021, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Fair Value of Stock Options, Restricted Stock Units, and Warrants

Critical Audit Matter Description:

As discussed in Note 10 of the notes to consolidated financial statements, the Company uses the Black-Scholes option pricing model to estimate the fair value of its stock options, restricted stock units, and warrants issued for goods and services. The Black-Scholes option pricing model involves the use of several significant estimates such as the expected life of the award expected, expected share price volatility, dividend yield, and risk-free interest rate.

Given the significant estimates involved in estimating the fair value of stock options, restricted stock units, and warrants granted, the related audit effort in evaluating management’s estimates in determining the fair value of stock options required a high degree of auditor judgment.

How the Critical Audit Matter was Addressed in the Audit:

We obtained an understanding of the Company’s process to estimate the fair value of stock options, including how the Company develops each of the estimates required to utilize the Black-Scholes option-pricing model. We applied the following audit procedures related to testing the Company’s estimates utilized in the Black-Scholes option-pricing model:

- We reviewed the Company’s dividend history, noting the Company has not issued dividends historically and management indicated that no future dividends were currently anticipated.
- We compared the Company’s risk-free interest rate used to the comparable United States treasury yield for a term comparable to the stock options’, restricted stock units’, and/or warrants’ expected term.
- We recalculated the Company’s historical share price volatility for a term comparable to the stock options’, restricted stock units’, and/or warrants’ expected term.
- We recalculated the expected term of the stock options, restricted stock units, and/or warrants using the simplified method.

/s/ *Turner, Stone & Company, L.L.P.*

Dallas, Texas
March 27, 2023

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

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NEXGEL, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2022	2021
ASSETS:		
Current Assets:		
Cash	\$ 1,101	\$ 13,350
Marketable securities	5,508	-
Accounts receivable, net	222	209
Inventory	502	291
Prepaid expenses and other current assets	172	77
Total current assets	7,505	13,927
Goodwill	311	311
Intangibles, net	20	33
Property and equipment, net	721	723
Operating lease - right of use asset	1,737	1,926
Other assets	63	63
Total assets	<u>\$ 10,357</u>	<u>\$ 16,983</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 265	\$ 254
Accrued expenses and other current liabilities	130	62
Convertible notes payable, net of deferred financing costs	-	2,037
Notes payable, current portion	15	10
Warrant liability	242	318
Operating lease liability, current portion	207	207
Total current liabilities	859	2,888
Operating lease liability, net of current portion	1,593	1,744
Notes payable, net of current portion	268	266
Total liabilities	<u>2,720</u>	<u>4,898</u>
Commitments and Contingencies (Note 15)		
Preferred stock, par value \$0.001 per share, 5,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, par value \$0.001 per share, 25,000,000 shares authorized; 5,577,916 and 5,572,234 shares issued and outstanding as of both December 31, 2022 and 2021	6	6
Additional paid-in capital	19,189	18,891
Accumulated deficit	(11,558)	(6,812)
Total stockholders' equity	<u>7,637</u>	<u>12,085</u>
Total liabilities and stockholders' equity	<u>\$ 10,357</u>	<u>\$ 16,983</u>

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

NEXGEL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2022	2021
Revenues, net	\$ 2,048	\$ 1,551
Cost of revenues	1,792	1,543
Gross profit	256	8
Operating expenses		
Research and development	367	31
Selling, general and administrative	3,237	2,547
Total operating expenses	3,604	2,578
Loss from operations	(3,348)	(2,570)
Other income (expense)		
Change in fair value of warrant liability and warrant modification expense	76	8
Forgiveness of debt	-	275
Debt financing costs	-	(68)
Unrealized gain on investments in marketable securities	9	-
Loss on debt extinguishment	(150)	(25)
Interest expense	(1,336)	(1,930)
Other income	3	-
Total other income (expense)	(1,398)	(1,740)
Net loss	\$ (4,746)	\$ (4,310)
Net loss per common share – basic and diluted	\$ (0.85)	\$ (1.45)
Weighted average shares used in computing net loss per common share – basic and diluted	5,574,818	2,979,962

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

NEXGEL, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2022 and 2021
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, December 31, 2020	2,838,047	\$ 3	\$ 2,570	\$ (2,502)	\$ 71
Issuance of common stock, net of issuance costs	2,686,800	3	13,468	-	13,471
Restricted stock vesting	39,524	-	61	-	61
Beneficial conversion and warrant features of convertible debt	-	-	2,587	-	2,587
Exercise of stock options	7,183	-	-	-	-
Share-based compensation	-	-	223	-	223
Derivative liability - COVA	-	-	(18)	-	(18)
Share adjustment for stock split rounding	680	-	-	-	-
Net loss	-	-	-	(4,310)	(4,310)
Balance, December 31, 2021	<u>5,572,234</u>	<u>\$ 6</u>	<u>\$ 18,891</u>	<u>\$ (6,812)</u>	<u>\$ 12,085</u>
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, December 31, 2021	5,572,234	\$ 6	\$ 18,891	\$ (6,812)	\$ 12,085
Stock-based compensation	-	-	231	-	231
Restricted stock vesting	5,682	-	67	-	67
Net loss	-	-	-	(4,746)	(4,746)
Balance, December 31, 2022	<u>5,577,916</u>	<u>\$ 6</u>	<u>\$ 19,189</u>	<u>\$ (11,558)</u>	<u>\$ 7,637</u>

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

NEXGEL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2022	2021
Operating Activities		
Net loss	\$ (4,746)	\$ (4,310)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	112	113
Share-based compensation	298	285
Gain on investment in marketable securities	(9)	-
Changes in fair value of warrant liability	(133)	(8)
Warrant modification expense	57	52
Forgiveness of debt	-	(275)
Amortization of right of use asset	189	25
Loss of extinguishment of debt	150	25
Amortization of deferred financing costs	1,324	1,933
Changes in operating assets and liabilities:		
Accounts receivable, net	(13)	(137)
Inventory	(211)	(58)
Prepaid expenses and other current assets	(95)	63
Accounts payable	11	(405)
Accrued expenses and other current liabilities	74	(18)
Deferred revenue	-	(38)
Net Cash Used in Operating Activities	(2,992)	(2,753)
Investing Activities		
Purchases of equipment	(96)	(269)
Proceeds from sales of marketable securities	1,500	-
Investments in or Purchases of marketable securities	(6,999)	-
Net Cash Used in Investing Activities	(5,595)	(269)
Financing Activities		
Principal payments on operating lease liability	(151)	-
Issuance of common stock, net of issuance costs	-	13,471
Proceeds from notes payable	-	15
Proceeds from convertible notes	-	2,957
Payment of financing costs	-	(115)
Principal payments of notes payable	-	(15)
Principal payments on convertible notes	(3,511)	(100)
Proceeds from notes payable (PPP)	-	127
Net Cash Used in Financing Activities	(3,662)	16,340
Net Increase (Decrease) in Cash	(12,249)	13,318
Cash – Beginning of year	13,350	32
Cash – End of year	\$ 1,101	\$ 13,350
Supplemental Non-cash Investing and Financing Activities		
Fair value of beneficial conversion and warrant features of convertible notes payable	\$ -	\$ 2,587
Original issue discounts recognized on convertible notes payable	\$ -	\$ 653
Warrants issued for debt and equity financing costs	\$ -	\$ 203
Operating lease, ROU assets and liabilities	\$ -	\$ 2,050

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

NEXGEL, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

1. Description of Business, Stock Split and Basis of Presentation

NexGel, Inc. (“NexGel” or the “Company”) manufactures high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. The Company specializes in custom gels by capitalizing on proprietary manufacturing technologies. NexGel has historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products, and has recently began producing the Company’s own consumer products using our gels focused on proprietary branded products and white label opportunities. Both the Company’s gels and consumer products are manufactured using proprietary and non-proprietary mixing, coating and cross-linking technologies. Together, these technologies enable NexGel to produce gels that can satisfy rigid tolerance specifications with respect to a wide range of physical characteristics (e.g., thickness, water content, adherence, absorption, moisture vapor transmission rate (a measure of the passage of water vapor through a substance) and release rate) while maintaining product integrity. Additionally, the Company has the manufacturing capability to offer broad choices in the selection of liners onto which the gels are coated. Consequently, NexGel and our customers are able to determine tolerances in moisture vapor transmission rate and active ingredient release rates while personalizing color and texture.

NexGel was previously known as AquaMed Technologies, Inc. (“AquaMed”) before changing its name to NexGel, Inc. on November 14, 2019.

The accompanying consolidated financial statements include the accounts of the Company and its consolidated wholly-owned subsidiary, NexGelRx, Inc.

Stock Split

On November 29, 2021, the Company effected a 1-for-35 reverse stock split of our issued and outstanding common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, each issued and outstanding share of our common stock, and the per share exercise price of and number of shares of the Company’s common stock underlying our outstanding equity awards and warrants, was automatically proportionally adjusted based on the 1-for-35 Reverse Stock Split ratio. No fractional shares of common stock were issued in connection with the reverse stock split, and all such fractional interests were rounded up to the nearest whole number. Except as otherwise provided herein, all share and per-share amounts of our common stock, equity awards and warrants, including the shares of common stock and warrants being offered hereby, have been adjusted to give effect to the Reverse Stock Split for all years presented. The Reverse Stock Split did not alter the par value of the Company’s common stock, which remains at \$0.001 per share, modify any voting rights or other terms of our common stock, or impact the amount of preferred stock the Company is authorized to issue.

