

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, 2021
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number: 001-36278

NexGel, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

26-4042544

(I.R.S. Employer Identification Number)

2150 Cabot Blvd West, Suite B
Langhorne, PA

(Address of principal executive office)

19047

(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 |

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

None

(Title of Class)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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, 2021, the last business day of the registrant's second fiscal quarter, was approximately \$5,675,244 based on the price at which the registrant last sold common equity.

As of March 21, 2022, the registrant had 5,572,234 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2022 annual meeting of stockholders (the "2022 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2022 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, 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.

Except as otherwise provided herein, all share and per-share amounts of our common stock, equity awards and warrants have been adjusted to give effect to the Reverse Stock Split for all periods presented. The Reverse Stock Split did not alter the par value of our 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 common stock and preferred stock we are 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;

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- 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.

Part I

Item 1. Business

In this Annual Report on Form 10-K, unless the content otherwise dictates, "NexGel", the "Company", "we" or "our" mean NexGel, Inc. NexGel was previously known as AquaMed Technologies, Inc. (“AquaMed”) before changing its name to NexGel, Inc. on November 14, 2019.

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.

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- *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, we recently completed a facility accelerator upgrade of approximately \$570,000 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.

Consumer Products

Beginning in the third quarter of 2020, we began selling our own branded products using our hydrogel technology on the Amazon marketplace. We currently have nine distinct product offerings which we market under the brand names MedaGel and LumaGel Beauty and intend to offer additional products in 2022 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.

We believe SilverSeal[®], a product marketed under our MedaGel brand for OTC wound care in connection with our partnership with Noble Fiber Technologies, Inc. (“Noble Fiber”), may also have applications for skin scar treatment. Pursuant to the terms of our agreement with Noble Fiber we pay them a small royalty fee for any Silver Seal[®] we sell.

Based on supporting clinical data from a forty patient, double blind study, SilverSeal[®] may reduce scar tissue at a more significant rate than a typical petroleum treatment. The study included 20 patients in each group, with one group being treated with SilverSeal[®] and the other group treated with the petroleum treatment. Scarring results were evaluated using the Patient and Observer Scar Assessment Scale (“POSAS”), which includes measuring scar length and width. Patients treated with SilverSeal[®] demonstrated statistically significant improvements in their POSAS scores as compared to patients in the control group. We have submitted this clinical data for peer review and publication, although we cannot guarantee it will be published. If the results are validated through peer

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view, we will be able claim that SilverSeal[®] reduces scarring. According to a report by Fior Markets, the scar treatment market is expected to grow to \$45 billion by 2028.

In a recent validation study, SilverSeal[®] was also found to be up to 99% effective in reducing common bacteria, fungus and yeasts that can be present after a superficial skin injury. The positive results of this study allow us to make important claims for its wound care products, particularly its ability to prevent common infections. We believe these antimicrobial properties are important for specific consumer segments such as athletes who often are exposed to infection due to frequent skin tears.

The SilverSeal[®] study design was as follows:

- NEXGEL's SilverSeal[®] product line underwent Test Method 100, which the American Association of Textile Chemists and Colorists (AATCC) lists as the industry standard for evaluating the antimicrobial efficacy of dressings.
- The AATCC Test Method 100 is also recognized by the U.S. Food and Drug Administration (FDA) as a standard technique for establishing antimicrobial activity within wound dressings for 510(k) filings.
- The Test Method 100 is designed to quantitatively test the ability of fabrics and textiles to inhibit the growth of microorganisms or kill them, over a 24-hour period of contact.
- During this test, control and test fabric swatches were inoculated with microorganisms. Bacteria levels on both control and test fabrics were determined at "time zero" by elution in a large volume of neutralizing broth, followed by dilution and plating.
- A control was performed to verify that the neutralization method effectively neutralizes the antimicrobial agent in the fabric. Additional inoculated control and test fabrics were incubated in sealed jars.
- The results were taken after the 24-hour period, and the reduction of microorganisms relative to initial concentrations and the control fabric was calculated.

Key results from a comparison of SilverSeal[®] to a standard-of-care gauze pad over a 24-hour interval showed:

- SilverSeal[®] was ~99% effective in reducing streptococcus pneumoniae, compared to ~13% efficacy of the reference gauze.
- SilverSeal[®] was ~99% effective in reducing staphylococcus epidermidis, compared to ~17% efficacy of the reference gauze.
- SilverSeal[®] was ~99% effective in reducing faecalis bacterial infection, compared to ~11% efficacy of the reference gauze.
- SilverSeal[®] was ~99% effective in reducing E. coli infection, compared to ~31% efficacy of the reference gauze.

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. We have entered into a partnership with MPG Promotions to assist with our strategy of retail distribution for these various products on an as-needed basis for a flat monthly fee.

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

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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(TM), a 3M Healthcare product. Based on our discussion with medical professionals, Tegaderm(TM) 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(TM): (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.

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. As of December 31, 2021, we did not have any employees solely dedicated to sales, however, some of our employees perform in a sales capacity in addition to their other duties and we did hire one employee solely dedicated to sale in the first quarter of 2022. In February 2021, the Company began contracting two independent salesmen for current year sales efforts that have been and will continue to focus 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 re-sell, 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, 2021, three major customers accounted for approximately 42% of our revenue, with each customer individually accounting for 15%, 14%, and 13% respectively. We cannot be certain as to these customers' intentions to use our services during and beyond the fiscal year ending December 31, 2022 since we do not currently have a contract with these customers. However, we have been supplying these customers for more than 15 years and have no reason to anticipate any change. Our contract manufacturing business, including with respect to these customers, operates on a purchase order basis.

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

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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.

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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.

Research and Development Costs

For the years ended December 31, 2021 and 2020, we incurred approximately \$31 thousand and \$0, 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, 2021, we had ten full-time employees. Of these employees, three are involved with finance, sales, marketing, and administration and seven 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, 2026. 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.

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 such as the global COVID-19 pandemic, 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.

The recent COVID-19 outbreak could harm our business and results of operations.

On January 30, 2020, the World Health Organization declared the COVID-19 outbreak a "Public Health Emergency of International Concern" and on March 11, 2020, declared it to be a pandemic. We have undertaken measures to protect our employees, partners and customers by requiring a majority of our employees to work remotely at certain times. There can be no assurance that these measures will be effective or that we can continue to adopt them without adversely affecting our business operations. The ultimate extent of the impact of any epidemic, pandemic or other health crisis in our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted.

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, 2021, three major customers accounted for approximately 42% of our revenue, with each customer individually accounting for 15%, 14%, and 13% respectively. The loss of any of our significant customers would have a significantly negative effect on our overall operations.

We rely heavily 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.

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 and 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, or at all, particularly while the COVID-19 pandemic persists. 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.

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 is 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.

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. As a Nasdaq listed company, 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;

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- 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 23% 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 9, 2022, our principal stockholders, officers and directors beneficially owned approximately 23% 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.

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 convertible notes, warrants and 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:

- 434,939 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$1.6757 per share;
- 3,637,190 shares of common stock issuable upon the exercise of warrants at a weighted average exercise price of approximately \$5.1628; and
- 345,600 shares of common stock issuable upon the conversion of the principal and accrued interest of the subordinated secured convertible promissory notes dated September 2, 2021.

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

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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.

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

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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, 2026. 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 trade on NASDAQ Capital Markets under the symbol "NXGLW."

Holders

As of March 21, 2022, there were over 1,176 shareholders of record and 5,572,234 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, 2021

On September 2, 2021, the Company conducted a closing of a private placement offering (the "September 2 Offering") with twenty accredited investors (the "September 2 Investors") whereby the Company entered into a securities purchase agreement (the "September Purchase Agreement") with the Investors pursuant to which the Company issued to the Investors subordinated secured convertible promissory notes in the aggregate principal amount of \$1,620,000 (the "September 2 Notes"). The net proceeds received by the Company were \$1,504,400. The September 2, 2021 Notes are convertible into shares of common stock at \$5.25 per shares. In connection with the issuance of the September 2 Notes, the Investors were also issued five-year warrants to purchase up to an aggregate

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of 308,572 shares of the Company's common stock at an exercise price of \$5.25 per share. Alere Financial, a division of Cova Capital Partners, LLC ("Alere"), served as the placement agent for the September 2 Notes and received, among other consideration, warrants to purchase up to 22,020 shares of the Company's common stock, with a term of five years, at a per share exercise price of \$5.25.

On March 11, 2021, the Company entered into a securities purchase agreement (the "Auctus Purchase Agreement") with Auctus Fund, LLC, a Delaware limited liability company ("Auctus"), pursuant to which the Company issued to Auctus a senior secured convertible promissory note in the principal amount of \$1,500,000 (the "Auctus Note"). The net proceeds received by the Company were \$1,337,000 after deducting fees and expenses related to the transaction. In connection with the issuance of the Auctus Note and Auctus Purchase Agreement, Auctus was also issued two five-year warrants as follows: the first warrant was to purchase up to an aggregate of 171,429 shares of the Company's common stock at an exercise price of \$4.375 per share (the "First Auctus Warrant") and the second warrant was to purchase up to an aggregate of 142,858 shares of the Company's common stock at an exercise price of \$5.25 per share (the "Second Auctus Warrant"). The First Auctus Warrant and the Second Auctus Warrant are referred to herein as the "Auctus Warrants". The Auctus Note was fully repaid, including all principle and interest, on March 15, 2022.

On January 19, 2021, the Company entered into a Securities Purchase Agreement, pursuant to which the Company issued a \$15,000 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 due on or before March 19, 2021 and fully repaid, including all principle and interest, on March 14, 2021.

