

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: September 30, 2021

OR

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

For the transition period from _____ to _____

Commission file number: 001-36278

NexGel, Inc.

(Exact name of registrant as specified in its charter)

Delaware

26-4042544

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

**2150 Cabot Blvd West, Suite B
Langhorne, PA**

19047

(Address of principal executive office)

(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	None	None

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>		
Smaller reporting company	<input checked="" type="checkbox"/>	Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of November 10, 2021, the registrant had 104,277,112 shares of common stock outstanding.

NEXGEL, INC.

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

ITEM 1.	Condensed Financial Statements (Unaudited)	3
	Condensed Balance Sheets as of September 30, 2021 and December 31, 2020	3
	Condensed Statements of Operations for the Three and Nine Months Ended September 30, 2021 and 2020	4
	Condensed Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2021 and 2020	5
	Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2021 and 2020	7
	Notes to Condensed Financial Statements	8
ITEM 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
ITEM 3.	Quantitative and Qualitative Disclosures About Market Risk	37
ITEM 4.	Controls and Procedures	37

PART II – OTHER INFORMATION

ITEM 1.	Legal Proceedings	37
ITEM 1A.	Risk Factors	37
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	38
ITEM 3.	Defaults Upon Senior Securities	38
ITEM 4.	Mine Safety Disclosures	38
ITEM 5.	Other Information	38
ITEM 6.	Exhibits	39
Signatures		40

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEXGEL, INC
CONDENSED BALANCE SHEETS
AS OF SEPTEMBER 30, 2021 AND DECEMBER 31, 2020
(in thousands, except share and per share data)

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS:		
Current Assets:		
Cash	\$ 1,255	\$ 32
Accounts receivable, net	193	73
Inventory	261	233
Prepaid expenses and other current assets	101	25
Total current assets	1,810	363
Goodwill	311	311
Intangibles	37	47
Property and equipment, net	747	553
Operating lease - right of use asset	1,973	805
Other assets	63	178
Total assets	<u>\$ 4,941</u>	<u>\$ 2,257</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 513	\$ 658
Accrued expenses and other current liabilities	77	90
Deferred Revenue	—	38
Convertible notes payable	1,162	59
Current portion of debt	7	10
Note payable – PPP	127	147
Warrant liability	316	123
Operating lease liability, current portion	207	207
Total current liabilities	2,409	1,332
Long-Term Liabilities:		
Notes payable	267	256
Lease liability, long term	1,781	598
Total long-term liabilities	2,048	854
Total liabilities	4,457	2,186
Commitments and Contingencies		
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; 104,277,112 and 99,331,279 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	104	99
Additional paid-in capital	5,553	2,474
Accumulated deficit	(5,173)	(2,502)
Total stockholders' equity	484	71
Total liabilities and stockholders' equity	<u>\$ 4,941</u>	<u>\$ 2,257</u>

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

NEXGEL, INC.
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues, net	\$ 335	\$ 242	\$ 1,018	\$ 573
Cost of revenues	392	269	1,113	726
Gross (loss)/profit	(57)	(27)	(95)	(153)
Operating expenses				
Selling, general and administrative	553	508	1,588	1,431
Total operating expenses	553	508	1,588	1,431
Loss from operations	(610)	(535)	(1,683)	(1,584)
Other income (expense)				
Interest expense	(534)	(13)	(1,052)	(5)
Loss on debt extinguishment	—	—	(25)	—
Debt discount costs	—	—	(68)	—
Forgiveness of debt	—	—	147	—
Other income	—	4	—	7
Changes in fair value of warrant liability	2	(1)	10	(1)
Total other income (expense)	(532)	(10)	(988)	1
Loss before income taxes	(1,142)	(545)	(2,671)	(1,583)
Income tax expense	—	—	—	—
Net loss	\$ (1,142)	\$ (545)	\$ (2,671)	\$ (1,583)
Net loss per common share - basic	\$ (0.01)	\$ (0.01)	\$ (0.03)	\$ (0.02)
Net loss per common share - diluted	\$ (0.01)	\$ (0.01)	\$ (0.03)	\$ (0.02)
Weighted average shares used in computing net loss per common share - basic	104,277,112	86,939,054	102,971,994	75,987,278
Weighted average shares used in computing net loss per common share - diluted	104,277,112	86,939,054	102,971,994	75,987,278

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

NEXGEL, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020
(Unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance, January 1, 2021	99,330,779	\$ 99	\$ 2,474	\$ (2,502)	\$ 71
Stock-based compensation	—	—	69	—	69
Restricted stock vesting	—	—	21	—	21
Issuances of common stock, net of issuance costs	3,563,000	4	281	—	285
Warrants issued for debt issuance	—	—	(18)	—	(18)
Beneficial conversion and warrant features of convertible debt	—	—	1,276	—	1,276
Net loss	—	—	—	(704)	(704)
Balance, March 31, 2021	<u>102,893,779</u>	<u>\$ 103</u>	<u>\$ 4,103</u>	<u>\$ (3,206)</u>	<u>\$ 1,000</u>
Stock-based compensation	—	—	74	—	74
Restricted stock vesting	1,383,333	1	20	—	21
Net loss	—	—	—	(825)	(825)
Balance, June 30, 2021	<u>104,277,112</u>	<u>\$ 104</u>	<u>\$ 4,197</u>	<u>\$ (4,031)</u>	<u>\$ 270</u>
Stock-based compensation	—	—	24	—	24
Restricted stock vesting	—	—	21	—	21
Beneficial conversion and warrant features of convertible debt	—	—	1,311	—	1,311
Net loss	—	—	—	(1,142)	(1,142)
Balance, September 30, 2021	<u>104,277,112</u>	<u>\$ 104</u>	<u>\$ 5,553</u>	<u>\$ (5,173)</u>	<u>\$ 484</u>