Basis of Presentation

The consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) and are presented in US dollars.

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2. Going Concern

As of December 31, 2022, the Company had a cash balance of \$1.1 million (including cash equivalents) and \$5.5 million of marketable securities (see Note 3 for details of our marketable securities). For the year ended December 31, 2022, the Company incurred a net loss of \$4.7 million and had a net usage of cash in operating activities of \$3.0 million. In addition, the Company had a working capital of \$6.6 million as of December 31, 2022. Additionally, we believe we have sufficient cash and marketable securities to operate our business plan through 2025.

On December 27, 2021, the Company sold an aggregate of 2,585,000 units at a price to the public of \$5.50 per unit (the “Offering”), each unit consisting of one share of the Company’s common stock and a warrant to purchase one share of common stock at an exercise price of \$5.50 per share, for net proceeds of \$14.2 million. Proceeds from the Offering have been and are expected to be used for working capital, new product development and testing, and general business operations.

Management is exploring new product channel sales in adjacent industries, such as cosmetics, athletic products, and proprietary medical devices. The Company has increased focus on sales and developing a sales pipeline for potential customers. This customer base expansion will enable us to provide financial stability for the foreseeable future, expand our current processes, and position us for long-term shareholder value creation.

We have sufficient capital to maintain as a going concern due to the capital raise that occurred on December 27, 2021. We intend to maintain and attempt to grow our existing contract manufacturing business. We also plan to continue building and developing our catalog of consumer products for sale to branding partners and to use our in-house capabilities to create and test market additional branded products. These products will be target marketed and sold online through social media, television and online marketplaces. Furthermore, the Company plans to develop its own proprietary medical devices and explore drug delivery programs for its technology. Additionally, the Company continues to evaluate strategic initiatives (e.g., acquisitions) and additional capital raises through debt or equity may be necessary to achieve these objectives.

We expect to continue incurring losses for the near-term future. Our ability to continue to operate as a going concern in the long-term is dependent upon our ability to manage and grow our current products and to ultimately achieve profitable operations. Management may consider various options to raise capital to fund potential acquisitions through equity or debt offerings. There can be no assurances, however, that management will be able to obtain sufficient additional funds, if needed, or that such funds, if available, will be obtained on terms satisfactory to us. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should we be unable to continue as a going concern. Additionally, it is reasonably possible that estimates made in the consolidated financial statements have been, or will be, materially and adversely impacted in the near term as a result of these conditions, including the recoverability of long-lived assets.

3. Significant Accounting Policies and Estimates

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. These estimates and assumptions include allowances for doubtful accounts, inventory reserves, deferred taxes, share-based compensation and related valuation allowances and fair value of long-lived assets. Actual results could differ from the estimates.

Reclassifications

We have reclassified, combined or separately disclosed certain amounts in the prior years’ consolidated financial statements and accompanying footnotes to conform with the current year’s presentation.

Cash

Cash is comprised of cash in banks and highly liquid investments, including U.S. treasury bills purchased with an original maturity of three months or less as well as investments in money market funds for which the carrying amount approximates fair value, due to the short maturities of these investments.

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Marketable Securities

The Company classifies its marketable securities as held-to-maturity, which include U.S. treasury bills with original maturities of greater than three months. These securities are carried at fair value with any change in fair value recorded as an unrealized gain (loss) in the statement of operations of the year in which such change occurs. The total unrealized gain related to the marketable securities was inconsequential during the year ended December 31, 2022. The Company had no marketable securities as of December 31, 2021.

	December 31, 2022
Marketable Securities	
United States treasury bills (due February 23, 2023)	\$ 492
United States treasury bills (due April 27, 2023)	20
United States treasury bills (due June 15, 2023)	4,384
United States treasury bills (due July 13, 2023)	127
United States treasury bills (due August 10, 2023)	485
Total	\$ 5,508

Accounts Receivable, net

Trade accounts receivable are stated at the amount the Company expects to collect and do not bear interest. The Company evaluates the collectability of accounts receivable and records a provision to the allowance for doubtful accounts based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowances for doubtful accounts are recorded in selling, general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered. The allowance for doubtful accounts was \$9 thousand as of December 31, 2022 and \$4 thousand as of December 31, 2021.

Inventory and Cost of Revenues

Inventory is stated at the lower of cost, the value determined by the first-in, first-out method, or net realizable value. The Company evaluates inventories for excess quantities, obsolescence, and shelf-life expiration. This evaluation includes an analysis of historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions, and a review of the shelf-life expiration dates for products. These factors determine when, and if, the Company adjusts the carrying value of inventory to estimated net realizable value.

The Company produces proprietary branded products and white label opportunities in our manufacturing of consumer products. In our contract manufacturing, the Company builds its products based on customer orders and immediately ships the products upon completion of the production process.

The balance is made up of raw materials, work-in-progress, and finished goods of \$295 thousand, \$51 thousand, and \$156 thousand on December 31, 2022, respectively, and the balance was made up of raw materials, work-in-progress, and finished goods of \$178 thousand, \$88 thousand, and \$25 thousand on December 31, 2021, respectively. Inventory is maintained at the Company's warehouse and at an Amazon fulfillment center.

The "Cost of revenues" line item in the consolidated statements of operations is comprised of the book value of inventory sold to customers during the reporting period. When circumstances dictate that we use net realizable value as the basis for recording inventory, we base our estimates on expected future selling prices less expected disposal costs.

Research and Development

Our research and development activities focus on new and innovative products designed to support revenue growth. Research and development expenses consist primarily of contracted development and testing efforts associated with development of products.

Shipping and Handling Revenue and Expense

Shipping and handling revenue and expense are included in our consolidated statements of operations in revenues and cost of revenues, respectively. This is primarily through shipping fees incurred in the Amazon marketplace.

Property and Equipment, net

Property and equipment is recorded at historical cost, net of accumulated depreciation and amortization. Depreciation is provided over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. Repairs and maintenance costs are expensed as incurred.

Management periodically assesses the estimated useful life over which assets are depreciated or amortized. If the analysis warrants a change in the estimated useful life of property and equipment, management will reduce the estimated useful life and depreciate or amortize the carrying value prospectively over the shorter remaining useful life.

The carrying amounts of assets sold or retired and the related accumulated depreciation are eliminated in the year of disposal and any resulting gains and losses are included in the results of operations during the same year.

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Impairment of Long-Lived Assets

The Company reviews its property and equipment and any identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted operating cash flow expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less costs to sell.

Goodwill and Intangible Assets

In applying the acquisition method of accounting, amounts assigned to identifiable assets and liabilities acquired were based on estimated fair values as of the date of acquisition, with the remainder recorded as goodwill. Identifiable intangible assets are initially recorded at fair value using generally accepted valuation methods appropriate for the type of intangible asset. Identifiable intangible assets with definite lives are amortized over their estimated useful lives and are reviewed for impairment if indicators of impairment arise. Intangible assets with indefinite lives are tested for impairment within one year of acquisitions or annually as of December 31, and whenever indicators of impairment exist. The fair value of intangible assets is compared with their carrying values, and an impairment loss would be recognized for the amount by which a carrying amount exceeds its fair value.

The Company performed the annual assessment and concluded it is more likely than not that the fair value exceeds the carrying value and no impairments were recognized in the years ended December 31, 2022 and 2021.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are recorded at historical cost and is primarily made up of \$63 thousand and \$23 thousand of prepaid insurance, and \$109 thousand and \$54 thousand general prepaid expenses and other current assets in the years ended December 31, 2022 and 2021 respectively.

Other Assets

Other Assets is recorded at historical costs, and as of December 31, 2022 and 2021, the balance is primarily comprised of spare parts for manufacturing equipment. Other assets are stated at cost and are not subject to depreciation, until such time that they are placed into service and the part that is being replaced is disposed.

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Fair Value Measurements

The Company utilizes the fair value hierarchy to apply fair value measurements. The fair value hierarchy is based on inputs to valuation techniques that are used to measure fair values that are either observable or unobservable. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources, while unobservable inputs reflect a reporting entity's pricing based upon its own market assumptions. The basis for fair value measurements for each level within the hierarchy is described below:

Level 1 —Quoted prices for identical assets or liabilities in active markets.

Level 2 —Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 —Valuations derived from valuation techniques in which one or more significant inputs to the valuation model are unobservable.

The Company considers the carrying amounts of its financial instruments (cash, accounts receivable and accounts payable) in the balance sheet to approximate fair value because of the short-term or highly liquid nature of these financial instruments.