From January 27, 2021 through March 1, 2021, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 101,800 shares of our common stock at a price per share equal to \$2.80 for an aggregate purchase price of \$285,000. Proceeds from this private placement are expected to be used for working capital, new product development and testing, and general business operations.

All of the shares issued and sold described above were not registered under the Securities Act of 1933, as amended (the "Securities Act"), or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act, provided by Section 4(a)(2) and Regulation D (Rule 506) under the Securities Act. Each investor represented that it was an accredited investor (as defined by Rule 501 under the Securities Act).

Issuer Repurchases of Securities during the Fiscal Year Ended December 31, 2021

The Company did not repurchase any of its securities during the fiscal year ended December 31, 2021.

Item 6. Selected Financial Data

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 is 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 consolidated 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 periods 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 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.

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, par value \$0.001 per share (the “Common Stock”), and a warrant to purchase one share of Common Stock at an exercise price of \$5.50 per share (the “Warrants”), pursuant to that certain Underwriting Agreement, dated as of December 21, 2021 (the “Underwriting Agreement”), between the Company and Maxim Group LLC (the “Underwriter”). In addition, pursuant to the Underwriting Agreement, the Company granted the Underwriter a 45-day option to purchase up to 387,750 additional shares of 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.

The Common Stock and the Warrants were offered and sold to the public pursuant to the Company’s registration statement on Form S-1 (File No. 333-260897), filed by the Company with the Securities and Exchange Commission (the “SEC”) under the Securities Act of 1933, as amended (the “Securities Act”), on November 9, 2021, as amended, and the Company’s registration statement on Form S-1MEF (File No. 333-261821), filed by the Company with the SEC under the Securities Act on December 21, 2021, each of which became effective on December 21, 2021.

On the Closing Date, 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.

The Underwriting Agreement contains customary representations, warranties, and covenants by the Company. It also provides for customary indemnification by each of the Company and the underwriters for losses or damages arising out of or in connection with the offering, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

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Pursuant to the Underwriting Agreement, the Company also agreed to issue to the Underwriter warrants (the “Underwriter’s Warrants”) to purchase up to a total of 155,100 shares of Common Stock (6% of the shares of Common Stock sold in the Offering). The Underwriter’s Warrants are exercisable at \$6.1875 per share of Common Stock and have a term of five years. The Underwriter’s Warrants are subject to a lock-up for 180 days from the commencement of sales in the Offering, including a mandatory lock-up period in accordance with FINRA Rule 5110(e), and will be non-exercisable for six (6) months after December 21, 2021.

Results of Operations

Year Ended December 31, 2021 Compared to the Year Ended December 31, 2020

Revenues, net.

For the year ended December 31, 2021 revenues were \$1.55 million and increased by \$877 thousand, or 130%, when compared to \$674 thousand for the year ended December 31, 2020. The increase in our overall revenues was due to sales growth of new products as well as our initiatives in custom label manufacturing and branded consumer product.

Gross profit (loss). Our gross profit was \$9 thousand for the year ended December 31, 2021 compared to a gross loss of \$291 thousand for the year ended December 31, 2020. The profit recorded for the year ended December 31, 2021, as compared to a loss recorded for the year ended December 31, 2020, was primarily due to the higher volume of contract manufacturing sales against fixed costs and lower manufacturing labor costs. Gross profit was approximately 0.6% for the year ended December 31, 2021 compared to a gross loss of (43.2%) for the year ended December 31, 2020.

The components of cost of revenues are as follows for the years ended December 31, 2021 and 2020 (\$ in thousands):

| | Year Ended December 31, | |
|--|-------------------------|---------------|
| | 2021 | 2020 |
| Cost of revenues | | |
| Materials and finished products | \$ 520 | \$ 190 |
| Share-based compensation | — | 1 |
| Compensation and benefits | 569 | 464 |
| Depreciation and amortization | 86 | 28 |
| Equipment, production and other expenses | 367 | 282 |
| Total cost of revenues | <u>\$ 1,542</u> | <u>\$ 965</u> |

Cost of revenues increased by \$577 thousand, or 60%, to \$1.5 million for the year ended December 31, 2021, as compared to \$965 thousand for the year ended December 31, 2020. The increase in cost of revenues is primarily aligned with the new product line growth in the current year.

Selling, general and administrative expenses. The following table highlights selling, general and administrative expenses by type for the years ended December 31, 2021 and 2020 (\$ in thousands):

| | Year Ended December 31, | |
|---|-------------------------|-----------------|
| | 2021 | 2020 |
| Selling, general and administrative expenses | | |
| Compensation and benefits | \$ 381 | \$ 462 |
| Share-based compensation | 285 | 232 |
| Depreciation and amortization | 13 | 13 |
| Other expenses and professional fees | 1,869 | 1,262 |
| Total selling, general and administrative expenses | <u>\$ 2,548</u> | <u>\$ 1,969</u> |

Selling, general and administrative expenses increased by \$579 thousand, or 29%, to \$2.55 million for the year ended December 31, 2021, as compared to \$1.97 million for the year ended December 31, 2020. The increase in selling, general and administrative expenses is primarily attributable to our costs for professional fees and other administrative expenses in the current period in conjunction with our initial public offering.

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Compensation and benefits decreased by \$81 thousand, or 18%, to \$381 thousand for the year ended December 31, 2021, as compared to \$462 thousand for the year ended December 31, 2020. The number of employees increased compared to the prior period, however a restructuring of certain staff resulted in cost efficiency.

Share-based compensation increased by \$53 thousand, or 23%, to \$285 thousand for the year ended December 31, 2021, as compared to \$232 thousand for the year ended December 31, 2020. The increase in share-based compensation related to the issuance of stock options and restricted awards to our officers, employees, and advisors.

Other Expenses and professional fees increased by \$607 thousand, or 48%, to \$1.87 million for the year ended December 31, 2021 from \$1.26 million for the year ended December 31, 2020. 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. We continued to incur legal, accounting and consulting fees associated with public company governance requirements, however, the increase in professional fees compared to the prior year period was the primary an increase in professional fees in preparation for and in connections with our in the NASDAQ up-listing on December 27, 2021.

Research and development expenses. Research and Development expenses increased by \$31 thousand compared to zero for consulting fees in the year end December 31, 2021 and 2020, respectively. The Company anticipates an increase in consulting fees in the current year for produce development.

Liquidity and Capital Resources

Cash Flow

(in thousands)

| | Years Ended December 31, | |
|--|--------------------------|------------|
| | 2021 | 2020 |
| Net cash used in operating activities | \$ (2,753) | \$ (1,801) |
| Net cash used in investing activities | (269) | (312) |
| Net cash provided by financing activities | 16,340 | 1,884 |
| Net increase (decrease) in cash and cash equivalents | 13,318 | (229) |
| Cash and cash equivalents at beginning of year | 32 | 261 |
| Cash and cash equivalent at end of year | \$ 13,350 | \$ 32 |

As of December 31, 2021, we had \$13.4 million of cash, compared to \$32 thousand of cash at December 31, 2020. Net cash used in operating activities was \$2.8 million and \$1.80 million for the years ended December 31, 2021 and 2020, respectively.

Net cash used in investing activities was \$269 thousand and \$312 thousand for the years ended December 31, 2021 and 2020, respectively.

Net cash provided by financing activities for the year ended December 31, 2021 was \$16.3 million which is 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. For the year ended December 31, 2020 cash flows from financing activities were \$1.9 million which is attributable to the issuance of common stock of \$1.4 million and proceeds of a notes payable of \$414 thousand and convertible notes payable of \$100 thousand.

At December 31, 2021, current assets totaled \$13.9 million and current liabilities totaled \$2.9 million, as compared to current assets totaling \$363 thousand and current liabilities totaling \$1.3 million at December 31, 2020. As a result, we had working capital of \$11.0 million at December 31, 2021, compared to a working capital deficit of \$970 thousand at December 31, 2020. The increase in the working capital as of December 31, 2021 is primarily attributable to the December 2021 equity offering and the issuance of convertible notes payable of \$3.0 million, net of fees, in the current year.

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On December 27, 2021 and as further described above, 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, par value \$0.001 per share (the “Common Stock”), and a warrant to purchase one share of Common Stock at an exercise price of \$5.50 per share. The net proceeds from the offering amounted to \$13.2 million.

On September 2, 2021, the Company entered into a securities purchase agreement pursuant to which the Company issued to twenty investors a 12% senior secured convertible promissory note in the principal amount of \$1.8 million, including Original Issue Discount (“OID”) of \$194 thousand (which OID represents the twelve months of guaranteed interest which was earned in full as of September 2, 2021), which is convertible into shares of the Company’s common stock at a price per share of \$5.25 subject to certain adjustments as discussed herein in Note 13 in the Notes to the Consolidated Financials. The net proceeds received by the Company were \$1.5 million after deducting fees and expenses related to the transaction. The purchasers in the September 2021 securities purchase agreement also received warrants to purchase shares of our common stock.

On March 11, 2021, the Company entered into a securities purchase agreement with Auctus Fund, LLC, a Delaware limited liability company (“Auctus”), pursuant to which the Company issued to Auctus a 12% senior secured convertible promissory note in the principal amount of \$1.6 million, including OID of \$180 thousand (which OID represents the twelve months of guaranteed interest which was earned in full as of March 11, 2021), which is convertible into shares of the Company’s common stock at a price per share of \$3.50 subject to certain adjustments as discussed herein in Note 13 in the Notes to the Consolidated Financials. The net proceeds received by the Company were \$1.3 million after deducting fees and expenses related to the transaction. Auctus also received warrants to purchase shares of our common stock.

On March 4, 2021, the Company received a second PPP Loan in the amount of \$127 thousand under Phase II of the Paycheck Protection Program which commenced on January 13, 2021 and allowed certain businesses that received an initial PPP Loan to seek a second draw PPP Loan.