[Table of Contents](#)

	Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance, January 1, 2020	57,505,208	\$ 57	\$ 561	\$ (239)	\$ 379
Stock compensation	—	—	64	—	64
Issuance of common stock	15,500,000	16	604	—	620
Net loss	—	—	—	(507)	(507)
Balance, March 31, 2020	<u>73,005,208</u>	<u>\$ 73</u>	<u>\$ 1,229</u>	<u>\$ (746)</u>	<u>\$ 556</u>
Stock compensation	—	—	40	—	40
Issuance of common stock for acquisition	9,375,000	9	366	—	375
Net loss	—	—	—	(530)	(530)
Balance, June 30, 2020	<u>82,380,208</u>	<u>\$ 82</u>	<u>\$ 1,635</u>	<u>\$ (1,276)</u>	<u>\$ 441</u>
Stock compensation	—	—	83	—	83
Issuance of common stock for acquisition	6,585,000	7	388	—	395
Net loss	—	—	—	(545)	(545)
Balance, September 30, 2020	<u>88,965,208</u>	<u>\$ 89</u>	<u>\$ 2,106</u>	<u>\$ (1,821)</u>	<u>\$ 374</u>

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

NEXGEL, INC.
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2021	2020
Operating Activities		
Net loss	\$ (2,671)	\$ (1,583)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	206	70
Share-based compensation	229	187
Changes in fair value of warrant liability	(10)	1
Amortization of deferred financing costs	1,058	—
Loss on extinguishment of debt	25	—
Change in ROU asset and operating lease liability	16	—
Forgiveness of debt	(147)	—
Beneficial conversion feature in excess of face value	52	—
Changes in operating assets and liabilities:		
Accounts receivable	(121)	(16)
Inventory	(28)	(23)
Prepaid expenses and other assets	39	8
Accounts payable	(145)	(88)
Accrued expenses and other liabilities	(21)	66
Deferred revenue	(38)	—
Net Cash Used in Operating Activities	<u>(1,556)</u>	<u>(1,378)</u>
Investing Activities		
Capital expenditures	(390)	(152)
Net Cash Used in Investing Activities	<u>(390)</u>	<u>(152)</u>
Financing Activities		
Issuance of common stock, net of issuance costs	285	1,015
Proceeds from notes payable	15	411
Proceeds from notes payable (PPP)	127	—
Proceeds from convertible notes	2,957	—
Payment of financing costs	(115)	—
Principal payment on convertible notes	(100)	—
Net Cash Provided by Financing Activities	<u>3,169</u>	<u>1,426</u>
Net Increase in Cash	<u>1,223</u>	<u>(104)</u>
Cash – Beginning of period	32	261
Cash – End of period	<u>\$ 1,255</u>	<u>\$ 157</u>
Supplemental Disclosure of Cash Flows Information		
Cash paid during the year for:		
Interest	—	—
Taxes	—	—
Supplemental Non-cash Investing and Financing activities		
Fair value of beneficial conversion and warrant features of Convertible Notes Payable	\$ 2,587	\$ —
Original issue discounts recognized on Convertible Notes Payable	\$ 653	\$ —
Warrants issued for debt and equity financing costs	\$ 203	\$ —
Operating lease, ROU assets and liabilities	\$ 2,050	\$ —
Common shares issued for acquisition	\$ —	\$ 375
Inventory acquired from acquisition	\$ —	\$ 21
Accounts payable acquired from acquisition	\$ —	\$ 13

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

NEXGEL, INC.

NOTES TO CONDENSED UNAUDITED 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. (the “Company” or “NexGel”) manufactures high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. NexGel specializes in custom gels by capitalizing on proprietary manufacturing technologies. The Company 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 our own consumer products using the Company’s 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 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”) of NexGel’s common stock for common stock of Parent. 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 5,005,211 shares of common stock of NexGel. Following the distribution, all existing operations were distributed to NexGel with the exception of a corporate lease for property in Yardley, Pennsylvania which was retained by Adynxx, Inc.

[Table of Contents](#)

Pursuant to the Spin-Off and in exchange for the 5,005,211 shares of common stock, NexGel assumed the following net assets and liabilities from Parent as of June 21, 2019 (\$ in thousands):

Assets:	
Cash	\$ 186
Accounts receivable, net	72
Inventory, net	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	<u>1,808</u>
Liabilities:	
Accounts payable	(496)
Accrued expenses and other current liabilities	(395)
Operating lease liability - current	(207)
Long-term operating lease liability	(769)
Total liabilities	<u>(1,867)</u>
Net liabilities assumed in Spin-Off on June 21, 2019	<u>\$ (59)</u>

Basis of Presentation

The balance sheet as of September 30, 2021 and December 31, 2020 and the statements of operations, stockholders' equity, and cash flows for the nine months ended September 30, 2021 consists of the balances of NexGel as prepared on a stand-alone basis. Prior to the separation, these financial statements were derived from the consolidated financial statements and accounting records of Adynxx, Inc.