The following table sets forth the fair value of the Company's financial assets within the fair value hierarchy:

	December 31, 2022			
	Level 1	Level 2	Level 3	Fair Value
Assets				
Marketable securities:				
United States treasury bills	\$ 5,508	\$ -	\$ -	\$ 5,508
Total	<u>\$ 5,508</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 5,508</u>

Warrant Liability

Warrants to purchase common stock were issued in connection with equity financing raises, which occurred during 2019 through 2021. The fair values of the warrants are estimated as of the date of issuance and again at each year end using a Black-Scholes option valuation model. At issuance, the fair values of the warrant are recognized as an equity issuance cost within additional paid-in-capital. Fair value adjustments to the warrant liability are recognized in other income (expense) in the statements of operations.

Revenue Recognition

On January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The Company adopted ASC 606 for all applicable contracts using the modified retrospective method, which would have required a cumulative-effect adjustment, if any, as of the date of adoption. The adoption of ASC 606 did not have a material impact on the Company's consolidated financial statements as of the date of adoption. As a result, a cumulative-effect adjustment was not required.

The Company currently recognizes revenue predominately from three types of revenue, contract manufacturing, custom and white label finished goods manufacturing and our branded products. Revenues from manufactured products are recognized at the point where the customer obtains control of the goods and the Company satisfies its performance obligation, which generally is at the time the customer receives the product.

The Company's customers consist of other life sciences companies and Amazon retail customers. Revenues are entirely concentrated in the United States. Payment terms vary by the type and location of customer and may differ by jurisdiction and customer but payment is generally required in a term ranging from 30 to 60 days from date of shipment.

Estimates for product returns, allowances and discounts are recorded as a reduction of revenue and are established at the time of sale. Returns are estimated through a comparison of historical return data and are determined for each product and adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have not been material. Amounts accrued for sales allowances and discounts are based on estimates of amounts that are expected to be claimed on the related sales and are based on historical data. Payments for allowances and discounts have historically been immaterial.

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Disaggregated revenue by sales type:

	Year Ended December 31,	
	2022	2021
Contract manufacturing	\$ 1,033	\$ 767
Custom and white label finished goods manufacturing	34	194
NexGel branded consumer products	815	488
Other	166	102
Total	\$ 2,048	\$ 1,551

As of December 31, 2022 and 2021, the Company did not have any contract assets or contract liabilities from contracts with customers and there were no remaining performance obligations that the Company had not satisfied.

The Company has four distinct lines of business; Contract Manufacturing, Custom & White Label, Consumer Branded Products, and Medical Devices.

Contract Manufacturing

Customers order rolls of gel (“rollstock”). The rollstock is shipped to our customers, which they package into finished goods. Historically, this has been the Company’s primary source of revenue.

Custom & White Label

These products often infuse various ingredients into our base gel to develop unique product offerings to satisfy market demand (e.g. aloe infused into the gel for a beauty mask). The rollstock is converted and packaged into salable units. The finished goods are shipped to the customer, who is ultimately responsible for product distribution. Frequently these products started as development deals, in which the customer paid the Company a small fee to develop a specific product. Once completed, the customer places a large order for newly developed product.

Consumer Branded Products

These products are finished goods marketed and sold directly to the customer by the Company through online and retail channels. The Company is responsible for sales, marketing, and distribution. These products carry the Company’s brand names.

Medical Devices

Medical Devices are a hybrid business, combining elements of Custom & White Label and Consumer Branded Products. Medical Devices, which are not yet marketed, are expected to be distributed through strategic partnerships. The Company will manufacture and possibly convert/package the device while the strategic partner brings the product to market. Small market Medical Devices could be launched by the Company, but also be offered to a distributor to reach the full scale of the market.

Share-based Compensation

On August 28, 2019, the Company adopted the 2019 Long-Term Incentive Plan, as amended (the “2019 Plan”). See Note 10 and note 18 below for further details regarding the 2019 Plan.

The 2019 Plan provides certain employees, contractors, and outside directors with share-based compensation in the form of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalent rights and other awards. The fair values of incentive stock option award grants are estimated as of the date of grant using a Black-Scholes option valuation model. Compensation expense is recognized in the statements of operations on a straight-line basis over the requisite service period, which is generally the vesting period required to obtain full vesting. Forfeitures are accounted for when they occur.

In June 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2018-07, *Compensation - Stock Compensation (Topic 718) - Improvements to Nonemployee Share-Based Payment Accounting*. These amendments expand the scope of Topic 718, *Compensation - Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This new standard was effective for the Company on January 1, 2020. The Company early adopted this new standard in the third quarter of 2019 and it did not have a material impact to its consolidated financial statements.

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Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement and tax bases of assets and liabilities at the applicable tax rates. Deferred tax assets are reduced by a valuation allowance when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates.

Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by a tax authority and based upon the technical merits of the tax position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement. An unrecognized tax benefit, or a portion thereof, is presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed.

Leases

ASC 842 requires recognition of leases on the consolidated balance sheets as right-of-use (“ROU”) assets and lease liabilities. ROU assets represent the Company’s right to use underlying assets for the lease terms and lease liabilities represent the Company’s obligation to make lease payments arising from the leases. Operating lease ROU assets and operating lease liabilities are recognized based on the present value and future minimum lease payments over the lease term at commencement date. As the Company’s leases do not provide an implicit rate, the Company used its estimated incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. A number of the lease agreements contain options to renew and options to terminate the leases early. The lease term used to calculate ROU assets and lease liabilities only includes renewal and termination options that are deemed reasonably certain to be exercised.

The Company recognized lease liabilities, with corresponding ROU assets, based on the present value of unpaid lease payments for existing operating leases longer than twelve months. The ROU assets were adjusted per ASC 842 transition guidance for existing lease-related balances of accrued and prepaid rent, and unamortized lease incentives provided by lessors. Operating lease cost is recognized as a single lease cost on a straight-line basis over the lease term and is recorded in selling, general and administrative expenses. Variable lease payments for common area maintenance, property taxes and other operating expenses are recognized as expense in the year when the changes in facts and circumstances on which the variable lease payments are based occur. The Company has elected not to separate lease and non-lease components for all property leases for the purposes of calculating ROU assets and lease liabilities.

Segment reporting

The Company operates in one business segment as a contract manufacturer of aqueous polymer hydrogels. As a result, the Company’s operations are a single reportable segment, which is consistent with the Company’s internal management reporting.

Comprehensive loss

Comprehensive loss consists of net loss and changes in equity during a year from transactions and other equity and circumstances generated from non-owner sources. The Company’s net loss equals comprehensive loss for all years presented.

Recently Issued Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position or results of operations upon adoption.

In June 2016, FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 significantly changes the impairment model for most financial assets and certain other instruments. ASU 2016-13 will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets, which will generally result in earlier recognition of allowances for credit losses on loans and other financial instruments. ASU 2016-13 is effective for the Company’s fiscal year beginning January 1, 2023 and subsequent interim periods. The Company is currently evaluating the impact the adoption of ASU 2016-13 will have on the Company’s consolidated financial statements.

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In January 2017, the FASB issued ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. ASU 2017-04 simplifies the manner in which an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Under the amendments in ASU 2017-04, an entity should (1) perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount, and (2) recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, with the understanding that the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, ASU 2017-04 requires any reporting unit with a zero or negative carrying amount to perform Step 2 of the goodwill impairment test. We adopted ASU 2017-04 effective January 1, 2021.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes. This guidance will be effective for entities for the fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 on a prospective basis, with early adoption permitted. We adopted ASU 2019-12 effective January 1, 2021 and the adoption of this guidance did not have a material impact on our consolidated financial statements.

4. Leases

The Company has one operating lease for a commercial manufacturing facility and administrative offices located in Langhorne, Pennsylvania that runs through January 2031. There are two options that can extend the lease term for five years each. The exercise of the lease options to renew is solely at the Company's discretion.

The following table presents information about the amount and timing of the liability arising from the Company's operating lease as of December 31, 2022 (\$ in thousands):

Maturity of Lease Liability	Operating Lease Liability
2023	\$ 207
2024	207
2025	207
2026	263
2027	274
Thereafter	890
Total undiscounted operating lease payments	\$ 2,048
Less: Imputed interest	(248)
Present value of operating lease liability	<u><u>\$ 1,800</u></u>
Weighted average remaining lease term	8.1 years
Weighted average discount rate	3.0%

Total operating lease expense for the year ended December 31, 2022 and 2021 was \$246 and \$233 thousand respectively, and is recorded in cost of revenues and selling, general and administrative expenses within the statements of operations.

Supplemental cash flows information related to leases was as follows (\$ in thousands):

	December 31, 2022
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	\$ 207

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5. Inventory

Inventory consists of the following (\$ in thousands):

	December 31, 2022	December 31, 2021
Raw materials	\$ 295	\$ 178
Work-in-progress	51	88
Finished goods	156	25
	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Less: Inventory reserve for excess and slow moving inventory	502	291
Total	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
	\$ 502	\$ 291

Inventory is maintained at the Company's warehouse, an outsourced third-party contract manufacturing vendor, and at Amazon fulfillment centers. The Company builds its contract manufacturing products based on customer orders and immediately ships the products upon completion of the production process.