From January 1, 2021 through March, 2021, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 101,786 shares of our common stock at a price per share equal to \$2.80 for an aggregate purchase price of \$285,000.

From October 13, 2020 through December 24, 2020, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 126,786 shares of our common stock at a price per share equal to \$2.80 for an aggregate purchase price of \$355,000.

From July 30, 2020 through August 14, 2020, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 188,143 shares of our common stock at a price per share equal to \$2.10 for an aggregate purchase price of \$395,100.

From February 6, 2020 through March 20, 2020, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 442,858 shares of our common stock at a price per share equal to \$1.40 for an aggregate purchase price of \$620,000.

Proceeds from these offering are expected to be used for working capital, new product development and testing, and general business operations.

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, we anticipate that all available fund 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. We intend to maintain and attempt to grow our existing contract manufacturing business. We also plan to continue building and developing its 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.

Off Balance Sheet Arrangements

As of December 31, 2021, 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 Consolidated 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 Consolidated Financial Statements. Actual results could differ from our estimates and assumptions, and any such differences could be material to our Consolidated Financial Statements.

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 on September 2, 2021, March 11, 2021, February 3, 2021, December 24, 2020, March 18, 2020, September 10, 2019 and November 6, 2019. The fair values of the warrants are estimated as of the date of issuance and again at each period 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

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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

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 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of NexGel, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying balance sheets of NexGel, Inc. (the “Company”) as of December 31, 2021 and 2020 and the related statements of operations, stockholders’ equity and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, 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 the Company’s 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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

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

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

Dallas, Texas
March 21, 2022

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

| | Year Ended December 31, | |
|--|-------------------------|-----------------|
| | 2021 | 2020 |
| ASSETS: | | |
| Current Assets: | | |
| Cash | \$ 13,350 | \$ 32 |
| Accounts receivable, net | 209 | 73 |
| Inventory | 291 | 233 |
| Prepaid expenses and other current assets | 77 | 25 |
| Total current assets | <u>13,927</u> | <u>363</u> |
| Goodwill | 311 | 311 |
| Intangibles | 33 | 47 |
| Property and equipment, net | 723 | 553 |
| Operating lease - right of use asset | 1,926 | 805 |
| Other assets | 63 | 178 |
| Total assets | <u>\$ 16,983</u> | <u>\$ 2,257</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$ 254 | \$ 658 |
| Accrued expenses and other current liabilities | 62 | 90 |
| Deferred Revenue | — | 38 |
| Convertible notes payable | 2,037 | 59 |
| Note payable, current portion | 10 | 10 |
| Note payable - PPP | — | 147 |
| Warrant liability | 318 | 123 |
| Operating lease liability, current portion | 207 | 207 |
| Total current liabilities | <u>2,888</u> | <u>1,332</u> |
| Operating lease liability, net of current portion | 1,744 | 598 |
| Notes payable, net of current portion | 266 | 256 |
| Total liabilities | <u>\$ 4,898</u> | <u>\$ 2,186</u> |
| Commitments and Contingencies (Note 17) | — | — |
| 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, 750,000,000 shares authorized; 5,572,234 and 2,838,047 shares issued and outstanding as of December 31, 2021 and 2020, respectively | 6 | 3 |
| Additional paid-in capital | 18,891 | 2,570 |
| Accumulated deficit | (6,812) | (2,502) |
| Total stockholders' equity | <u>12,085</u> | <u>71</u> |
| Total liabilities and stockholders' equity | <u>\$ 16,983</u> | <u>\$ 2,257</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, | |
|---|-------------------------|------------|
| | 2021 | 2020 |
| Revenues, net | \$ 1,551 | \$ 674 |
| Cost of revenues | 1,542 | 965 |
| Gross (loss)/profit | 9 | (291) |
| Operating expenses | | |
| Research and development | 31 | — |
| Selling, general and administrative | 2,548 | 1,969 |
| Total operating expenses | 2,579 | 1,969 |
| Loss from operations | (2,570) | (2,260) |
| Other income (expense) | | |
| Change in fair value of warrant liability | 8 | (2) |
| Forgiveness of debt | 275 | — |
| Debt discount costs | (68) | (2) |
| Loss on debt extinguishment | (25) | — |
| Interest expense | (1,930) | (8) |
| Other income | — | 8 |
| Total other income (expense) | (1,740) | (4) |
| Net loss | \$ (4,310) | \$ (2,264) |
| Net loss per common share - diluted and diluted | \$ (1.45) | \$ (1.05) |
| Weighted average shares used in computing net loss per common share - basic and diluted | 2,979,962 | 2,254,145 |

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

NEXGEL, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|--|---------------------|-------------|----------------------------------|------------------------|----------------------------------|
| | Shares | Amount | | | |
| Balance, December 31, 2019 | 1,643,006 | \$ 2 | \$ 616 | \$ (238) | 380 |
| Issuance of common stock, net of issuance costs | 757,786 | 1 | 1,369 | — | 1,370 |
| Issuance of common stock for acquisition | 267,858 | — | 375 | — | 375 |
| Restricted stock vesting | 169,397 | — | — | — | — |
| Warrants issued for equity raising costs | — | — | (65) | — | (65) |
| Beneficial conversion and warrant features of convertible debt | — | — | 43 | — | 43 |
| Share-based compensation | — | — | 232 | — | 232 |
| Net loss | — | — | — | (2,264) | (2,264) |
| Balance, December 31, 2020 | <u>2,838,047</u> | <u>\$ 3</u> | <u>\$ 2,570</u> | <u>\$ (2,502)</u> | <u>\$ 71</u> |
| | | | | | |
| | 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> |

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

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

| | Year Ended December 31, | |
|---|--------------------------------|----------------|
| | 2021 | 2020 |
| Operating Activities | | |
| Net loss | \$ (4,310) | \$ (2,264) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 113 | 50 |
| Share-based compensation | 285 | 232 |
| Changes in ROU asset and operating lease liability | (8) | 2 |
| Forgiveness of debt | (275) | — |
| Changes in fair value of warrant liability | 25 | — |
| Loss of extinguishment of debt | 25 | — |
| Amortization of deferred financing costs | 1,933 | 2 |
| Beneficial conversion feature in excess of face value | 52 | |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (137) | 29 |
| Inventory | (58) | (99) |
| Prepaid expenses and other assets | 63 | 10 |
| Accounts payable | (405) | 137 |
| Accrued expenses and other liabilities | (18) | 62 |
| Deferred revenue | (38) | 38 |
| Net Cash Used in Operating Activities | (2,753) | (1,801) |
| Investing Activities | | |
| Purchase of equipment | (269) | (312) |
| Net Cash Used in Investing Activities | (269) | (312) |
| Financing Activities | | |
| Issuance of common stock, net of issuance costs | 13,471 | 1,370 |
| Proceeds from notes payable | 15 | 414 |
| Proceeds from convertible notes | 2,957 | 100 |
| Payment of financing costs | (115) | |
| Principal payment of notes payable | (15) | — |
| Principal payment on convertible notes | (100) | — |
| Proceeds from notes payable (PPP) | 127 | — |
| Net Cash Provided by Financing Activities | 16,340 | 1,884 |
| Net Increase (Decrease) in Cash | 13,318 | (229) |
| Cash – Beginning of period | 32 | 261 |
| Cash – End of period | \$ 13,350 | \$ 32 |
| Supplemental Disclosure of Cash Flows Information | | |
| Non-Cash Transactions: | | |
| 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 | \$ — |
| Common Shares issued for acquisition | \$ — | \$ 375 |
| Inventory acquired from acquisition | \$ — | \$ 21 |
| Accounts payable assumed from acquisition | \$ — | \$ 13 |

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, the Spin-off and Basis of Presentation

Description of Business

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 have 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 ability 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 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 periods 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.

The Spin-Off

On June 21, 2019, NexGel became an independent company through the pro rata distribution (“Spin-Off”) by Adynxx, Inc. (“Adynxx” and the “Parent”) in connection with the closing of a reverse merger between Adynxx, Inc. and Alliqua BioMedical, Inc., Adynxx, Inc. was previously known as Alliqua BioMedical, Inc. and subsequently changed its name to Adynxx, Inc. on May 3, 2019. The terms and conditions of the Spin-Off provided that each record holder of Parent stock as of April 22, 2019, received one share of NexGel common stock in book-entry form and resulted in the distribution of 143,006 shares of common stock of NexGel. Following the distribution (“Capitalization”), all existing operations were distributed to NexGel with the exception of a corporate lease for property in Yardley, Pennsylvania which was retained by Adynxx.

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Pursuant to the Spin-Off and in exchange for the 143,006 shares of common stock, NexGel assumed the following net liabilities from Parent as of June 21, 2019 (\$ in thousands):

| | |
|---|----------------|
| Assets: | |
| Cash | \$ 186 |
| Accounts receivable, net | 72 |
| Inventory | 140 |
| Prepaid expenses and other current assets | 101 |
| Property and equipment, net | 155 |
| Operating lease - right of use asset | 976 |
| Other assets | 178 |
| Total assets | 1,808 |
| Liabilities: | |
| Accounts payable | (496) |
| Accrued expenses and other current liabilities | (395) |
| Operating lease liability | (976) |
| Total liabilities | (1,867) |
| Net liabilities assumed in Spin-Off on June 21, 2019 | \$ (59) |

Basis of Presentation

The consolidated financial statements of the Company have been prepared without audit in accordance with generally accepted accounting principles in the United States of America ("GAAP") and are presented in US dollars.

2. Going Concern

As of December 31, 2021, the Company had a cash balance of \$13.35 million. For the year ended December 31, 2021, the Company incurred a net loss of \$4.31 million and had a net usage of cash in operating activities of \$2.75 million. In addition, the Company had a working capital of \$11.04 million as of December 31, 2021.