Prior to the Spin-Off, Adynxx used a centralized approach to cash management and financing its operations, including the operations of the Company. Accordingly, none of the cash of Adynxx have been attributed to the Company in the financial statements. Transactions between Adynxx and the Company were accounted for through Parent's Net Investment.

The expenses, including executive compensation, have been allocated by management based either on specific attribution of those expenses or, where necessary and appropriate, based on management's best estimate of an appropriate proportional allocation.

These interim condensed financial statements have been prepared pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC"), which permit reduced disclosure for interim periods. The condensed balance sheet as of December 31, 2020 was derived from audited financial statements for the fiscal year then ended, but does not include all necessary disclosures required by generally accepted accounting principles in the United States of America ("GAAP") with respect to annual financial statements. In the opinion of management, the condensed financial statements include all adjustments, which are of a normal recurring nature, necessary to present fairly the Company's financial position as of September 30, 2021 and results of operations and cash flows for the nine months ended September 30, 2021 and 2020. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto in the Company's year-end financial statements for the years ended December 31, 2020 and 2019, which are included in the Company's Form 10-K filed with SEC on March 31, 2021. Results for interim periods are not necessarily indicative of the results to be expected for a full fiscal year or for any future period.

Reclassifications

Certain Statements of Operations reclassifications have been made in the presentation of our prior financial statements and accompanying notes to conform to the presentation as of and for the three months and nine months ended September 30, 2021.

Significant Accounting Policies and Estimates

The preparation of the condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed 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.

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 September 30, 2021 and \$1 thousand as of December 31, 2020.

Inventory

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 or 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 of \$231 thousand and \$190 thousand, work-in-progress of \$0 thousand and \$22 thousand, and finished goods of \$30 thousand and \$21 thousand on September 30, 2021 and December 31, 2020, respectively.

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.

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 valued 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 1, and whenever indicators of impairment exist. The fair value of intangible assets is compared with their carrying values, and an impairment loss would be recognized for the amount by which a carrying amount exceeds its fair value.

Acquired identifiable intangible assets are amortized over the following periods:

Acquired intangible Asset	Amortization Basis	Expected Life (years)
Technology-Related	Straight-line basis	3
Marketing-Related	Straight-line basis	4

Impairment of Long-Lived Assets

We review the recoverability of our long-lived assets, including equipment and right-of-use assets, when events or changes in circumstances occur that indicate that the carrying value of the asset, or asset group, may not be recoverable. Events or circumstances that might cause management to perform impairment testing include, but are not limited to, significant underperformance relative to historical or projected future operating results of the asset or asset group, significant changes in the manner or use of assets or the strategy for our overall business; and significant negative industry or economic trends. If indicators of potential impairment are present, management performs a recoverability test and, if necessary, records an impairment loss. If the total estimated future undiscounted cash flows to be generated from the use and ultimate disposition of an asset or asset group is less than its carrying value, an impairment loss is recorded in the Company's results of operations, measured as the amount required to reduce the carrying value to fair value. Fair value is determined in accordance with the best available information per the hierarchy described under *Fair Value Measurements* below. For example, the Company would first seek to identify quoted prices or other observable market data. If observable data is not available, Management would apply the best available information under the circumstances to a technique such as a discounted cash flow model to estimate fair value. Impairment analysis involves estimates and the use of assumptions due to the inherently judgmental nature of forecasting long-term estimated inflows and outflows resulting from the use and ultimate disposition of an asset, and determining the ultimate useful lives of assets. Actual results may differ from these estimates using different assumptions, which could materially impact the results of an impairment assessment.

Prepaid expenses and other current assets

Prepaid expenses and other current assets is recorded at historical cost and is primarily made up of \$7 thousand and \$16 thousand of prepaid insurance, and \$64 thousand and \$9 thousand general prepaid expenses and other current assets in the period ended September 30, 2021 and December 31, 2020, respectively.

Other Assets

Other Assets is recorded at historical costs, and as of September 30, 2021 and December 31, 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.

Fair value measurements

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

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

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

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

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

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 financial statements as of the date of adoption. As a result, a cumulative-effect adjustment was not required.

The Company recognizes revenue predominately from three types of revenue, contract manufacturing, custom and white label manufacturing and proprietary branded products. 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 it ships the product to the customer.

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:

	Nine Months Ended	
	September 30,	
	2021	2020
Contract manufacturing	\$ 559	\$ 573
Custom and white label finished goods manufacturing	194	—
Nexgel branded consumer products	265	—
Total	\$ 1,018	\$ 573

As of September 30, 2021, the Company did not have any contract assets or contract liabilities from contracts with customers. As of September 30, 2021, 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 2,000,000 shares of the Company’s common stock for awards under the 2019 Plan.

Effective as of May 26, 2020 and May 3, 2021, respectively, the Board approved an increase of the number of authorized shares of common stock reserved under the 2019 Plan from 2,000,000 shares of common stock to 17,000,000 shares of common stock and from 17,000,000 shares of common stock to 20,000,000 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 500,000 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 condensed 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.