6. Property and Equipment, Net

Property and equipment consist of the following (\$ in thousands):

	Useful Life (Years)	December 31, 2022	December 31, 2021
Machinery and equipment	3 - 10	\$ 973	\$ 940
Office furniture and equipment	3 - 10	59	50
Leasehold improvements	6	228	228
Construction in progress	N/A	55	-
		<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Less: accumulated depreciation and amortization		1,315	1,218
Property and equipment, net		<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
		\$ 721	\$ 723

Depreciation expense for the year ended December 31, 2022 and 2021 was \$99 thousand and \$99 thousand, respectively.

7. Intangible Assets

The following provides a breakdown of identifiable intangible assets as of December 31, 2022 and 2021 (\$ in thousands):

	December 31, 2022	December 31, 2021
Product/Technology Related		
Identifiable intangible assets, gross	\$ 31	\$ 31
Accumulated amortization	(26)	(16)
Product/Technology related identifiable intangible assets, net	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
	5	15
Marketing Related		
Customer related intangible asset, gross	17	17
Tradename related intangible asset, gross	7	7
Accumulated amortization	(9)	(6)
Marketing related identifiable intangible assets, net	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Total identifiable intangible assets, net	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
	\$ 20	\$ 33

In connection with the May 29, 2020 acquisition of Sports Defense, the Company identified intangible assets of \$55 thousand representing technology related and customer related intangibles. These assets are being amortized on a straight-line basis over their weighted average estimated useful life of 5.1 years and amortization expense amounted to \$13 thousand for the years ended December 31, 2022 and 2021.

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As of December 31, 2022, the estimated annual amortization expense for each of the next five fiscal years is as follows (\$ in thousands):

2023	\$ 8
2024	2
2025	2
2026	2
2027	2
Thereafter	4
Total	\$ 20

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (\$ in thousands):

	December 31, 2022	December 31, 2021
Salaries, benefits, and incentive compensation	\$ 56	\$ 54
Franchise tax accrual	52	-
Other	22	8
Total accrued expenses and other current liabilities	\$ 130	\$ 62

9. Common Stock

Share issuances

On December 27, 2021, the Company sold an aggregate of 2,585,000 units at a price to the public of \$5.50 per unit (the “Offering”), each unit consisting of one share of our common stock, and a warrant to purchase one share of our common stock at an exercise price of \$5.50 per share. In addition, the Company granted the Underwriter a 45-day option to purchase up to 387,750 additional shares of our common Stock, and/or 387,750 additional warrants, to cover over-allotments in connection with the Offering, which the Underwriter partially exercised to purchase 387,750 Warrants on the Closing Date.

From January 1, 2021 through March 31, 2021, the Company entered into securities purchase agreements with certain accredited investors whereby the Company sold 101,800 shares of our common stock at a price per share equal to \$2.80 for an aggregate purchase price of \$285 thousand.

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At December 31, 2022, the Company has reserved common stock for issuance in relation to the following:

Share-based compensation plan	524,937
Warrants to purchase common stock	3,637,190
Restricted stock units	90,432

10. Share-based Compensation

The 2019 Plan provides for the granting of incentive stock options, nonqualified stock options, restricted stock, stock appreciation rights (“SARs”), restricted stock units, performance awards, dividend equivalent rights and other awards, which may be granted singly, in combination, or in tandem, and which may be paid in cash, shares of common stock of the Company or a combination of cash and shares of common stock of the Company. The Company initially reserved a total of 57,143 shares of the Company’s common stock for awards under the 2019 Plan. Effective as of May 26, 2020 and May 3, 2021, respectively, the Board approved an increase of the number of authorized shares of common stock reserved under the 2019 Plan from 57,143 shares of common stock to 485,715 and from 485,715 shares of common stock to 571,429 shares of common stock, all of which may be delivered pursuant to incentive stock options. See Note 18 below relating the Board’s approval of an additional 300,000 shares of common stock to be reserved under the 2019 Plan, such that total of number of shares underlying the Plan is 871,429 of which 609,687 shares have already been awarded or exercised. Subject to adjustments pursuant to the 2019 Plan, the maximum number of shares of common stock with respect to which stock options or SARs may be granted to an executive officer during any calendar year is 14,286 shares of common stock.

The following table contains information about the 2019 Plan as of December 31, 2022:

	Awards Reserved for Issuance	Awards Issued	Awards Exercised	Awards Available for Grant
2019 Plan ⁽¹⁾	571,429	564,246	7,183	-
Awards issued in excess of 2019 Plan	-	45,441	-	-
Total	571,429	609,687	7,183	-

(1) includes incentive stock options and restricted stock units discussed below.

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Incentive stock options

On October 1, 2022, the Company appointed Dr. Neil Chesen to the Company's Scientific Advisory Board and in consideration for his appointment to the board, the Company granted Dr. Chesen an option to purchase up to 65,000 shares of common stock at a per share exercise price of \$2.00 under the Company's 2019 Long-Term Incentive Plan. A portion of the award, 15,000 options, fully vested as of the date of grant and the remaining 50,000 options are contingent upon certain sales based milestones being achieved. The options expire on December 31, 2023 if the milestones are not achieved prior to that date. Also on October 1, 2022, the Company issued a second option grant to Dr. Chesen, to purchase up to 25,000 shares of common stock at a per share exercise price of \$2.00 under the Company's 2019 Long-Term Incentive Plan and are fully contingent upon certain sales based milestones being achieved with 18 months of commercial release. Also on October 1, 2022, the Company issued a third option grant to Dr. Chesen to purchase up to 37,500 shares of common stock at a per share exercise price of \$5.50 under the Company's 2019 Long-Term Incentive Plan and are fully contingent upon certain sales based milestones being achieved within 36 months of commercial release. As of December 31, 2022 the new product has not launched.

On October 1, 2022, the Company granted Dr. Leonard Nelson an option to purchase up to 30,000 shares of the Company's common stock at a per share price of \$2.00 under the Company's 2019 Long-Term Incentive Plan. A portion of the award, 5,000 options, fully vested as of the date of the grant and the remaining 25,000 options are contingent upon certain sales based milestones being achieved. The options expire within 18 months of commercial launch of a new product if the milestones are not achieved prior to that date or 10 years from the grant date, whichever comes first. As of December 31, 2022 the new product has not launched.

On October 1, 2022, the Company granted Dr. Leonard Nelson an option to purchase up to 37,500 shares of the Company's common stock at a per share price of \$5.50 under the Company's 2019 Long-Term Incentive Plan. The options are contingent upon certain sales based milestones being achieved. The options expire within 36 months of commercial launch of a new product if the milestones are not achieved prior to that date or 10 years from the grant date, whichever comes first. As of December 31, 2022 the new product has not launched.

On January 15, 2021, the Company awarded a contractor options to purchase an aggregate of 14,286 shares of the Company's common stock at a per share exercise price of \$2.80 under the Company's 2019 Long-Term Incentive Plan. A portion of the award, 2,857 options, fully vested as of the date of grant and the remaining 11,429 options vested in November 2022.

On March 8, 2021, the Company granted Dr. Jerome Zeldis, a member of the Company Board, an option to purchase up to 19,048 shares of the Company's common stock at a per share exercise price of \$2.80 under the Company's 2019 Long-Term Incentive Plan. This option award fully vested as of the date of grant.

On March 8, 2021, the Company appointed Steven Glassman to the Board of Directors to serve for a term expiring at the next annual meeting of stockholders or until his successor is duly elected and qualified. On March 8, 2021 and in consideration for his appointment to the board of directors, the Company granted Mr. Glassman an option to purchase up to 14,286 shares of common stock at a per share exercise price of \$2.80 under the Company's 2019 Long-Term Incentive Plan. This option award fully vested as of the date of grant.

On September 2, 2021, the Company appointed Adam Levy, Yaakov Spinrad and Miranda J. Toledano to the Board of Directors to serve for a term expiring at the next annual meeting of stockholders or until their successor is duly elected and qualified. On September 9, 2021 and in consideration for each person's appointment to the board of directors, the Company granted each of Mr. Levy, Mr. Spinrad, and Ms. Toledano an option to purchase up to 14,286 shares of common stock at a per share exercise price of \$5.25 under the Company's 2019 Long-Term Incentive Plan. These option awards vested in four equal calendar quarter installments beginning on October 1, 2021.

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The following table summarizes the Company's incentive stock option activity and related information for the years ended December 31, 2022 and 2021.

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term in Years
Outstanding at January 1, 2021	387,318	\$ 1,124418	9.32
Granted	90,478	3.960526	10.00
Exercised	(7,183)	1.75	—
Forfeited	—	—	—
Cancelled	(28,571)	1.40	—
Expired	(7,103)	1.75	—
Outstanding at December 31, 2021	<u>434,939</u>	<u>\$ 1.678955</u>	<u>8.56</u>
Granted	195,000	\$ 3.3461538	10.00
Exercised	—	—	—
Forfeited	—	—	—
Cancelled	(100,001)	1.40000	—
Expired	(5,001)	1.40000	—
Outstanding at December 31, 2022	<u>524,937</u>	<u>\$ 2.351416</u>	<u>8.38</u>
Exercisable at December 31, 2022	<u>379,937</u>	<u>\$ 1.777020</u>	<u>7.86</u>

As of December 31, 2022 and 2021, vested outstanding stock options had \$124 thousand and \$408 thousand intrinsic value as the exercise price is greater than the estimated fair value of the underlying common stock, respectively. As of December 31, 2022, there was no unrecognized share-based compensation related to unvested stock options, excluding options fully contingent upon certain sales-based milestones being achieved within 18 to 36 months of commercial release.