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, par value \$0.001 per share (the "Common Stock"), and a warrant to purchase one share of Common Stock at an exercise price of \$5.50 per share (the "Warrants"), for net proceeds of \$13.2 million.

Proceeds from the offerings 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 focused 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 its 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.

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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 allowance 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.

Cash

Cash include cash on hand and highly liquid investments having an original maturity of three months or less.

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 \$4 thousand as of December 31, 2021 and \$1 thousand as of December 31, 2020.

Inventory and Cost of Goods Sold

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 balance is made up of raw materials, work-in-progress, and finished goods of \$178 thousand, \$88 thousand, and \$25 thousand on December 31, 2021, respectively, and the balance was made up of raw materials, work-in-progress, and finished goods of \$190 thousand, \$22 thousand, and \$21 thousand on December 31, 2020, respectively.

As a contract manufacturer, the Company builds its products based on customer orders and immediately ships the products upon completion of the production process.

The "Cost of goods sold" line item in the consolidated statements of income 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.

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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 Revenue, net. 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 period of disposal and the resulting gains and losses are included in the results of operations during the same period.

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. The test for impairment is required to be performed by management at least annually. 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 are 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.

Prepaid expenses and other current assets

Prepaid expenses and other current assets is recorded at historical cost and is primarily made up of \$23 thousand and \$16 thousand of prepaid insurance, and \$54 thousand and \$9 thousand general prepaid expenses and other current assets in the years ended December 31, 2021 and 2020 respectively.

Other Assets

Other Assets is recorded at historical costs, and as of December 31, 2021 and 2020, the balance is entirely made up 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, notes payable and convertible notes payable) in the balance sheet to approximate fair value because of the short-term or highly liquid nature of these financial instruments.

Warrant Liability

Warrants to purchase common stock were issued in connection with equity financing raises, which occurred on September 2, 2021, March 11, 2021, February 3, 2021, December 24, 2020, March 18, 2020, September 10, 2019 and November 6, 2019. The fair values of the warrants are estimated as of the date of issuance and again at each period 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.

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 accounting principles generally accepted in the United States of America (“U.S. 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 recognizes revenue predominately from one type of revenue, contract manufacturing. Revenue from contract manufacturing is 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 revenues are 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.

Disaggregated revenue by sales type:

Year Ended

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| | December 31, | |
|---|-----------------|---------------|
| | 2021 | 2020 |
| Contract manufacturing | \$ 767 | \$ 615 |
| Custom and white label finished goods manufacturing | 492 | — |
| NexGel branded consumer products | 194 | 42 |
| Other | 98 | 17 |
| Total | <u>\$ 1,551</u> | <u>\$ 674</u> |

As of December 31, 2021 and 2020, the Company did not have any contract assets or contract liabilities from contracts with customers. As of December 31, 2021 and December 31, 2020, there were no remaining performance obligations that the Company had not satisfied.

Share-based compensation

On August 28, 2019, the Company adopted the 2019 Long-Term Incentive Plan (the “2019 Plan”). 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, 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 485,714 shares of common stock all of which may be delivered pursuant to incentive stock options. 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 14,285 shares of common stock.

The Company’s 2019 Long-Term Incentive 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 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 is 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 material impact to its consolidated financial statements.

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 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

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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 period 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 period from transactions and other equity and circumstances generated from non-owner sources. The Company's net loss equals comprehensive loss for all periods presented,

Recently Issued Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or 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 financial position or results of operations upon adoption.

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 March 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.

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 March 1, 2020 (the first quarter of our 2021 fiscal year).

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 will adopt ASU 2019-12 effective March 1, 2021 and do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

4. Acquisition

On May 29, 2020, the Company entered into a Membership Interest Purchase Agreement (the “Purchase Agreement”) whereby the Company purchased all of the outstanding equity securities of Sport Defense LLC, a Delaware limited liability company (“Sport Defense”), from the members of Sport Defense (the “Sellers”). Subsequent to the Closing Date, Sport Defense is a wholly-owned subsidiary of the Company.

Sport Defense is a marketing and distribution company that leverages the unique benefits of ultra-gentle, high-water content hydrogels, manufactured by the Company, to build brands that treat various ailments of the skin caused by athletic training, such as blisters, turf burns, scrapes and skin irritations. To date the Company has commercialized four branded products acquired from the acquisition of Sport Defense.

Under the terms of the Purchase Agreement, the purchase price paid to the Sellers was an aggregate of \$375 thousand (the “Purchase Price”) which was paid by the Company through the issuance of an aggregate of 9,375,000 shares of the Company’s common stock, par value \$0.001 (the “Shares”), which equates to a per share purchase price of \$0.04. The Shares are “restricted securities” as such term is defined by Rule 144 promulgated under the Securities Act of 1933, as amended.

Adam Levy, the Company’s Chief Executive Officer and Chief Financial Officer, and Nachum Stein, a member of the Company’s Board of Directors (the “Board”), were each members of Sport Defense and part of the Sellers. Mr. Levy received 1,546,875 of the Shares and Mr. Stein received 3,187,500 of the Shares. Due to the potential conflict of interest that existed because of Messrs. Levy and Stein’s partial ownership of Sport Defense, the Board obtained an independent investment bank to prepare a valuation report with respect to Sport Defense. This valuation report supported the Purchase Price. Also, Mr. Stein recused himself from the vote of the Board regarding the approval to purchase Sport Defense.

The Purchase Agreement and the Sport Defense acquisition were not subject to approval by the shareholders of the Company. The Purchase Agreement contained minimal representations and warranties regarding Sport Defense and certain limited representations and warranties regarding the Company and the Sellers.

The provisional fair value of the purchase consideration issued to the Seller was allocated to the net tangible assets acquired. The Company accounted for the Sport Defense acquisition as the purchase of a business under GAAP under the acquisition method of accounting, and the assets and liabilities acquired were recorded as of the acquisition date, at their respective fair values and consolidated with those of the Company. The fair value of the net assets acquired was approximately \$375 thousand. The excess of the aggregate fair value of the net tangible assets has been allocated to goodwill.

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The table below shows an analysis for the Sport Defense acquisition:

| | |
|--|---------------|
| Provisional Purchase Consideration at preliminary fair value: | |
| Purchase price | \$ 375 |
| Amount of consideration | <u>\$ 375</u> |
| Assets acquired and liabilities assumed at preliminary fair value | |
| Inventories | 21 |
| Product/Technology related intangibles | 31 |
| Marketing related intangibles | 8 |
| Customer related intangibles | 17 |
| Accounts payable and accrued expenses | (13) |
| Other liabilities | — |
| Net tangible assets acquired | <u>\$ 64</u> |
| | |
| Total net assets acquired | <u>\$ 64</u> |
| Consideration paid | 375 |
| Preliminary goodwill | <u>\$ 311</u> |

The unaudited pro-forma results of operations are presented for information purposes only. The unaudited pro-forma results of operations are not intended to present actual results that would have been attained had the Sport Defense acquisition been completed as of January 1, 2020 or to project potential operating results as of any future date or for any future periods.

| | For the Year Ended December 31, | |
|---|------------------------------------|------------|
| | 2021 | 2020 |
| Revenues, net | \$ 1,551 | \$ 691 |
| Net loss allocable to common shareholders | \$ (4,310) | \$ (2,254) |
| Net loss per share | \$ (1.46) | \$ (0.03) |
| Weighted average number of shares outstanding | 2,942,057 | 2,477,359 |

5. Leases

The Company has one operating lease for a commercial manufacturing facility and administrative offices located in Langhorne, Pennsylvania that runs through January 2031.

The following table presents information about the amount and timing of the liability arising from the Company's operating lease as of December 31, 2021 (\$ in thousands):

| Maturity of Lease Liability | Operating Lease Liability |
|---|---------------------------------|
| 2022 | \$ 207 |
| 2023 | 207 |
| 2024 | 207 |
| 2025 | 207 |
| 2026 | 263 |
| Thereafter | 1,165 |
| Total undiscounted operating lease payments | <u>\$ 2,256</u> |
| Less: Imputed interest | (305) |
| Present value of operating lease liability | <u>\$ 1,951</u> |
| Weighted average remaining lease term | 9.1 years |
| Weighted average discount rate | 3.0 % |

Total operating lease expense for the year ended December 31, 2021 and 2020 was \$207 thousand, and is recorded in cost of goods sold and selling, general and administrative expenses on the statement of operations.

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

| | <u>December 31,</u> <u>2021</u> |
|---|------------------------------------|
| Cash paid for amounts included in the measurement of lease liability: | |
| Operating cash flows from operating lease | \$ 207 |
| Right-of-use asset obtained in exchange for lease obligation: | |
| Operating lease | \$ 2,050 |

6. Inventory

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

| | <u>December 31,</u> <u>2021</u> | <u>December 31,</u> <u>2020</u> |
|--|------------------------------------|------------------------------------|
| Raw materials | \$ 178 | \$ 190 |
| Work-in-progress | 88 | 22 |
| Finished goods | 25 | 21 |
| | <u>291</u> | <u>233</u> |
| Less: Inventory reserve for excess and slow moving inventory | — | — |
| Total | <u>\$ 291</u> | <u>\$ 233</u> |

As a contract manufacturer, the Company builds its products based on customer orders and immediately ships the products upon completion of the production process.