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 Adopted Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)* which simplifies the accounting for convertible instruments. The guidance removes certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. Either a modified retrospective method of transition or a fully retrospective method of transition is permissible for the adoption of this standard. Update No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted no earlier than the fiscal year beginning after December 15, 2020. The Company does not expect this ASU to have a material impact on its consolidated results of operations, cash flows and financial position.

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.

Fair Value Measurement—Disclosure Framework

In August 2018, the FASB issued *ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”), which amends ASC Topic 820, Fair Value Measurements. ASU 2018-13 modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The effective date is the first quarter of fiscal year 2021, with early adoption permitted for the removed disclosures and delayed adoption permitted until fiscal year 2021 for the new disclosures. The removed and modified disclosures will be adopted on a retrospective basis and the new disclosures will be adopted on a prospective basis. The Company has not yet adopted ASU 2018-13 and currently assessing the impact of this new standard on its financial statements.

2. Going Concern

As of September 30, 2021, the Company had a cash balance of \$1,255,000. For the nine months ended September 30, 2021, the Company incurred a net loss of \$2,671,000 and had a net usage of cash in operating activities of \$1,556,000. In addition, the Company had a working capital deficit of \$599,000 as of September 30, 2021.

The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital to support ongoing operations. The ability of the Company to continue to operate as a going concern is dependent upon its ability to raise additional capital and to ultimately achieve profitable operations. Management is evaluating various options to raise capital to fund the Company's working capital requirements through equity offerings. There can be no assurances, however, that management will be able to obtain sufficient additional funds when needed, or that such funds, if available, will be obtained on terms satisfactory to the Company. These factors raise substantial doubt as to the Company's ability to continue as a going concern. The condensed financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should the Company be unable to continue as a going concern.

3. Net Loss Per Common Share

Basic loss per share data is computed using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share data is computed using the weighted-average number of common and dilutive common-equivalent shares outstanding during the period. Dilutive common-equivalent shares consist of shares that would be issued upon the exercise of stock options and other common stock equivalents, computed using the treasury stock method. The number of shares that may be issued for share-based payment awards under the Company's 2019 Long-Term Incentive Plan are excluded from the calculation of weighted average dilutive common shares for the nine months ended September 30, 2021 and 2020, to the extent they are issued and outstanding, because their effect would be anti-dilutive.

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 ("Sports 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.

Under the terms of the Purchase Agreement, the purchase price paid to the Sellers was an aggregate of \$75 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 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 fair value of the purchase consideration issued to the Seller was allocated to the net tangible assets acquired. The Company accounted for the Sports 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 \$375,000. The excess of the aggregate fair value of the net tangible assets has been allocated to goodwill.

The Company is currently in the process of completing the preliminary purchase price allocation as an acquisition of certain assets. The final purchase price allocation for Sports Defense's will be included in the Company's financial statements in future periods. The table below shows analysis for the Sports Defense acquisition (\$in thousands):

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	<u>375</u>
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 Sports Defense acquisition been completed as of January 1, 2019 or to project potential operating results as of any future date or for any future periods.

	For the Nine Months Ended	
	September 30,	
	2021	2020
Revenues, net	\$ 1,018	\$ 590
Net loss allocable to common shareholders	\$ (2,672)	\$ (1,535)
Net loss per share	\$ (0.03)	\$ (0.02)
Weighted average number of shares outstanding	102,971,994	83,799,778

5. Leases

The Company has one operating lease for a commercial manufacturing facility and administrative offices located in Langhorne, Pennsylvania that expired in January 2026. On April 14, 2021, the Company extended the term of the lease for an additional five years commencing on February 1, 2026 and continuing through January 31, 2031.

The right-of-use asset and lease liability from this operating lease were recognized in the opening balance sheet as of January 1, 2019 and are based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rate.

The following table presents information about the amount and timing of the liability arising from the Company's operating lease as of September 30, 2021 (\$ in thousands):

Maturity of Lease Liability	Operating Lease Liability
2021 (remainder of year)	\$ 52
2022	207
2023	207
2024	207
2025	207
Thereafter	1,428
Total undiscounted operating lease payments	\$ 2,308
Less: Imputed interest	(320)
Present value of operating lease liability	\$ 1,988
Weighted average remaining lease term	9.3 years
Weighted average discount rate	3.0 %

Total operating lease expense for the nine months ended September 30, 2021 and 2020 was \$192 thousand and \$156 thousand related to the lease extension, and is recorded in cost of goods sold and selling, general and administrative expenses on the statement of operations under Accounting Standards Codification Topic 840, *Leases*.

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

	September 30, 2021
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	\$ 155
Change in right-of-use asset/liability due to lease amendments	\$ 1,275

6. Inventory

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

	September 30, 2021	December 31, 2020
Raw materials	\$ 231	\$ 190
Work-in-progress	—	22
Finished goods	30	21
	<u>261</u>	<u>233</u>
Less: Inventory reserve for excess and slow moving inventory	—	—
Total	<u>\$ 261</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):

	Useful Life (Years)	September 30, 2021	December 31, 2020
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		(471)	(3,079)
Property and equipment, net		<u>\$ 747</u>	<u>\$ 553</u>

Depreciation and amortization expense for the nine months ended September 30, 2021 and 2020 was \$75 thousand and \$31 thousand, respectively.