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period. The following assumptions were used to calculate share-based compensation expense for year ended December 31, 2022 and 2021:

	2022	2021
Volatility	277.84%	171.12%-183.48%
Risk-free interest rate	4.06%	0.46% - 0.86%
Dividend yield	0.0%	0.0%
Expected term	5.0 years	5.0-5.75 years

The Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. Accordingly, the Company has elected to use the "simplified method" to estimate the expected term of its share-based awards. The simplified method computes the expected term as the sum of the award's vesting term plus the original contractual term divided by two.

Based on the lack of historical data of volatility for the Company's common stock, the Company based its estimate of expected volatility on a weighted-average of the historical volatility of comparable public companies that manufacture similar products and are similar in size, stage of life cycle, and financial leverage.

Restrictive stock awards

Effective as of August 1, 2022, the Company granted a restricted stock award of 84,750 shares of the Company's common stock to certain officers and employees, all of which shares vest in four equal installments on each of January 1, 2023, January 1, 2024, January 1, 2025 and January 1, 2026. Under ASC 718, *Compensation-Stock Compensation* ("ASC 718"), the Company has measured the value of the 84,750 shares granted based on a closing price of the closing price of the Company's stock at the grant date of the RSU Grant (\$1.82 per share).

Effective as of January 1, 2022, the Company granted a restricted stock award of 11,364 shares of the Company's common stock to Adam Levy for his service as our Chief Executive Officer pursuant to the terms of his Executive Employment Agreement dated November 4, 2021, all of which shares vested monthly from January 1, 2022 through December 31, 2022. Under ASC 718, the Company has measured the value of the 11,364 shares granted based on the closing price of the Company's stock at the grant date of the RSU Grant (\$4.40 per share).

On March 8, 2021, the Company granted a restricted stock award of 39,524 shares of the Company's common stock to Adam Levy for his service as our Chief Executive Officer and Chief Financial Officer from October 1, 2020 through September 30, 2021, all of which shares vested immediately. Under ASC 718, the Company has measured the value of the 39,524 shares granted based on the closing price of the Company's stock at the grant date of the RSU Grant (\$2.10 per share).

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	Number of Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	39,524	\$ 2.10
Granted	—	—
Exercised and converted to common shares	(39,524)	2.10
Forfeited	—	—
Outstanding at December 31, 2021	—	—
Granted	96,114	1.61
Exercised and converted to common shares	(5,682)	4.40
Forfeited	—	—
Outstanding at December 31, 2022	90,432	\$ 1.43
Exercisable at December 31, 2022	5,682	\$ 4.40

Under ASC 718, the Company has measured the value of its January 2022 award as if it were vested and issued on the grant date with a value of \$50 thousand based on the closing price of the Company's stock at the grant date of the RSU Grant (\$4.40 per share) and in August 2022 an additional issuance of 84,750 shares was granted based on a closing price of the closing price of the Company's stock at the grant date of the RSU Grant (\$1.82 per share).

Compensation expense will be recognized ratably over the total vesting schedule. The Company will periodically adjust the cumulative compensation expense for forfeited awards. Stock based compensation of \$89 thousand and \$285 thousand has been recorded for the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022, there was \$116 thousand unrecognized share-based compensation related to unvested RSUs, which the Company expects to recognize over the next 36 months.

Warrants

The following table shows a summary of common stock warrants for the years ended December 31, 2022 and 2021.

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Contractual Term in Years
Outstanding at December 31, 2020	210,500	\$ 0.85938	2.54
Granted	3,426,690	\$ 5.42717	4.98
Exercised	—	—	—
Forfeited	—	—	—
Cancelled	—	—	—
Expired	—	—	—
Outstanding at December 31, 2021	3,637,190	\$ 5.16281	4.63
Granted	—	—	—
Exercised	—	—	—
Forfeited	—	—	—
Cancelled	—	—	—
Expired	—	—	—
Outstanding at December 31, 2022	3,637,190	\$ 5.16281	3.65
Exercisable at December 31, 2022	3,637,190	\$ 5.16281	3.65

As of December 31, 2022 and 2021, vested outstanding warrants had \$114 thousand and \$372 thousand, respectively, intrinsic value as the exercise price is greater than the estimated fair value of the underlying common stock.

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11. Notes Payable

PPP Loan

On April 22, 2020, the Company, entered into a promissory note with PNC Bank, N.A. (“PNC Bank”), which provided for a loan in the amount of \$147,300 (the “PPP Loan”) pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act. On March 4, 2021, the Company received a second PPP Loan in the amount of \$127,400 under Phase II of the Paycheck Protection Program. On June 2, 2021, the Company received notice from PNC Bank that its initial loan of \$147,300 had been forgiven in its entirety by the Small Business Administration (“SBA”). On November 16, 2021, the Company received notice from PNC Bank that its second PPP loan of \$127,400 had been forgiven in its entirety by the SBA.

Economic Injury Disaster Loan

On May 28, 2020, the Company entered into the standard loan documents required for securing a loan (the “EIDL Loan”) from the SBA under its Economic Injury Disaster Loan (“EIDL”) assistance program in light of the impact of the COVID-19 pandemic on the Company’s business. Pursuant to that certain Loan Authorization and Agreement (the “SBA Loan Agreement”), the principal amount of the EIDL Loan is up to \$260,500, with proceeds to be used for working capital purposes. Interest accrues at the rate of 3.75% per annum. Installment payments, including principal and interest, are due monthly beginning May 28, 2021 (twelve months from the date of the SBA Note) in the amount of \$1,270. The balance of principal and interest is payable thirty years from the date of the SBA Note. In connection therewith, the Company received an \$8 thousand advance, which does not have to be repaid. On March 26, 2021, the SBA announced that all EIDL loans issued in 2020 will start repayment 24 months from the date of the SBA Note. The SBA has since extended the repayment start to 30 months from the date of the SBA Note. The Company made its first payment in December 2022. The balances of the principal and accrued interest amounted to \$283 thousand and \$276 thousand as of December 31, 2022 and 2021, respectively.

The future annual principal amounts and accrued interest to be paid as of December 31, 2022 are as follows:

	<u>Amount</u>
For the year ending December 31 (\$ in thousands):	
2023	\$ 5
2024	5
2025	5
2026	6
2027	6
Thereafter	256
Total	\$ 283

12. Convertible Notes Payable

On December 24, 2020, the Company issued a \$100 thousand 6% Secured Convertible Promissory Note which was convertible into shares of the Company’s common stock at a price per share of \$2.80. The note was fully repaid (including all accrued but unpaid interest) on March 14, 2021.

On January 19, 2021, the Company issued a \$15 thousand Secured Convertible Promissory Note which was convertible into shares of the Company’s common stock at a price per share of \$1.05. The note was fully-repaid (including all accrued but unpaid interest) on March 14, 2021.

On March 11, 2021, the Company issued Auctus Fund, LLC, a Delaware limited liability company a one-year senior secured convertible promissory note in the principal amount of \$1.68 million, which included \$180 thousand of interest which was deemed fully earned as of the issuance date (the “Auctus Note”). The Auctus Note was fully repaid (including all principal and interest) on March 15, 2022 with a one-time cash payment of \$1.68 million.

On September 2, 2021, the Company issued to certain holders one-year subordinated secured convertible promissory notes in the aggregate principal amount of \$1,814 thousand, which included \$194 thousand of interest which was deemed fully earned as of the issuance date (the “September 2 Notes”). On January 25, 2022, the Company repaid one of the September 2 Notes in full with a one-time cash payment of \$300 thousand of outstanding principal and accrued but unpaid interest. The Company incurred pre-payment penalty of \$17 thousand with respect to the repayment of the note and the remaining unamortized debt discount in the amount of \$133 thousand was written off and both amounts were recorded as a loss on extinguishment of debt of \$150 thousand in accompany statement of operations during 2022. The repayment extinguished the note in its entirety. On September 6, 2022, the outstanding balance on the remaining September 2 Notes’ was repaid in full which consisted of principal of \$1,478 thousand.

13. Warrant Liability

On September 2, 2021, March 11, 2021, February 3, 2021, December 24, 2020, March 18, 2020, September 10, 2019, and November 6, 2019, the Company issued 22,019, 34,285, 7,429, 7,286, 44,286, 35,714 and 114,286 warrants, respectively, as equity issuance consideration, in connection with a private placement of the Company’s common stock. The warrants entitle the holder to purchase one share of our common stock at an exercise price equal to \$0.49 to \$5.25 per share at any time on or after their issuance date and on or prior to the close of business 3 years after the issuance date (the “Termination Date”). The Company determined that these warrants are free standing financial instruments that are legally detachable and separately exercisable from the common stock included in the public share offering. Management also determined that the warrants required classification as a liability pursuant to ASC 815, *Derivatives and Hedging*. In accordance with the accounting guidance, the outstanding warrants are recognized as a warrant liability on the balance sheet and are measured at their inception date fair value and subsequently re-measured at each reporting period with changes being recorded as a component of other income (expense) in the statement of operations.