7. Property and Equipment, Net

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

| | <u>Useful Life</u> <u>(Years)</u> | <u>December 31,</u> <u>2021</u> | <u>December 31,</u> <u>2020</u> |
|---|--------------------------------------|------------------------------------|------------------------------------|
| Machinery and equipment | 3 - 10 | \$ 940 | \$ 2,894 |
| Office furniture and equipment | 3 - 10 | 50 | 49 |
| Leasehold improvements | 6 | 228 | 228 |
| Construction in progress | N/A | — | 461 |
| | | <u>1,218</u> | <u>3,632</u> |
| Less: accumulated depreciation and amortization | | (495) | (3,079) |
| Property and equipment, net | | <u>\$ 723</u> | <u>\$ 553</u> |

Depreciation expense for the year ended December 31, 2021 and 2020 was \$99 thousand and \$42 thousand, respectively.

8. Intangible Assets

The following provides a breakdown of identifiable intangible assets as of December 31, 2021:

| | December 31, 2021 | December 31, 2020 |
|--|----------------------|----------------------|
| Product/Technology Related | | |
| Identifiable intangible assets, gross | \$ 31 | \$ 31 |
| Accumulated amortization | (16) | (6) |
| Product/Technology Related identifiable intangible assets, net | <u>15</u> | <u>25</u> |
| Marketing Related | | |
| Customer related intangible asset, gross | 17 | 17 |
| Tradename related intangible asset, gross | 7 | 7 |
| Accumulated amortization | (6) | (2) |
| Marketing related identifiable intangible assets, net | <u>18</u> | <u>22</u> |
| Total identifiable intangible assets, net | <u>\$ 33</u> | <u>\$ 47</u> |

In connection with the acquisitions of Sport 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 4.5 years and amortization expense amounted to \$14 thousand and \$8 thousand for the year ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, the estimated annual amortization expense for each of the next five fiscal years is as follows:

| | |
|--------------|--------------|
| 2022 | \$ 14 |
| 2023 | 8 |
| 2024 | 2 |
| 2025 | 2 |
| 2026 | 2 |
| Thereafter | 5 |
| Total | <u>\$ 33</u> |

9. Accrued Expenses and Other Current Liabilities

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

| | December 31, 2021 | December 31, 2020 |
|--|----------------------|----------------------|
| Salaries, benefits, and incentive compensation | \$ 54 | \$ 43 |
| Professional fees | — | — |
| Other | 8 | 47 |
| Total accrued expenses and other current liabilities | <u>\$ 62</u> | <u>\$ 90</u> |

10. 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 we sold 101,800 shares of our common stock at a price per share equal to \$2.80 for an aggregate purchase price of \$285,000.

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From February 6, 2020 through March 20, 2020, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 442,858 shares of our common stock at a price per share equal to \$1.40 for an aggregate purchase price of \$620,000. Proceeds from this offering are expected to be used for working capital, new product development and testing, and general business operations. The placement agent for the private placement and is entitled to receive a total fee equal to 6% of the total gross proceeds and warrants to purchase the number of shares of Common Stock equal to 10% of the number of shares of Common Stock issued to the Investors, for such services rendered. The warrants are exercisable for 3 years at an exercise price equal to \$1.40.

From July 30, 2020 through August 14, 2020, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 188,143 shares of our common stock at a price per share equal to \$2.10 for an aggregate purchase price of \$395,100.

From October 13, 2020 through December 24, 2020, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 126,786 shares of our common stock at a price per share equal to \$2.80 for an aggregate purchase price of \$355,000. Proceeds from this offering are expected to be used for working capital, new product development and testing, and general business operations.

On February 10, 2020, a majority of our stockholder through a written consent approved the following: an amendment to our Restated Certificate of Incorporation which will increase the number of authorized shares of Common Stock from 100,000,000 shares of Common Stock to 3,000,000,000 shares of Common Stock and (ii) an amendment to our Restated Certificate of Incorporation to effect a reverse stock split of our Common Stock by a ratio of not less than one-for-thirty and not more than one-for-one hundred, with the exact number to be set at a whole number within this range to be determined by our board of directors in its sole discretion and to authorize our board of directors to implement the reverse stock split by filing an amendment to our Amended and Restated Certificate of Incorporation. On May 26, 2020, the Company filed an amendment to the certificate of incorporation to increase the number of the Company's authorized shares of common stock from 100,000,000 shares of common stock to 3,000,000,000 shares of common stock. The reverse stock split has not been effected as of date of the filing of this prospectus. For more information on these amendments, please see the Company's Definitive Information Statement on Schedule 14C filed with the SEC on March 16, 2020.

On February 17, 2020, the Company granted certain equity awards to the members of the Company's Board of Director with the following terms: each of Messrs. Stefansky and Stein received two annual awards of stock options equal to \$40,000 of the Company's common stock, granted under the Company 2019 Long-Term Incentive Plan (the "Incentive Plan"), with (i) the first grant being the right to purchase up to 81,633 shares of the Company's common stock at a per share exercise price of \$0.49 with one-half of such option vesting on March 31, 2020 and the remaining one-half vesting in equal installments on June 30, 2020 and September 30, 2020, respectively, and with an acceleration of any unvested options upon the departure of applicable Board member from the Board for any reason and (ii) the second grant being the right to purchase up to a number of shares of the Company's common stock equal to \$40,000 divided by the Fair Market Value (as defined in the Incentive Plan) of the Company's common stock as of October 10, 2020 at a per share exercise price equal to Fair Market Value of the Company's common stock as of October 10, 2020 with one-fourth of such option vesting on each of December 31, 2020, March 31, 2021, June 30, 2021 and September 30, 2021, respectively, and with an acceleration of any unvested options upon the departure of applicable Board member from the Board for any reason.

On February 17, 2020, the Company granted a restricted stock award of 169,388 shares of the Company's common stock to the Company's Chief Executive Officer and Chief Financial Officer, Adam Levy, with the following vesting terms: (i) 3/12th of such shares vested as of February 17, 2020; (ii) 1/12th of such shares vest on each of the eight months following February 17, 2020 and (iii) all remaining shares vest on September 10, 2020. In November 2020, the Company issued 169,397 shares to our Chief Executive Officer upon the vesting of the restricted stock awards (See Note 12).

At December 31, 2021, the Company has reserved common stock for issuance in relation to the following:

| | |
|-----------------------------------|-----------|
| Share-based compensation plan | 434,939 |
| Warrants to purchase common stock | 3,637,190 |

11. Share-based Compensation

On August 28, 2019, the Company adopted the 2019 Long-Term Incentive Plan (the “2019 Plan”). 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 2,000,000 shares of the Company’s common stock for awards under the 2019 Plan. Effective as of May 26, 2020, the Board approved an increase of the number of authorized shares of common stock reserved under the 2019 Plan from 2,000,000 shares of common stock to 17,000,000 shares of common stock all of which may be delivered pursuant to incentive stock options., all of which may be delivered pursuant to incentive stock options. 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 500,000 shares of common stock.

Incentive stock options

On February 17, 2020, the Company granted certain equity awards to the members of the Company’s Board of Director with the following terms: each of Messrs. Stefansky and Stein received two annual awards of stock options equal to \$40,000 of the Company’s common stock, granted under the Company 2019 Long-Term Incentive Plan (the “Incentive Plan”), with (i) the first grant being the right to purchase up to 81,633 shares of the Company’s common stock at a per share exercise price of \$0.49 with one-half of such option vesting on March 31, 2020 and the remaining one-half vesting in equal installments on June 30, 2020 and September 30, 2020, respectively, and with an acceleration of any unvested options upon the departure of applicable Board member from the Board for any reason and (ii) the second grant being the right to purchase up to a number of shares of the Company’s common stock equal to \$40,000 divided by the Fair Market Value (as defined in the Incentive Plan) of the Company’s common stock as of October 10, 2020 at a per share exercise price equal to Fair Market Value of the Company’s common stock as of October 10, 2020, which the Board determined to be \$2.10 and equates to 19,048 shares underlying each of the second grants, with one-fourth of such option vesting on each of December 31, 2020, March 31, 2021, June 30, 2021 and September 30, 2021, respectively, and with an acceleration of any unvested options upon the departure of applicable Board member from the Board for any reason.

In May 2020 and July 2020, pursuant to the terms of the 2019 Plan, the Company awarded options to purchase an aggregate of 152,143 shares of common stock to two of its employees and one contractor. Pursuant to the terms of the option agreements, 9,286 of the options vested on the date of grant, and of the 142,858 options, 10% of such options vested on the date of grant, and the remaining of such options will vest upon meeting established criteria. The term of the options is ten years.

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. This option award fully vested 20% as of the date of grant and the remaining 80% 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. This option award vests in four equal calendar quarter installments beginning on October 1, 2021.

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The following table contains information about the 2019 Plan as of December 31, 2021:

| | Awards Reserved for Issuance | Awards Issued | Awards Available for Grant |
|-----------|------------------------------|---------------|----------------------------|
| 2019 Plan | 571,429 | 434,939 | 136,490 |

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

| | Number of Options | Weighted Average Exercise Price | Weighted Average Contractual Term in Years |
|----------------------------------|-------------------|---------------------------------|--|
| Outstanding at January 1, 2020 | 28,576 | 1.873375 | 9.6 |
| Granted | 363,028 | \$ 1.0185 | 10.0 |
| Exercised | — | — | — |
| Forfeited | — | — | — |
| Cancelled | — | — | — |
| Expired | — | — | — |
| Outstanding at December 31, 2020 | 391,604 | \$ 0.97076 | 9.32 |
| Granted | 90,478 | \$ 3.960526 | 10.00 |
| Exercised | (7,183) | 1.75 | — |
| Forfeited | — | — | — |
| Cancelled | (39,960) | 1.49975 | — |
| Expired | — | — | — |
| Outstanding at December 31, 2021 | 434,939 | \$ 1.675747 | 8.56 |
| Exercisable at December 31, 2021 | 291,364 | \$ 1.331957 | 8.43 |

As of December 31, 2021, vested outstanding stock options had \$529 thousand intrinsic value as the exercise price is greater than the estimated fair value of the underlying common stock. As of December 31, 2021, there was approximately \$195 thousand of total unrecognized share-based compensation related to unvested stock options, which the Company expects to recognize over the next 12 months.