8. Intangible Assets

The following provides a breakdown of identifiable intangible assets as of September 30, 2021 and December 31, 2020 (\$ in thousands):

	September 30, 2021	December 31, 2020
Product/Technology Related		
Identifiable intangible assets, gross	\$ 31	\$ 31
Accumulated amortization	(14)	(6)
Product/Technology Related identifiable intangible assets, net	<u>17</u>	<u>25</u>
Marketing Related		
Customer related intangible asset, gross	17	17
Tradenname related intangible asset, gross	7	7
Accumulated amortization	(4)	(2)
Marketing related identifiable intangible assets, net	<u>20</u>	<u>22</u>
Total identifiable intangible assets, net	<u>\$ 37</u>	<u>\$ 47</u>

In connection with the acquisitions of Sports Defense, the Company identified intangible assets of \$55 thousand representing technology related and customer related intangibles. These assets are being amortized on a straight-line basis over their weighted average estimated useful life of 4.7 years and amortization expense amounted to \$10 thousand for the nine months ended September 30, 2021.

As of September 30, 2021, the estimated annual amortization expense for each of the next five fiscal years is as follows:

2021 (remainder of year)	\$	4
2022		14
2023		8
2024		3
2025		2
Thereafter		6
Total	\$	<u>37</u>

9. Accrued Expenses and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Salaries, benefits and incentive compensation	\$ 65	\$ 43
Other	12	47
Total accrued expenses and other current liabilities	\$ <u>77</u>	\$ <u>90</u>

10. Common Stock

Share issuances

On September 10, 2019, the Company entered into a Stock Purchase Agreement to issue and sell shares of the Company's common stock, par value \$0.001 per share, in a private placement offering to accredited investors for an aggregate of up to \$175 on the initial closing date, and an aggregate of up to \$575 of shares of common stock on a subsequent closing date at a price per share equal to \$0.053525. On September 10, 2019, certain accredited investors purchased 3,269,500 shares of the Company's common stock that resulted in cash proceeds of \$175 thousand. For their commitment to invest the \$175 thousand, the two shareholders who invested in the September 10, 2019 private placement each became a member of the Company's Board of Directors and gained control of the Company. Their investments carried full ratchet protection on the purchase price per share of \$0.053525 because the actual price of the shares in the September 10, 2019 private placement was undetermined at that time. The final price per share of the September 10, 2019 private placement, which was governed by a term sheet dated August 27, 2019, was ultimately determined to be \$0.014. On November 6, 2019 and pursuant to the Stock Purchase Agreement, the Company issued an additional 39,999,998 shares of its common stock, par value \$0.001 per share, in a private placement offering to accredited investors valued at \$0.014 per share and raised \$560 thousand. Proceeds from this offering are expected to be used for working capital and general business operations. Upon the completion of the secondary offering on November 6, 2019 that provided for the settlement of the ratchet protection, there was a reclassification from Additional paid-in capital to Common stock for the par value of the 9,230,500 additional shares that were issued to the two shareholders who invested in the September 10, 2019 private placement. Issuance costs related to the September 10, 2019 and November 6, 2019 private placements totaled \$5 dollars in legal fees and \$56 thousand related to warrants issued as an equity issuance cost. See Note 15- Warrant Liability.

From January 1, 2021 through March 31, 2021, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 3,563,000 shares of our common stock at a price per share equal to \$0.08 for an aggregate purchase price of \$285,000.

From February 6, 2020 through March 20, 2020, the Company entered into Securities Purchase Agreements with certain accredited investors whereby we sold 15,500,000 shares of our common stock at a price per share equal to \$0.04 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 \$0.04.

As of September 30, 2021, the Company has reserved common stock for issuance in relation to the following:

Share-based compensation plan	20,000,000
Warrants to purchase common stock	31,398,167

On February 10, 2020, a majority of our stockholders through a written consent approved the following: (i) 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 its 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, which was subsequently amended as described in the next paragraph. The reverse stock split has not been effected as of date of the filing of this Form 10-Q. 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 June 22, 2021, a majority of our stockholders through a written consent approved an amendment to our Restated Certificate of Incorporation to decrease the number of authorized shares of Common Stock from 3,000,000,000 shares of Common Stock to 750,000,000 shares of Common Stock. On August 2, 2021, the Company filed the amendment to its certificate of incorporation to decrease the number of the Company's authorized shares of common stock from 3,000,000,000 shares of common stock to 750,000,000 shares of common stock. For more information on this amendments, please see the Company's Definitive Information Statement on Schedule 14C filed with the SEC on July 12, 2021.

11. 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 period ended September 30, 2021 were 33%, 38%, and 24%. The accounts receivable from the top three customers were 16%, 17%, and 0% as well as 18% from one other customer of the total accounts receivable as of September 30, 2021.

Revenues from three customers that exceeded 10% of total revenues for the period ended September 30, 2020 were 13%, 26% and 45%. The accounts receivable from the same three customers were 0%, 42%, and 37% of the total accounts receivable as of September 30, 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.

12. 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 and May 3, 2021, respectively, the Board approved an increase of the number of authorized shares of common stock reserved under the 2019 Plan from 2,000,000 shares of common stock to 17,000,000 shares of common stock and from 17,000,000 shares of common stock to 20,000,000 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 September 9, 2021, the Company granted Yaakov Spinrad, Miranda J. Toledano and Adam Levy, members of the Company Board, an option to purchase up to 500,000 each of the Company's common stock at a per share exercise price of \$0.15 under the Company's 2019 Long-Term Incentive Plan. This option awards vest in four equal calendar quarterly installments beginning on October 1, 2021.