On September 6, 2022, the Company agreed to extend the September 10, 2019 and November 6, 2019 warrants an additional six months until March 9, 2023 and May 5, 2023, respectively. The warrants were remeasured as of September 6, 2022 and consequently resulted in a warrant modification expense of \$57 thousand.

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The warrants outstanding and fair values at each of the respective valuation dates are summarized below:

Warrant Liability	Warrants Outstanding	Fair Value per Share	Fair Value
Fair value as of year ended 12/31/2020	201,572		\$ 123
Fair value at initial measurement dates	63,733	\$ 3.2097	\$ 203
Change in fair value of warrant liability			(8)
Fair value as of year ended 12/31/2021	265,305		\$ 318
Modification of warrants	-		\$ 57
Change in fair value of warrant liability	-		(133)
Fair value as of year ended 12/31/2022	265,305		\$ 242

The warrant liabilities are considered Level 3 liabilities on the fair value hierarchy as the determination of fair value includes various assumptions about future activities and the Company's stock prices and historical volatility of other comparable public companies used as inputs. As of December 31, 2022, none of the warrants have been exercised.

The fair value of the warrant liabilities was measured using a Black-Scholes model. Significant inputs into the model at the inception are as follows:

Black -Scholes Assumptions	Exercise Price	Warrant Expiration Date	Stock Price ⁽⁸⁾	Interest Rate (annual)⁽⁹⁾	Volatility (annual)⁽¹⁰⁾	Time to Maturity (Years)	Calculated fair value per share	Future Estimated Quarterly Dividend per share⁽¹¹⁾
September 2, 2021 ⁽¹⁾	\$.0525	September 2, 2026	\$ 3.50	0.78%	182.74%	5.0	\$ 0.3325	\$ —
March 11, 2021 ⁽²⁾	\$ 4.375 – 5.25	March 11, 2026	\$ 3.50	0.17%	172.54%	5.0	\$ 0.3325- 0.0329	\$ —
February 3, 2021 ⁽³⁾	\$ 2.80	February 3, 2024	\$ 2.80	0.18%	171.71%	3.0	\$ 2.417461	\$ —
December 24, 2020 ⁽⁴⁾	\$ 2.80	December 24, 2023	\$ 2.80	0.17%	172.54%	3.0	\$ 2.422658	\$ —
March 18, 2020 ⁽⁵⁾	\$ 1.40	March 18, 2023	\$ 1.40	0.66%	137.41%	3.0	\$ 1.075547	\$ —
September 10, 2019 ⁽⁶⁾	\$ 0.49	September 10, 2022	\$ 0.49	1.61%	139.84%	3.0	\$ 0.38185	\$ —
November 6, 2019 ⁽⁷⁾	\$ 0.49	November 6, 2022	\$ 0.49	1.60%	138.48%	3.0	\$ 0.38255	\$ —

Significant inputs into the model at the reporting period measurement dates are as follows:

Black-Scholes Assumptions	Exercise Price	Warrant Expiration Date	Stock Price ⁽⁸⁾	Interest Rate (annual)⁽⁹⁾	Volatility (annual)⁽¹⁰⁾	Time to Maturity (Years)	Calculated fair value per share	Future Estimated Quarterly Dividend per share⁽¹¹⁾
December 31, 2022 ⁽¹⁾	\$.0525	September 2, 2026	\$ 1.25	4.22%	287.87%	3.68	\$ 0.0968371 0.096101	\$ —
December 31, 2022 ⁽²⁾	\$ 4.375 – 5.25	March 11, 2026	\$ 1.25	4.22%	288.66%	3.20	\$ 0.0957467	\$ —
December 31, 2022 ⁽³⁾	\$ 2.80	February 3, 2024	\$ 1.25	4.73%	352.74%	1.10	\$ 0.0690620	\$ —
December 31, 2022 ⁽⁴⁾	\$ 2.80	December 24, 2023	\$ 1.25	4.73%	331.00%	0.98	\$ 0.0681813	\$ —
December 31, 2022 ⁽⁵⁾	\$ 1.40	March 18, 2023	\$ 1.25	4.42%	147.61%	0.22	\$ 0.0296661	\$ —
December 31, 2022 ⁽⁶⁾	\$ 0.49	September 10, 2022	\$ 1.25	4.42%	137.02%	0.35	\$ 0.0091855	\$ —
December 31, 2022 ⁽⁷⁾	\$ 0.49	November 6, 2022	\$ 1.25	4.42%	149.27%	0.18	\$ 0.0085006	\$ —

Black-Scholes Assumptions	Exercise Price	Warrant Expiration Date	Stock Price ⁽⁸⁾	Interest Rate (annual)⁽⁹⁾	Volatility (annual)⁽¹⁰⁾	Time to Maturity (Years)	Calculated fair value per share	Future Estimated Quarterly Dividend per share⁽¹¹⁾
December 31, 2021 ⁽¹⁾	\$.0525	September 2, 2026	\$ 3.50	0.98%	205.16%	4.67	\$ 0.0968371 0.096101	\$ —
December 31, 2021 ⁽²⁾	\$ 4.375 – 5.25	March 11, 2026	\$ 3.50	0.98%	205.16%	4.19	\$ 0.0957467	\$ —

December 31, 2021 ⁽³⁾	\$ 2.80	February 3, 2024	\$ 2.80	0.28%	205.16%	2.09	\$ 0.0690620	\$ —
December 31, 2021 ⁽⁴⁾	\$ 2.80	December 24, 2023	\$ 2.80	0.28%	205.16%	1.98	\$ 0.0681813	\$ —
December 31, 2021 ⁽⁵⁾	\$ 1.40	March 18, 2023	\$ 1.40	0.28%	205.16%	1.21	\$ 0.0296661	\$ —
December 31, 2021 ⁽⁶⁾	\$ 0.49	September 10, 2022	\$ 0.49	0.09%	205.16%	0.69	\$ 0.0091855	\$ —
December 31, 2021 ⁽⁷⁾	\$ 0.49	November 6, 2022	\$ 0.49	0.19%	205.16%	0.85	\$ 0.0085006	\$ —

(1) Based on the terms provided in the warrant agreement related to the issuance of common stock of on September 2nd, 2021

(2) Based on the terms provided in the warrant agreement related to the issuance of common stock of on March 11th, 2021

(3) Based on the terms provided in the warrant agreement related to the issuance of common stock of on February 3rd, 2021

(4) Based on the terms provided in the warrant agreement related to the issuance of common stock of on December 24th, 2020

(5) Based on the terms provided in the warrant agreement related to the issuance of common stock of on March 18th, 2020

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- (6) Based on the terms provided in the warrant agreement related to the issuance of common stock of on September 10th, 2019
- (7) Based on the terms provided in the warrant agreement related to the issuance of common stock of on November 6th, 2019
- (8) Based on the observable transaction value of common stock of per the most recent stock issuance financing agreements.
- (9) Interest rate for U.S. Treasury Bonds, as of the issuance dates and each presented year ended date, as published by the U.S. Federal Reserve.
- (10) Based on the historical daily volatility of guideline public companies in the healthcare industry and each presented year ended date.
- (11) Current estimated dividend payments beyond initial four quarters. At a future date, the Company will review the working capital needs and make a final determination of any future dividend payments.

14. Commitments and Contingencies

Litigation

The Company may be subject to legal proceedings and claims that arise in the ordinary course of business. Management is not currently aware of any matters that will have a material effect on the financial position, results of operations, or cash flows of the Company.

15. Concentrations of Risk

The Company's revenues are concentrated in a small group of customers with some individually having more than 10% of total revenues.

For the year ended December 31, 2022, the Company had revenue from one customer that approximated 29% of total revenue. The Company had three customers with accounts receivable balances that approximated 40%, 22% and 18% of total accounts receivable as of December 31, 2022.

Revenues from three customers that exceeded 10% of total revenues for the year ended December 31, 2021 were 15% and 14% and 13%. The Company had three customers with accounts receivable balances approximating 45%, 20%, and 12% of total accounts receivable as of December 31, 2021.

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. Cash balances are maintained principally at major U.S. financial institutions and are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. Such cash balances are currently in excess of the FDIC insurance limit of \$250 thousand. As of December 31, 2022, the total amount exceeding such limit was \$501 thousand. The Company has not experienced any credit losses associated with its cash balances in the past. The Company invests its cash equivalents in U.S. treasury bills with original maturities of three months or less.

Marketable securities are comprised of U.S. treasury bills with original maturities greater than three months. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash, cash equivalents, and marketable securities and performs periodic evaluations of the credit standing of such institutions.

16. Related Party Transactions

Convertible Promissory Note

On December 24, 2020, the Company issued two Secured Convertible Promissory Notes in an aggregate amount of \$100,000 to Mr. Stein, a member of the board of directors and an entity affiliated to Mr. Stein, N&F Trust 774 (See Note 12). The notes were repaid in March, 2021.