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, 2021:

| | |
|-------------------------|------------------|
| Volatility | 171.12%-183.48 % |
| Risk-free interest rate | 0.46% - 0.86 % |
| Dividend yield | 0.0 % |
| Expected term | 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

On February 17, 2020, the Company granted a restricted stock award of 169,388 shares of the Company's common stock to the Company's Chief Executive Officer and Interim Chief Financial Officer, Adam Levy, with the following vesting terms: (i) 3/12th of

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such shares vested as of February 17, 2020; (ii) 1/12th of such shares vest on each of the eight months following February 17, 2020 and (iii) all remaining shares vest on September 10, 2020.

On March 8, 2021, the Company granted a restricted stock award of 39,524 shares of the Company's common stock to the 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.

| | Number of Units | Weighted Average Grant Date Fair Value |
|--|--------------------|---|
| Granted | 208,912 | \$ 0.805 |
| Exercised and converted to common shares | (169,388) | 0.490 |
| Forfeited | — | — |
| Outstanding at December 31, 2020 | <u>39,524</u> | <u>\$ 2.100</u> |
| Granted | — | — |
| Exercised and converted to common shares | (39,524) | 2.100 |
| Forfeited | — | — |
| Outstanding at December 31, 2021 | <u>—</u> | <u>\$ —</u> |
| Exercisable at December 31, 2021 | <u>—</u> | <u>\$ —</u> |

Under ASC 718, Compensation-Stock Compensation ("ASC 718"), the Company has measured the value of its February 2020 award as if it were vested and issued on the grant date with a value of \$83 thousand based on the closing price of the Company's stock at the grant date of the RSU Grant (\$0.49 per share). An additional issuance of 39,924 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 (\$2.10 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 \$284 thousand and \$232 thousand has been recorded for the year ended December 31, 2021 and 2020, respectively.

Warrants

The following table shows a summary of common stock warrants through December 31, 2021:

| | Number of Warrants | Weighted Average Exercise Price | Weighted Average Contractual Term in Years |
|----------------------------------|-----------------------|--|---|
| Outstanding at December 31, 2019 | <u>150,000</u> | <u>\$ 0.49000</u> | <u>2.81</u> |
| Granted | 60,500 | \$ 1.7752 | 5.00 |
| Exercised | — | — | — |
| Forfeited | — | — | — |
| Cancelled | — | — | — |
| Expired | — | — | — |
| Outstanding at December 31, 2020 | <u>210,500</u> | <u>\$ 0.85938</u> | <u>2.54</u> |
| Granted | 3,426,690 | \$ 5.42717 | 4.98 |
| Exercised | — | — | — |
| Forfeited | — | — | — |
| Cancelled | — | — | — |
| Expired | — | — | — |
| Outstanding at December 31, 2021 | <u>3,637,190</u> | <u>\$ 5.16281</u> | <u>4.63</u> |
| Exercisable at December 31, 2021 | <u>3,637,190</u> | <u>\$ 5.16281</u> | <u>4.63</u> |

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

12. Note Payable

PPP Loan

On April 22, 2020, the Company entered into a promissory note (the “Promissory Note”) with PNC Bank, N.A. (the “Bank”), which provides 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 (the “CARES Act”). On March 4, 2021, the Company received a second PPP Loan in the amount of \$127,400 thousand under Phase II of the Paycheck Protection Program which commenced on January 13, 2021 and allowed certain businesses that received an initial PPP Loan to seek a second draw PPP Loan. The PPP Loan has a two-year term and bears interest at a rate of 1.0% per annum. Monthly principal and interest payments are deferred for six months after the date of disbursement. The PPP Loan may be prepaid at any time prior to maturity with no prepayment penalties. The Promissory Note contains events of default and other provisions customary for a loan of this type. The Paycheck Protection Program provides that the PPP Loan may be partially or wholly forgiven if the funds are used for certain qualifying expenses as described in the CARES Act. The Company used the proceeds from the PPP Loan for qualifying expenses and plans to apply for forgiveness of the PPP Loan in accordance with the terms of the CARES Act. 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 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. The balance of the PPP loan as of December 31, 2020 amounted to \$147,300.

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 \$8,000 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.

13. Convertible Notes Payable

On December 24, 2020, the Company entered into two Securities Purchase Agreement, dated December 24, 2020 (the “Purchase Agreement”) pursuant to which the Company issued the following (i) \$100,000 6% Secured Convertible Promissory Note which was convertible into shares of the Company’s common stock at a price per share of \$2.80 and (ii) Common Stock purchase warrants to purchase up to 8,929 shares of common stock with an exercise price of \$2.80. The notes are secured by all of the assets and equipment owned by the Company. The notes were due on or before June 24, 2021 and fully-repaid (including all accrued but unpaid interest) on March 14, 2021.

On January 19, 2021, the Company entered into a Securities Purchase Agreement, (the “2021 Purchase Agreement”) pursuant to which the Company issued the following (i) \$15,000 Secured Convertible Promissory Note which was convertible into shares of the Company’s common stock at a price per share of \$1.05. The notes were due on or before March 19, 2021 and fully-repaid (including all accrued but unpaid interest) on March 14, 2021.

Auctus Fund Financing

On March 11, 2021 (the “Issuance Date”), the Company entered into a securities purchase agreement (the “Auctus Purchase Agreement”) with Auctus Fund, LLC, a Delaware limited liability company (“Auctus”), pursuant to which the Company issued to Auctus a senior secured convertible promissory note in the principal amount of \$1,680,000, including Original Issue Discount (OID) of \$180,000 (the “Auctus Note”). The net proceeds received by the Company were \$1,337,000 (after deducting fees and expenses related to the transaction, including a payment to Alere (as defined and discussed below). The Company intends to use the net proceeds for working capital and general corporate purposes.

On August 13, 2021, the Company and Auctus entered a First Amendment to the Senior Secured Promissory Note, Warrants and Securities Purchase Agreement dated March 11, 2011 (the “Auctus Amendment”).

On October 28, 2021, the Company and Auctus Fund, LLC entered a Second Amendment to the Senior Secured Promissory Note, Warrants and Securities Purchase Agreement dated March 11, 2011 (the “Auctus Second Amendment”).

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The Auctus Note has a maturity date of one year from the Issuance Date. The Auctus Note bears interest at a rate of 12% per annum, which is also payable on maturity, with the understanding that the first 12 months of interest (equal to \$180,000) is guaranteed and deemed to be earned in full as of the Issuance Date. In the event the Company fails to pay any amount when due under the Auctus Note, the interest rate will increase to the greater of 16% or the maximum amount permitted by law. The Auctus Note may be prepaid during the first 180 calendar days from the Issuance Date subject to a 110% prepayment penalty on all principal and accrued but unpaid interest then outstanding. The Auctus Note may not be paid in whole or in part after 180 calendar days from the Issuance Date.

Auctus may convert any amount due under the Auctus Note at any time, and from time to time, into shares of the Company's common stock at a conversion price of \$3.50 per share; provided, however, that Auctus may not convert any portion of the Auctus Note that would cause it to beneficially own in excess of 4.99% of the Company's common stock. The conversion price and number of shares of the Company's common stock issuable upon conversion of the Auctus Note will be subject to adjustment from time to time for any subdivision or consolidation of shares and other standard dilutive events.

The Auctus Note (as amended by the Auctus Amendment and Auctus Second Amendment) contains a number of events of default, including but not limited to the following: (i) the Company's failure to be quoted or listed (as applicable) on the OTCQB, OTCQX, any tier of the NASDAQ Stock Market, the New York Stock Exchange, or the NYSE American by December 15, 2021 (the "Trading Date") and (ii) the Company's failure to file a registration statement covering the Auctus' resale at prevailing market prices (and not fixed prices) of all of the common stock underlying the Auctus Note and the Auctus Warrants (as defined below) within 30 calendar days following the Issuance Date, (iii) cause the registration statement to become effective by the Trading Date and (iv) maintain a certain share reserve for the conversion of the note. An event of default is subject to a confession of judgment against the Company in the favor of Auctus. Additionally, the Auctus Note is secured by all of the assets of the Company pursuant to a security agreement that was entered into in connection with the issuance of the Auctus Note (the "Security Agreement"); provided, however, the Security Agreement will be automatically terminated as of the Trading Date assuming no event of default then exists. The Auctus Amendment waived any events of default which may have existed under Sections 3.18 and 3.19 of the Auctus Note prior to August 13, 2021. There were no events of default for the year ended December 31, 2021 and through the note repayment on March 15, 2022 (see Note 19).

In connection with the issuance of the Auctus Note, Auctus was also issued two five-year warrants as follows: the first warrant was to purchase up to an aggregate of 171,429 shares of the Company's common stock at an exercise price of \$4.375 per share (the "First Auctus Warrant") and the second warrant was to purchase up to an aggregate of 142,858 shares of the Company's common stock at an exercise price of \$5.25 per share (the "Second Auctus Warrant"). The First Auctus Warrant and the Second Auctus Warrant are referred to herein as the "Auctus Warrants" and the shares of the Company's common stock underlying the Auctus Warrants are referred to as the "Auctus Warrant Shares".

Auctus may not exercise the Auctus Warrants with respect to any number of Auctus Warrant Shares that would cause it to beneficially own in excess of 4.99% of the Company's common stock. The Auctus Warrants may be exercised for cash, or, if the "market price" of the Company's common stock is greater than the Auctus Warrant's exercise price, and there is not an effective registration statement covering the Auctus Warrant Shares, the Auctus Warrants may be exercised on a cashless basis. The number of shares of common stock to be deliverable upon exercise of the Auctus Warrants is subject to adjustment for subdivision or consolidation of shares and other standard dilutive events, or in the event the Company effects a reorganization, reclassification, merger, consolidation, disposition of assets, or other fundamental transaction.