In consideration for their appointment to the Board, each of the Board Appointees received a non-qualified stock option to purchase 500,000 shares of the Company's common stock, par value \$0.001, pursuant to the NexGel Inc. 2019 Long-Term Incentive Plan with a per share exercise price of \$0.15 which will vest in four equal calendar quarterly installments beginning on October 1, 2021. Additionally, in anticipation to Ms. Toledano acting as the Chairperson of to-be-formed Audit Committee and, in consideration for acting as the Chairperson, the Board has agreed to pay Ms. Toledano a calendar quarter cash retainer of \$10,000; provided, however, such cash retainer shall not be payable unless and until the Company's common stock becomes listed on a national securities exchange.

On March 8, 2021, the Company granted Dr. Jerome Zeldis, a member of the Company Board, an option to purchase up to 666,667 shares of the Company's common stock at a per share exercise price of \$0.06 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 500,000 shares of common stock at a per share exercise price of \$0.08 under the Company's 2019 Long-Term Incentive Plan. This option award fully vested as of the date of grant.

On January 15, 2021, the Company awarded a contractor options to purchase an aggregate of 500,000 shares of the Company's common stock at a per share exercise price of \$0.06 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.

In May 2020 and July 2020, pursuant to the terms of the 2019 Plan, the Company awarded options to purchase an aggregate of 5,325,000 shares of common stock to two of its employees and one contractor. Pursuant to the terms of the option agreements, 325,000 of the options vested on the date of grant, and of the 5,000,000 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 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 2,857,141 shares of the Company's common stock at a per share exercise price of \$0.014 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 \$0.06 and equates to 666,667 shares underlying each of the second grants, with all of these options having vested as of September 30, 2021.

The following table contains information about the 2019 Plan as of September 30, 2021:

	Awards Reserved for Issuance	Awards Issued	Awards Available for Grant
2019 Plan	20,000,000	16,722,616	3,277,384

[Table of Contents](#)

The following table summarizes the Company's incentive stock option activity and related information for the period ended December 31, 2020 and for the period ended September 30, 2021:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term in Years
Outstanding at January 1, 2020	1,000,000	\$ 0.053525	9.6
Granted	12,705,949	\$ 0.0291	10.0
Exercised	—	—	—
Forfeited	—	—	—
Cancelled	—	—	—
Expired	—	—	—
Outstanding at December 31, 2020	<u>13,705,949</u>	<u>\$ 0.027736</u>	<u>9.32</u>
Granted	3,166,667	\$ 0.113158	10.0
Exercised	—	—	—
Forfeited	(1,000,000)	0.04	—
Cancelled	(150,000)	0.01	—
Expired	—	—	—
Outstanding at September 30, 2021	<u>15,722,616</u>	<u>\$ 0.045783</u>	<u>8.78</u>
Exercisable at September 30, 2021	<u>10,322,616</u>	<u>\$ 0.031274</u>	<u>8.63</u>

As of September 30, 2021, vested outstanding stock options had \$88 thousand intrinsic value as the exercise price is greater than the estimated fair value of the underlying common stock. As of September 30, 2021, there was approximately \$247 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 six months ended September 30, 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 5,928,571 shares of the Company's common stock to the Company's Chief Executive Officer and then Interim 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 vested 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 1,383,333 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	7,311,904	\$ 0.023
Exercised and converted to common shares	(5,928,571)	0.014
Forfeited	—	—
Outstanding at December 31, 2020	<u>1,383,333</u>	<u>\$ 0.060</u>
Granted	—	—
Exercised and converted to common shares	(1,383,333)	0.060
Forfeited	—	—
Outstanding at September 30, 2021	<u>—</u>	<u>\$ —</u>
Exercisable at September 30, 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 (\$0.014 per share). An additional issuance of 1,383,333 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 (\$0.06 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 \$167 thousand and \$187 thousand has been recorded for the nine months ended September 30, 2021 and 2020, respectively.

Warrants

The following table shows a summary of common stock warrants through September 30, 2021:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Contractual Term in Years
Outstanding at December 31, 2019	5,250,000	\$ 0.014000	2.81
Granted	2,117,500	\$ 0.050720	5.00
Exercised	—	—	—
Forfeited	—	—	—
Cancelled	—	—	—
Expired	—	—	—
Outstanding at December 31, 2020	7,367,500	\$ 0.050720	2.54
Granted	24,030,667	\$ 0.142320	4.88
Exercised	—	—	—
Forfeited	—	—	—
Cancelled	—	—	—
Expired	—	—	—
Outstanding at September 30, 2021	31,398,167	\$ 0.114686	3.79
Exercisable at September 30, 2021	31,398,167	\$ 0.114686	3.79

As of September 30, 2021, vested outstanding warrants had \$561 thousand intrinsic value as the exercise price is greater than the estimated fair value of the underlying common stock.

13. 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. However, the Company cannot completely assure at this time that such forgiveness of the PPP Loan, under Phase II, will occur. 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. The balance of the PPP loan as of September 30, 2021 and December 31, 2020 amounts to \$127,400 and \$147,300, respectively.