On September 2, 2021, the Company issued three Secured Convertible Promissory Notes to members of the board of directors in an aggregate amounts of \$150,000 to Mr. Stein, \$150,000 to Mr. Stefansky (Bezalel Partners, LLC), and \$50,000 to Dr. Zeldis as part of the September 2 Notes. The notes were repaid in full in 2022 (See Note 12).

Advances

Dr. Jerome Zeldis, a member of the Company board of directors, has an outstanding balance due of \$40,000 for services as of December 31, 2022 and 2021, included in accounts payable in the accompanying consolidated balance sheets.

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17. Income Taxes

The Company has established a full valuation allowance for its deferred tax assets based on management's belief that it is not more likely than not that the related deferred tax assets will be realized. For the years ended December 31, 2022 and 2021, there was no income tax expense or benefit.

At December 31, 2022 and 2021, the Company had no recorded tax liabilities for uncertain tax positions. The Company does not expect any significant changes to the estimate amount of liabilities associated with uncertain tax positions in the next 12 months.

The income tax (benefit) provision consists of the following:

	For The Years Ended December 31	
	2022	2021
Federal:		
Current	\$ —	\$ —
Deferred	—	—
State and local:		
Current	—	—
Deferred	—	—
Income tax provision	\$ —	\$ —

For the years ended December 31, 2022 and 2021, the expected tax benefit based on the statutory rate reconciled with the actual benefit is as follows:

	For The Years Ended December 31,	
	2022	2021
U.S. federal statutory rate	21.0%	21.0%
State tax rate, net of federal benefit	5.3%	5.3%
Permanent differences		
Non-deductible expenses	(9.7)%	(10.5)%
Timing differences	(0.0)%	0.6%
Change in valuation allowance	(16.6)%	(16.4)%
Income tax provision	0.0%	0.0%

For the years ended December 31, 2022 and 2021, differences between the expected tax expense based on the federal statutory rate and the actual tax expense is primarily attributable to the net losses incurred and the corresponding increase to the valuation allowance.

As of December 31, 2022 and 2021, the Company's deferred tax assets consisted of the effects of temporary differences attributable to the following:

	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 4,112	\$ 3,326
Other	6	4
Total deferred tax assets	4,118	3,330
Valuation allowance	(4,118)	(3,330)
Deferred tax assets, net of valuation allowance	\$ —	\$ —
Deferred tax liabilities:		
Property and equipment, net	—	—
Total deferred tax liabilities	—	—
Net deferred tax liabilities	\$ —	\$ —

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As of December 31, 2022 and 2021, the Company has approximately \$15.6 million and \$12.6 million of federal NOL carryovers, respectively, which begin to expire in 2029 through 2036. Similarly, the subsidiary's Pennsylvania state returns reported state NOL carryovers of approximately \$15.6 million and \$12.6 million, as of December 31, 2022 and 2021, respectively. However, these loss carryforwards on a separate company basis may be subject to limitations on the amounts that may be utilized pursuant to Internal Revenue Code section 382 and applicable state law. Section 382 imposes significant limitations on the utilization of net operating losses after certain changes of corporate ownership. The Company will need to determine the amount of loss carryforwards that may be utilized in the future as necessary.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of the deferred tax assets is dependent upon the future generation of taxable income during the years in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all the evidence, both positive and negative, management has recorded a full valuation allowance against net deferred tax assets at December 31, 2022 and 2021 because management has determined that it is more likely than not that these deferred tax assets will not be realized.

The Company is subject to taxation in the U.S. and various states. Based on the history of net operating losses all jurisdictions and tax years are open for examination until the operating losses are utilized or the statute of limitations expires. As of December 31, 2022 and 2021, the Company does not have any significant uncertain tax positions.

18. Subsequent Events

Management of the Company has performed a review of events and transactions occurring after the consolidated balance sheet date to determine if there were any such events or transactions requiring adjustment to or disclosure in the accompanying consolidated financial statements, noting no such events other than the following.

On January 16, 2023, Scott R. Henry was appointed to the board of directors of the Company to serve for a term expiring at the Company's next annual meeting of stockholders or his successor is duly elected and qualified. Mr. Henry was also appointed as a member to the Audit Committee of the board of directors.

On March 1, 2023, the Company acquired a 50% interest in a newly formed joint venture ("JV"), named CG Converting and Packaging, LLC, with C.G. Laboratories Inc. ("CG Labs") for its converting and packaging business. The JV is owned 50% by the Company and 50% by CG Labs. CG Labs contributed its existing converting and packaging division to the JV, including, but not limited to, its facilities, equipment, employees, and customers. The Company will contribute \$500,000 to the JV on a schedule to be determined to be used for equipment and facility upgrades as well as general corporate purposes.

On March 21, 2023, the Company entered into a Services Agreement with GlaxoSmithKline Consumer Healthcare Holdings (US) LLC ("Haleon") to supply material for a consumer product to be developed and released in the future. There can be no guaranty that a consumer product will be released or, if released, that it will be successful. GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is a Haleon group company.

On March 23, 2023, the board of directors of the Company approved an increase of the number of shares to be reserved under the Company's 2019 Long-Term Incentive Plan by 300,000 shares of common stock, or from an aggregate number of 571,429 to 871,429 shares of common stock (the "2019 Plan Increase"). The Company expects the 2019 Plan Increase to satisfy the Company's anticipated equity incentive award requirements for the next two to three years. The Company plans to submit the 2019 Plan Increase for approval to the Company's stockholders at the Company's 2023 annual meeting of stockholders.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

As of December 31, 2022, we conducted an evaluation of the effectiveness of our “disclosure controls and procedures” (“Disclosure Controls”), as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The Disclosure Controls evaluation was done under the supervision and with the participation of management, including our chief executive officer and chief financial officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon this evaluation, our chief executive officer and chief financial officer have concluded that our Disclosure Controls and Procedures were effective as of December 31, 2022 at a reasonable level of assurance.

Change in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the fiscal year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management’s Annual Report on Internal Control over Financial Reporting and Attestation Report of the Registered Accounting Firm

This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies or an attestation report of the Company’s registered public accounting firm which is not required for non-accelerated filers.

Item 9B. Other Information

Not applicable.

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Part III.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is set forth under the headings “Directors, Executive Officers and Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in the Company’s 2023 Proxy Statement to be filed with the U.S. Securities and Exchange Commission (“SEC”) within 120 days after December 31, 2022 in connection with the solicitation of proxies for the Company’s 2023 annual meeting of shareholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item is set forth under the heading “Executive Compensation” and under the subheadings “Board Oversight of Risk Management,” “Compensation of Directors,” “Director Compensation-2022” and “Compensation Committee Interlocks and Insider Participation” under the heading “Directors, Executive Officers and Corporate Governance” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is set forth under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this Item is set forth under the heading “Review, Approval or Ratification of Transactions with Related Persons” and under the subheading “Board Committees” under the heading “Directors, Executive Officers and Corporate Governance” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is Turner Stone & Company, LLP, Dallas, Texas, PCAOB Auditor ID 76.

The information required by this Item is set forth under the subheadings “Fees Paid to Auditors” and “Policy on Audit Committee Pre-Approval of Audit and Non-Audit Services Performed by the Independent Registered Public Accounting Firm” under the proposal “Ratification of Appointment of Independent Registered Public Accounting Firm” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 and is incorporated herein by reference.

Part IV.

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this report:

(1) Financial Statements

The following financial statements are included herein:

[Report of Independent Registered Public Accounting Firm \(PCAOB ID: 76\)](#)

[Consolidated Balance Sheets as of December 31, 2022 and 2021](#)

[Consolidated Statements of Operations for the years ended December 31, 2022 and 2021](#)

[Consolidated Statement of Stockholders’ Equity \(Deficit\) for the years ended December 31, 2022 and 2021](#)

[Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021](#)

[Notes to Consolidated Financial Statements](#)

(2) Financial Statement Schedules

None.