Pursuant to the Auctus Purchase Agreement, the Company granted Auctus piggyback registration rights with respect to the shares underlying the Auctus Note and the Auctus Warrant. In addition, the Company agreed that, while any amount remains unpaid under the Auctus Note, it would not sell securities on more favorable terms than those provided to Auctus, without adjusting Auctus' terms accordingly. Further, among other things, the Company agreed that, while any amount remains unpaid under the Auctus Note, it would not enter into any variable rate transactions.

Further and in connection with the issuance of the Auctus Note, the Company entered into a registration rights agreement with Auctus (the "Registration Rights Agreement") whereby it the Company agreed to (i) file with the Securities and Exchange Commission a registration statement covering resale by Auctus at prevailing market prices (and not fixed prices) of all of the common stock underlying the Auctus Note and the Auctus Warrants within 30 calendar days following the Issuance Date, (ii) cause the registration statement to become effective by the Trading Date.

Alere Financial, A Division of Cova Capital Partners, LLC ("Alere"), served as the placement agent for the Auctus Note and received a total cash fee equal to \$120,000 (or 8% of the principal amount of the Auctus Note). Additionally, Alere received warrants to purchase 654,545 and 545,455 shares of common stock at an exercise price equal to \$4.375 and \$5.25, respectively, for such services rendered. Alere's warrants are in a customary form reasonably acceptable to Alere and exercisable for 3 years. Mr. Levy, the Company's Chief

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Executive Officer, is affiliated with Alere but has waived any portion of such fee received by Alere to which he is entitled as an affiliate of Alere.

As of December 31, 2021, the Auctus Fund Financing note outstanding was \$1,357,808, which consisted of principal of \$1,680,000, net of unamortized balance of \$256,410 of a beneficial conversion and warrant features, unamortized original issue discount of \$34,521. and unamortized debt issuance costs of \$31,261.

Investor Private Placement Offering

On September 2, 2021, the Company conducted a closing of a private placement offering (the “September 2 Offering”) with twenty accredited investors (the “September 2 Investors”) whereby the Company entered into a securities purchase agreement (the “September Purchase Agreement”) with the Investors pursuant to which the Company issued to the Investors subordinated secured convertible promissory notes in the aggregate principal amount of \$1,620,000 (the “September 2 Notes”). The net proceeds received by the Company were \$1,504,400 (after deducting fees owed to its placement agent, Alere (as defined and discussed below)). The Company intends to use the net proceeds for working capital and general corporate purposes.

The Notes have a maturity date of one year from September 2, 2021. The Notes bear interest at a rate of 12% per annum, which is also payable on maturity, with the understanding that the first 12 months of interest (equal to an aggregate of \$194,400) is guaranteed and deemed to be earned in full as of September 2, 2021. In the event the Company fails to pay any amount when due under the September 2 Notes, the interest rate will increase to the greater of 18% or the maximum amount permitted by law. The Notes may be prepaid during the first 180 calendar days from September 2, 2021 subject to a 110% prepayment penalty on all principal and accrued but unpaid interest then outstanding. The Notes may not be prepaid in whole or in part after 180 calendar days from September 2, 2021. The September 2 Investors may convert any amount due under the September 2 Notes at any time, and from time to time, into shares of the Company’s common stock at a conversion price of \$5.25 per share; provided, however, that the Investors may not convert any portion of the September 2 Notes that would cause such Investor to beneficially own in excess of 4.99% of the Company’s common stock. The conversion price and number of shares of the Company’s common stock issuable upon conversion of the September Notes will be subject to adjustment from time to time for any subdivision or consolidation of shares and other dilutive events. If the Company issues Common Stock or securities convertible into Common Stock at a per share price lower than the conversion price of \$5.25 (the “Base Price”), then the conversion price of the Notes will be reduced to the new Base Price at the option of the holder.

Additionally, the September 2 Notes are secured by all of the assets of the Company pursuant to a security agreement that was entered into in connection with the issuance of the September 2 Notes (the “September 2 Security Agreement”); provided, however, the Security Agreement will automatically terminate on the business day immediately preceding the Company’s common stock being quoted or listed for trading on the OTCQB Marketplace, OTCQX, any tier of the NASDAQ, Stock Market, the New York Stock Exchange, or the NYSE American assuming that no event of default under the Notes then exists. The secured interest in all of the Company’s assets granted to the Investors is subordinated to a first priority secured interest previously granted to Auctus Fund, LLC pursuant to the terms of a September 2 Subordination Agreement (the “September 2 Subordination Agreement”).

In connection with the issuance of the Notes, the Investors were also issued five-year warrants to purchase up to an aggregate of 308,571 shares of the Company’s common stock (the “September Warrant Shares”) at an exercise price of \$5.25 per share (the “September 2 Warrants”).

The Investors may not exercise the September 2 Warrants with respect to any number of September 2 Warrant Shares that would cause such Investor to beneficially own in excess of 4.99% of the Company’s common stock. The September 2 Warrants may be exercised for cash, or, if the “market price” of the Company’s common stock is greater than the September 2 Warrant’s exercise price, and there is not an effective registration statement covering the September 2 Warrant Shares, the September 2 Warrants may be exercised on a cashless basis. The number of shares of common stock to be deliverable upon exercise of the September 2 Warrants is subject to adjustment for subdivision or consolidation of shares and other standard dilutive events, or in the event the Company effects a reorganization, reclassification, merger, consolidation, disposition of assets, or other fundamental transaction. In the event that the Company issues Common Stock, securities convertible into Common Stock, or the right to acquire Common Stock at an effective per share price less than \$5.25 (the “Base Price”), the per share price the of September 2 Warrants are adjustable down to the new Base Price at the option of the holder. If such adjustment occurs, the number of warrant shares issuable under the September 2 Warrants shall also be increased such that the aggregate exercise price of the warrants shall be the same of the aggregate price prior to the adjustment.

Pursuant to the September 2 Purchase Agreement, the Company agreed that, while any amount remains unpaid under the September 2 Notes, it would not sell securities on more favorable terms than those provided to the Investors, without adjusting the Investors’ terms accordingly. This right will terminate as of the Post Lock-Up Termination Date (as defined in the September 2 Purchase Agreement).

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Further, among other things, the Company agreed that, while any amount remains unpaid under the Notes, it would not enter into any variable rate transactions.

In connection with the issuance of the September 2 Notes, the Company entered into a registration rights agreement with the September 2 Investors (the “September 2 Registration Rights Agreement”) whereby the Company agreed to file a registration statement covering the September 2 Investors’ resale of all of the common stock underlying the September 2 Notes and the September 2 Warrants upon the earlier of 30 calendar days following the effectiveness of a registration statement relating to an underwritten public offering of the Company or December 31, 2021 and cause such registration statement to become effective within 150 calendar days following the initial filing date. In connection with the September 2 Offering, the Investors entered into a Lock-Up Agreement (the “Lock-Up Agreement”) whereby each Investor agreed not to sell certain percentages of the equity such Investor owns in the Company for a certain period of time subsequent to an initial public offering of the Company’s equity.

Alere Financial, a division of Cova Capital Partners, LLC (“Alere”), served as the placement agent for the September 2 Notes and received a total cash fee equal to \$115,600 and warrants to purchase up to 770,667 shares of the Company’s common stock, with a term of five years, at a per share exercise price of \$5.25. Mr. Levy, the Company’s Chief Executive Officer, is affiliated with Alere but has waived any portion of such fee received by Alere to which he is entitled as an affiliate of Alere.

As of December 31, 2021, the September 2 Notes’ outstanding balance was \$678,864, which consisted of principal of \$1,814,400, net of unamortized balance of \$927,734 of a beneficial conversion and warrant features, unamortized original issue discount of \$130,312 and unamortized debt issuance costs of \$77,490.

14. 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, 34,286, 7,429, 7,286, 44,286, 35,715 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. 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 in the statement of operations.

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:

| <i>Black-Scholes Assumptions</i> | Exercise | Warrant Expiration | Interest Rate | Volatility | Time to Maturity | Calculated fair value | Future Estimated Quarterly Dividend | |
|-----------------------------------|-----------------|--------------------|---------------|------------|------------------|-----------------------|-------------------------------------|----------------------------|
| | Price | Date | | | | | | Stock Price ⁽⁸⁾ |
| 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 | \$ — |

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

| <i>Black-Scholes Assumptions</i> | 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 | \$ — |
| December 31, 2021 ⁽²⁾ | \$ 4.375 - 5.25 | March 11, 2026 | \$ 3.50 | 0.98 % | 205.16 % | 4.19 | \$ 0.096101 - 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 | \$ — |

| <i>Black-Scholes Assumptions</i> | 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, 2020 ⁽⁴⁾ | \$ 2.80 | December 24, 2020 | \$ 2.80 | 0.17 % | 172.38 % | 2.98 | \$ 2.422658 | \$ — |
| December 31, 2020 ⁽⁵⁾ | \$ 1.40 | March 18, 2023 | \$ 1.40 | 0.13 % | 172.38 % | 2.21 | \$ 1.075547 | \$ — |
| December 31, 2020 ⁽⁶⁾ | \$ 0.49 | September 10, 2022 | \$ 0.49 | 0.13 % | 172.38 % | 1.85 | \$ 0.38185 | \$ — |
| December 31, 2020 ⁽⁷⁾ | \$ 0.49 | November 6, 2022 | \$ 0.49 | 1.13 % | 172.38 % | 1.69 | \$ 0.3825 | \$ — |

(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

(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 period ending date, as published by the U.S. Federal Reserve.