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 SBA has deferred the initial installment payments until May 28, 2022. 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. The balance of the EIDL Loan as of September 30, 2021 and December 31, 2020 amounts to \$273,606, including accrued interest of \$13,106, and \$266,279, including accrued interest of \$5,780, respectively.

14. 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 \$0.08 and (ii) Common Stock purchase warrants to purchase up to 312,500 shares of common stock with an exercise price of \$0.08. 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 \$0.03. 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, 2021 (the “Auctus Amendment”). The Auctus Amendment is attached to this Form 10-Q as Exhibit 10.1 and is incorporated herein by reference.

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, 2021 (the “Auctus Second Amendment”). The Auctus Second Amendment is fully described in a Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on November 3, 2021 and is attached to this Form 10-Q as Exhibit 10.1 and is incorporated herein by reference.

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 \$0.10 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, (ii) cause the registration statement to become effective by the Trading Date. An event of default is subject to a confession of judgement 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.

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 6,000,000 shares of the Company's common stock at an exercise price of \$0.125 per share (the "First Auctus Warrant") and the second warrant was to purchase up to an aggregate of 5,000,000 shares of the Company's common stock at an exercise price of \$0.15 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 \$0.125 and \$0.15, 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 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 September 30, 2021, the Auctus Fund Financing note outstanding was \$510,904, which consisted of unamortized balance of \$852,288 of a beneficial conversion and warrant features, unamortized original issue discount of \$125,260 and unamortized debt issuance costs of \$191,547.

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, 2022. 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 \$0.15 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. The September 2 Notes contain a number of events of default, including but not limited to the Company’s failure to file a registration statement covering the Investors’ resale of all of the common stock underlying the September 2 Notes and the September 2 Warrants (as defined below) 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.

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 10,800,000 shares of the Company’s common stock (the “September Warrant Shares”) at an exercise price of \$0.15 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.

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). 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 \$0.15. 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 September 30, 2021, the September 2 Notes’ outstanding balance was \$250,710, which consisted of unamortized balance of \$1,277,536 of a beneficial conversion and warrant features, unamortized original issue discount of \$179,446 and unamortized debt issuance costs of \$106,708.

15. 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 770,667, 1,200,000, 260,000, 255,000, 1,550,000, 1,250,000 and 4,000,000 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 \$0.014 to \$0.15 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 Price	Warrant Expiration Date	Stock Price ⁽⁸⁾	Interest Rate (annual) ⁽⁹⁾	Volatility (annual) ⁽¹⁰⁾	Time to Maturity (Years)	Calculated fair value per share	Future Estimated Quarterly Dividend per share ⁽¹¹⁾
September 2, 2021 ⁽¹⁾	\$ 0.15	September 2, 2024	\$ 0.10	0.78 %	182.74 %	5.0	\$ 0.0095	\$ —
March 11, 2021 ⁽²⁾	\$ 0.125 – 0.15	March 11, 2024	\$ 0.10	0.17 %	172.54 %	5.0	\$ 0.0093 - 0.0094	\$ —
February 3, 2021 ⁽³⁾	\$ 0.08	February 3, 2024	\$ 0.08	0.18 %	171.71 %	3.0	\$ 0.0690703	\$ —
December 24, 2020 ⁽⁴⁾	\$ 0.08	December 24, 2020	\$ 0.08	0.17 %	172.54 %	3.0	\$ 0.0692188	\$ —
March 18, 2020 ⁽⁵⁾	\$ 0.04	March 18, 2020	\$ 0.04	0.66 %	137.41 %	3.0	\$ 0.0307299	\$ —
September 10, 2019 ⁽⁶⁾	\$ 0.014	September 10, 2022	\$ 0.014	1.61 %	139.84 %	3.0	\$ 0.01091	\$ —
November 6, 2019 ⁽⁷⁾	\$ 0.014	November 6, 2022	\$ 0.014	1.60 %	138.48 %	3.0	\$ 0.01095	\$ —

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⁾
September 30, 2021 ⁽¹⁾	\$ 0.15	September 2, 2024	\$ 0.10	0.98 %	186.60 %	5.00	\$ 0.00955743	\$ —
September 30, 2021 ⁽²⁾	\$ 0.125 – 0.15	March 11, 2024	\$ 0.10	0.98 %	186.60 %	4.45	\$ 0.00946 - 0.00941	\$ —
September 30, 2021 ⁽³⁾	\$ 0.08	February 3, 2024	\$ 0.08	0.28 %	186.60 %	4.45	\$ 0.0677956	\$ —
September 30, 2021 ⁽⁴⁾	\$ 0.08	December 24, 2020	\$ 0.08	0.28 %	186.60 %	2.35	\$ 0.0669797	\$ —
September 30, 2021 ⁽⁵⁾	\$ 0.04	March 18, 2020	\$ 0.04	0.28 %	186.60 %	2.23	\$ 0.0296428	\$ —
September 30, 2021 ⁽⁶⁾	\$ 0.014	September 10, 2022	\$ 0.014	0.09 %	186.60 %	1.46	\$ 0.0296428	\$ —
September 30, 2021 ⁽⁷⁾	\$ 0.014	November 6, 2022	\$ 0.014	0.09 %	186.60 %	0.95	\$ 0.0094172	\$ —

<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⁾	\$ 0.08	December 24, 2020	\$ 0.08	0.17 %	172.38 %	2.98	\$ 0.0692188	\$ —
December 31, 2020 ⁽⁵⁾	\$ 0.04	March 18, 2023	\$ 0.04	0.13 %	172.38 %	2.21	\$ 0.0307299	\$ —
December 31, 2020 ⁽⁶⁾	\$ 0.014	September 10, 2022	\$ 0.014	0.13 %	172.38 %	1.85	\$ 0.01091	\$ —
December 31, 2020 ⁽⁷⁾	\$ 0.014	November 6, 2022	\$ 0.014	1.13 %	172.38 %	1.69	\$ 0.01095	\$ —

(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 1st, 2021

(3) Based on the terms provided in the warrant agreement related to the issuance of common stock of on February 3^d, 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.