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(3) Exhibits

- 1.1 [Underwriting Agreement dated December 21, 2021 by and between NexGel, Inc. and Maxim Group LLC \(incorporated by reference to Exhibit 1.1 to Form 8-K, filed with the SEC on December 27, 2021\).](#)
- 2.1 [Form of Asset Contribution and Separation Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 2.3 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 2.2 [Form of Tax Matters Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 2.4 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 2.3 [Form of Bill of Sale and Assignment and Assumption Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 2.5 to Amendment No. 1 to Form S-1, filed with the SEC on March 11, 2019\).](#)
- 2.4 [Amendment No. 2, dated April 19, 2019, to Agreement and Plan of Merger \(incorporated by reference to Exhibit 2.6 to Amendment No. 3 to Form S-1, filed with the SEC on April 19, 2019\).](#)
- 3.1 [Certificate of Incorporation of AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 3.1 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 3.2 [Certificate of Amendment to Certificate of Incorporation of AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 3.2 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 3.3 [Amended and Restated Certificate of Incorporation of AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 3.3 to Amendment No. 1 to Form S-1, filed with the SEC on March 11, 2019\).](#)
- 3.4 [Certificate of Amendment to the Amended and Restated Certificate of Incorporation of AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, filed with the SEC on November 14, 2019\).](#)
- 3.5 [Certificate of Amendment to the Amended and Restated Certificate of Incorporation of NexGel, Inc. \(incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, filed with the SEC on May 29, 2020\).](#)

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- 3.6 [Certificate of Amendment to the Amended and Restated Certificate of Incorporation of NexGel, Inc. \(incorporated by reference to Exhibit 3.6 to Form S-1, filed with the SEC on December 2, 2021\)](#)
- 3.7 [Amended and Restated Bylaws of AquaMed Technologies, Inc. \(incorporated by reference to Exhibit 3.5 to Amendment No. 1 to Form S-1, filed with the SEC on March 11, 2019\).](#)
- 4.1 [12% Senior Secured Promissory Note, dated March 11, 2021, issued to Auctus Fund, LLC \(incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on March 17, 2021\).](#)
- 4.2 [First Common Stock Purchase Warrant, dated March 11, 2021, issued to Auctus Fund, LLC \(incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on March 17, 2021\).](#)
- 4.3 [Second Common Stock Purchase Warrant, dated March 11, 2021, issued to Auctus Fund, LLC \(incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the SEC on March 17, 2021\).](#)
- 4.4 [Form of 12% Subordinated Secured Promissory Note, dated September 2, 2021 \(incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on September 8, 2021\)](#)
- 4.5 [Form of Common Stock Purchase Warrant, dated September 2, 2021 \(incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on September 8, 2021\)](#)
- 4.6 [Warrant Agency Agreement \(including form of Common Warrant\) dated December 27, 2021 by and between NexGel, Inc. and Continental Stock Transfer & Trust Company \(incorporated by reference to Exhibit 10.1 to Form 8-K, filed with the SEC on December 27, 2021\).](#)
- 4.7 [Underwriter Warrant dated December 27, 2021 issued to Maxim Group LLC \(incorporated by reference to Exhibit 4.1 to Form 8-K, filed with the SEC on December 27, 2021\).](#)
- 10.1 [Assignment and Amended and Restated Lease, dated as of January 25, 2002, by and between 2150 Cabot LLC, Embryo Development Corporation and Hydrogel Design Systems, Inc. \(incorporated by reference to Exhibit 10.1 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 10.2 [Amendment to Lease, dated as of February 23, 2007, by and between 2150 Cabot LLC and Hydrogel Design Systems, Inc. \(incorporated by reference to Exhibit 10.2 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 10.3 [Third Amendment to Lease, dated as of February 27, 2009, by and between Exeter 2150 Cabot, L.P and Hydrogel Design Systems, Inc. \(incorporated by reference to Exhibit 10.3 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 10.4 [Assignment and Assumption of Lease Agreement, dated as of February 27, 2009, by and among Exeter 2150 Cabot, L.P, Hydrogel Design Systems, Inc. and Aquamed Technologies, Inc. \(incorporated by reference to Exhibit 10.4 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 10.5 [Fourth Amendment to Lease, dated as of July 24, 2013, by and between Exeter 2150 Cabot, L.P and Aquamed Technologies, Inc. \(incorporated by reference to Exhibit 10.5 to Form S-1, filed with the SEC on January 9, 2019\).](#)
- 10.6 [Form of Stock Purchase Agreement between NexGel, Inc. and certain accredited investors \(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 21, 2020\).](#)
- 10.7 [Membership Interest Purchase Agreement dated May 29, 2020 by and among NexGel, Inc. and the members of Sport Defense LLC \(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on May 29, 2020\).](#)

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- 10.8 [Form of 2019 Incentive Plan \(incorporated by reference to Exhibit 10.22 to Amendment No. 3 to Form S-1, filed with the SEC on April 19, 2019\).](#)
- 10.9 [Form of Incentive Option Agreement under 2019 Incentive Plan \(incorporated by reference to Exhibit 10.23 to Amendment No. 3 to Form S-1, filed with the SEC on April 19, 2019\).](#)
- 10.10 [Form of Nonqualified Stock Option Agreement under 2019 Incentive Plan \(incorporated by reference to Exhibit 10.24 to Amendment No. 3 to Form S-1, filed with the SEC on April 19, 2019\).](#)
- 10.12 [Securities Purchase Agreement, dated March 11, 2021, between NexGel, Inc. and Auctus Fund, LLC \(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on March 17, 2021\).](#)
- 10.13 [Security Agreement, dated March 11, 2021, between NexGel, Inc. and Auctus Fund, LLC \(incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 17, 2021\).](#)
- 10.14 [Registration Rights Agreement, dated March 11, 2021, between NexGel, Inc. and Auctus Fund, LLC \(incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on March 17, 2021\).](#)
- 10.15 [First Amendment to the Senior Secured Promissory Note, Warrants, and Securities Purchase Agreement \(March 11, 2021\) dated August 13, 2021 by and between NexGel, Inc. and Auctus Fund, LLC \(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on August 16, 2021\).](#)
- 10.16 [Form of Securities Purchase Agreement, dated September 2, 2021 \(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 8, 2021\).](#)
- 10.17 [Form of Security Agreement, dated September 2, 2021 \(incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on September 8, 2021\).](#)

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10.18	Form of Security Agreement, dated September 2, 2021 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on September 8, 2021).
10.19	Form of Registration Rights Agreement, dated September 2, 2021 (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on September 8, 2021).
10.20	Form of Lock-Up Agreement, dated September 2, 2021 (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the SEC on September 8, 2021).
10.21	Second Amendment to the Senior Secured Promissory Note, Warrants, and Securities Purchase Agreement (March 11, 2021) dated October 28, 2021 by and between NexGel, Inc. and Auctus Fund, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on November 3, 2021).
10.22	Third Amendment to the Senior Secured Promissory Note, Warrants, and Securities Purchase Agreement (March 11, 2021) dated December 10, 2021 by and between NexGel, Inc. and Auctus Fund, LLC (incorporated by reference to Exhibit 10.23 to Form S-1, filed with the SEC on December 10, 2021).
10.23	2023 Executive Employment Agreement, dated December 30, 2022 by and between NexGel, Inc. and Adam Levy (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 6, 2023).
21.1*	Subsidiaries
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1**	Section 1350 Certification of Principal Executive Officer
32.2**	Section 1350 Certification of Principal Financial Officer
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

** Furnished herewith.

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Signatures

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

NexGel, Inc.

Date: March 27, 2023

By: /s/ Adam Levy

Adam Levy

Chief Executive Officer and President

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

<u>Signature</u>	<u>Date</u>	<u>Title</u>
<u>/s/ Adam Levy</u> Adam Levy	March 27, 2023	Chief Executive Officer and President (Principal Executive Officer)
<u>/s/ Adam Drapczuk III</u> Adam Drapczuk III	March 27, 2023	Chief Financial Officer (Principal Accounting and Financial Officer)
<u>/s/ Steven Glassman</u> Steven Glassman	March 27, 2023	Director
<u>/s/ Scott Henry</u> Scott Henry	March 27, 2023	Director
<u>/s/ David Stefansky</u> David Stefansky	March 27, 2023	Director
<u>/s/ Nachum Stein</u> Nachum Stein	March 27, 2023	Director
<u>/s/ Miranda J. Toledano</u> Miranda J. Toledano	March 27, 2023	Director
<u>/s/ Jerome B. Zeldis</u> Jerome B. Zeldis	March 27, 2023	Director

Subsidiaries of the Registrant

Name of Subsidiary	State of Organization
NexGelRx, Inc. (wholly owned)	Delaware
Sport Defense LLC (wholly owned)	Delaware

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
(SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002)**

I, Adam Levy, certify that:

1. I have reviewed this Annual Report on Form 10-K of NexGel, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-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 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 registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2023

/s/ Adam Levy

Adam Levy
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
(SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002)**

I, Adam Drapczuk, certify that:

1. I have reviewed this Annual Report on Form 10-K of NexGel, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-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 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 registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2023

/s/ Adam E. Drapczuk III

Adam E. Drapczuk III
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 (AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)**

In connection with the Annual Report of NexGel, Inc. (the “Company”) on Form 10-K for the period ending December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Adam Levy, Chief Executive Officer, certify to my knowledge and in my capacity as an officer of the Company, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and,
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: March 27, 2023

/s/ Adam Levy

Adam Levy
Chief Executive Officer
(Principal Executive Officer)

A certification furnished pursuant to this Item will not be deemed “filed” for purposes of section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the small business issuer specifically incorporates it by reference.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 (AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)**

In connection with the Annual Report of NexGel, Inc. (the "Company") on Form 10-K for the period ending December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam Levy, Chief Financial Officer, certify to my knowledge and in my capacity as an officer of the Company, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and,
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: March 27, 2023

/s/ Adam E. Drapczuk III

Adam E. Drapczuk III
Chief Financial Officer
(Principal Financial and Accounting Officer)

A certification furnished pursuant to this Item will not be deemed "filed" for purposes of section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the small business issuer specifically incorporates it by reference.