(10) Based on the historical daily volatility of Guideline Public Companies and each presented period ending 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.

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

| <u>Warrant Liability</u> | <u>Warrants Outstanding</u> | <u>Fair Value per Share</u> | <u>Fair Value</u> |
|---|-----------------------------|-----------------------------|-------------------|
| Fair Value at initial measurement date of 12/31/19 | 150,000 | \$ 0.38185 | \$ 56 |
| Fair Value at initial measurement dates | 51,572 | \$ 1.2656 | \$ 65 |
| Change in fair value of warrant liability | | | 2 |
| Fair Value as of period ending 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 period ending 12/31/2021 | 265,305 | | \$ 318 |

The warrant liabilities are considered Level 3 liabilities on the fair value hierarchy as the determination of fair value includes various assumptions about of future activities and the Company's stock prices and historical volatility of Guideline Public Companies as inputs. As of December 31, 2020, none of the warrants have been exercised.

15. 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 13). 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 (See Note 13).

Sport Defense Acquisition

On May 29, 2020, the Company entered into a Membership Interest Purchase Agreement whereby the Company purchased all of the outstanding equity securities of Sport Defense LLC., Adam Levy, the Company's Chief Executive Officer and Chief Financial Officer, and Nachum Stein, a member of the Company's Board of Directors (the "Board"), were each members of Sport Defense and part of the Sellers. Mr. Levy received 44,197 of the shares and Mr. Stein received 91,072 of the shares (See Note 4).

Advances

Dr. Jerome Zeldis, a member of the Company Board, has an outstanding balance due of \$30,000 for services as of December 31, 2020. The fees were paid in March, 2021.

16. 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, 2021 and 2020, there was no income tax expense or benefit.

At December 31, 2021 and December 31, 2020, 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.

Pursuant to the Spin-off, the Company and Alliqua BioMedical, Inc. entered into a Tax Matters Agreement to provide for the payment of tax liabilities and entitlement of refunds; allocation of the responsibility for, and cooperation in, filing of tax returns; and other matters relating to taxes for the pre- and post-Spin-off periods.

Prior to the consummation of the Spin-Off, NexGel's operating results were included in Adynxx consolidated U.S. federal and state income tax returns. For the purposes of the Company's Consolidated and Combined Financial Statements for periods prior to the Separation, income tax expense and deferred tax balances have been recorded as if the Company filed tax returns on a standalone basis

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separate from Adynxx. The Separate Return Method applies the accounting guidance for income taxes to the standalone financial statements as if the Company was a separate taxpayer and a standalone enterprise prior to the separation from Adynxx.

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

| | For The Years Ended December 31 | |
|----------------------|------------------------------------|-------------|
| | 2021 | 2020 |
| Federal: | | |
| Current | \$ — | \$ — |
| Deferred | — | — |
| State and local: | | |
| Current | — | — |
| Deferred | — | — |
| Income tax provision | <u>\$ —</u> | <u>\$ —</u> |

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, 2021 and 2020, the expected tax benefit based on the statutory rate reconciled with the actual benefit is as follows:

| | For The Years Ended December 31, | |
|--|----------------------------------|--------------|
| | 2021 | 2020 |
| 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 | (10.5)% | (1.3)% |
| State tax change | 0.0 % | 0.0 % |
| Timing differences | 0.6 % | 0.0 % |
| Change in valuation allowance | (16.4)% | (25.0)% |
| Income tax provision | <u>0.0 %</u> | <u>0.0 %</u> |

For the years ended December 31, 2021 and 2020, differences between the expected tax expense based on the federal statutory rate and the actual tax expense is primarily attributable to losses for which no benefit is recognized.

As of December 31, 2021 and 2020, the Company's deferred tax assets consisted of the effects of temporary differences attributable to the following:

| | As of December 31, | |
|---|--------------------|---------------|
| | 2021 | 2020 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ 3,165 | \$ 2,494 |
| Intangible Assets | — | — |
| Other | 4 | 3 |
| Total deferred tax assets | 3,169 | 2,497 |
| Valuation allowance | (3,169) | (2,382) |
| Deferred tax assets, net of valuation allowance | <u>\$ —</u> | <u>\$ 115</u> |
| Deferred tax liabilities: | | |
| Property and equipment, net | — | (115) |
| Total deferred tax liabilities | — | (115) |
| Net deferred tax liabilities | <u>\$ —</u> | <u>\$ —</u> |

The deferred tax assets associated with net operating losses included in the table above reflect proforma net operating losses as if the Company were a separate taxpayer during the periods presented. As of December 31, 2021 and 2020, reported approximately \$12.6 million and \$10.0 million of federal NOL carryovers, respectively, which begin to expire in 2029 and through 2036. Similarly, the subsidiary's Pennsylvania state returns reported state NOL carryovers of approximately \$12.6 million and \$10 million, as of December 31, 2021 and 2020, 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 periods 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, 2021 and 2020 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, 2021 and 2020, the Company does not have any significant uncertain tax positions.

17. 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.

18. 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.

Revenues from three customers that exceeded 10% of total revenues for the year ended December 31, 2021 were 15%, 14%, and 13%. The accounts receivable from the top three customers were 45%, 12%, and 8% as well as 20% from one other customer of the total accounts receivable as of December 31, 2021.

Revenues from three customers that exceeded 10% of total revenues for the year ended December 31, 2020 were 45%, 22%, and 11%. The accounts receivable from the top three customers were 57%, 0%, and 0% as well as 12% from one other customer of the total accounts receivable as of December 31, 2020.

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash. 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. From time to time, cash balances may exceed the FDIC insurance limit. The Company has not experienced any credit losses associated with its cash balances in the past.

19. Subsequent Events

On March 11, 2021, the Company entered into a securities purchase agreement with Auctus Fund, LLC, a Delaware limited liability company ("Auctus"), pursuant to which the Company issued to Auctus a senior secured convertible promissory note in the principal amount of \$1,500,000 with a one-year term (the "Auctus Note"). The Auctus Note was fully repaid by the Company, including all principle and interest, on March 15, 2022 which thereby extinguished the Auctus Note in its entirety.

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

None.

Item 9A. Controls and Procedures

Management's Responsibility for Financial Statements

Our management is responsible for the integrity and objectivity of all information presented in this annual report. The financial statements were prepared in conformity with accounting principles generally accepted in the United States of America and include amounts based on management's best estimates and judgments. Management believes the financial statements fairly reflect the form and substance of transactions and that the financial statements fairly represent the Company's financial position and results of operations.

Disclosure Controls and Procedures

As of December 31, 2021, 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, 2021.

Change in Internal Control over Financial Reporting

In connection with the evaluation required by paragraph (d) of Rule 13a-15 under the Exchange Act, there was no change identified in our internal control over financial reporting that occurred during the last fiscal quarter ended December 31, 2021 that has materially affected, or is 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.

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 2022 Proxy Statement to be filed with the U.S. Securities and Exchange Commission (“SEC”) within 120 days after December 31, 2021 in connection with the solicitation of proxies for the Company’s 2022 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-2021” and “Compensation Committee Interlocks and Insider Participation” under the heading “Directors, Executive Officers and Corporate Governance” in the Company’s 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021 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 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021 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 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021 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 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021 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
Consolidated Balance Sheets as of December 31, 2021 and 2020
Consolidated Statements of Operations for the years ended December 31, 2021 and 2020
Consolidated Statement of Stockholders' Equity (Deficit) for the two years ended December 31, 2021 and 2020
Consolidated Statements of Cash Flows for the years ended December 31, 2021 and 2020
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

None.

(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 \(incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 27, 2020\)](#)
- 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 | <u>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).</u> |
| 10.9 | <u>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).</u> |
| 10.10 | <u>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).</u> |
| 10.12 | <u>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).</u> |
| 10.13 | <u>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).</u> |
| 10.14 | <u>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).</u> |
| 10.15 | <u>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).</u> |
| 10.16 | <u>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).</u> |
| 10.17 | <u>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).</u> |
| 10.18 | <u>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).</u> |
| 10.19 | <u>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).</u> |
| 10.20 | <u>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).</u> |
| 10.21 | <u>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).</u> |
| 10.22 | <u>Executive Employment Agreement, dated November 4, 2021 by and between NexGel, Inc. and Adam Levy (incorporated by reference to Exhibit 10.22 to Form S-1, filed with the SEC on November 9, 2021).</u> |
| 10.23 | <u>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).</u> |
| 21.1 | <u>Subsidiaries (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K for the period ended December 31, 2021 filed with the SEC on March 31, 2021).</u> |
| 31.1* | <u>Rule 13a-14(a) Certification of Principal Executive Officer</u> |
| 31.2* | <u>Rule 13a-14(a) Certification of Principal Financial Officer</u> |

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| 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.

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 21, 2022

By: /s/ Adam Levy
Adam Levy
Chief Executive Officer, President and Chief Financial Officer

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 21, 2022 | Chief Executive Officer, President and Chief Financial Officer (Principal Executive Officer and Principal Accounting Officer) (Principal Executive Officer) |
| <u>/s/ David Stefansky</u> David Stefansky | March 21, 2022 | Executive Chairman |
| <u>/s/ Nachum Stein</u> Nachum Stein | March 21, 2022 | Director |
| <u>/s/ Jerome B. Zeldis</u> Jerome B. Zeldis | March 21, 2022 | Director |
| <u>/s/ Steven Glassman</u> Steven Glassman | March 21, 2022 | 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 21, 2022

/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 21, 2022

/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, 2021, 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 21, 2022

/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, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam E. Drapczuk III, 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 21, 2022

/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.