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

Warrant Liability	Warrants Outstanding	Fair Value per Share	Fair Value
Fair Value as of period ending 12/31/19	5,250,000	\$ 0.01086	\$ 56
Fair Value at initial measurement date	1,805,000	\$ 0.03616	\$ 65
Change in fair value of warrant liability			2
Fair Value as of period ending 12/31/20	7,055,000		\$ 123
Fair Value at initial measurement dates	2,230,667	\$ 0.08933	\$ 203
Change in fair value of warrant liability			(10)
Fair Value as of period ending 9/30/2021	9,285,667		\$ 316

16. Related Party Transactions

Convertible Promissory Note

On December 24, 2020, the Company issued two Secured Convertible Promissory Notes in an aggregate amount of \$100,000 to Mr. Stein, a member of the board of directors and an entity affiliated to Mr. Stein, N&F Trust 774 (See Note 14). 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 14).

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 February 2021.

Sports 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, 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 (See Note 3).

17. Subsequent Events

The Company has evaluated subsequent events for the potential recognition or disclosure through November [10], 2021, the date the financial statements were available to be issued, and has determined that the following matter should be disclosed in the accompanying condensed financial statements.

Auctus Fund Second 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"). The Auctus Second Amendment is fully described in a Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on November 3, 2021 and is attached to this Form 10-Q as Exhibit 10.1 and is incorporated herein by reference.

Adam Levy Executive Employment Agreement

On November 4, 2021, we entered into an employment agreement with Adam Levy, the Company's current Chief Executive Officer and President. Mr. Levy has served as our Chief Executive Officer and President since September 10, 2019 without an employment agreement. Mr. Levy has also served as a member of our Board of Directors since September 9, 2021. Mr. Levy was approved by all of the disinterested members of the Board of Directors pursuant to the Delaware General Corporation Law. Mr. Levy's agreement will become effective upon our common stock being initially listed for trading on any tier of the NASDAQ Stock Market, the New York Stock Exchange, the NYSE American, or any other national securities exchange, which would occur if this offering is successful (the "Initial Public Offering"). The term of the agreement is for one year from the effective date.

If Mr. Levy's agreement becomes effective, Mr. Levy would be paid a base salary of \$300,000 per year. Additionally, Mr. Levy would be eligible for cash bonuses as follows: (i) \$33,000 in the event we achieve net income for two consecutive fiscal calendar quarters for the period which is one year after the Initial Public Offering (the "Net Income Bonus") and (ii) \$67,000 in the event the average closing price of our common stock over any consecutive three month period during the first year subsequent to the Initial Public Offering equals or exceeds one hundred and fifty percent (150%) the price per share at which our common stock is sold at the Initial Public Offering (the "Trading Price Bonus"). Both the Net Income Bonus and the Trading Price Bonus may be earned if both thresholds are achieved or either the Net Income Bonus or the Trading Price Bonus may be earned if only one of the thresholds is achieved. The Net Income Bonus and the Trading Price Bonus shall survive the termination of Mr. Levy so long as the termination is not for cause (as defined in the agreement) and the applicable thresholds are achieved within the one year period after the Initial Public Offering.

Upon effectiveness of the agreement, Mr. Levy will also receive a grant of shares of our common stock equal to \$50,000 divided by the per share price at which our common stock is sold at the Initial Public Offering (the "Equity Grant"). The Equity Grant would vest in twelve equal monthly installments (subject to any rounding adjustments) during the term of the agreement with the first installment vesting on the effective date. Mr. Levy would also be eligible to receive, from time to time, additional equity awards under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, and the terms and conditions of such awards, if any,

would be determined by our Board of Directors or Compensation Committee, in their discretion. Mr. Levy would also be eligible to participate in any benefit plan or program we adopt.

Pursuant to Mr. Levy's agreement, if Mr. Levy's employment is terminated upon his disability, Mr. Levy would be entitled to receive, in addition to other unpaid amounts owed to him (e.g., for base salary, accrued personal time and business expenses): (i) his then base salary for a period of three months (in accordance with our general payroll policy) commencing on the first payroll period following the fifteenth day after termination of employment and (ii) substantially similar coverage under our then-current medical, health and vision insurance coverage for a period of three months. Additionally, if Mr. Levy's employment is terminated for disability, the vesting of any option grants would continue to vest pursuant to the schedule and terms previously established during the three month severance period. Subsequent to the three month severance period the vesting of any option grants would immediately cease. The severance benefits described above are collectively referred to in this Form 10-Q as the "Severance Benefits".

Pursuant to Mr. Levy's agreement and during the initial six months of the term of the agreement, if Mr. Levy resigns for good reason (as defined in the agreement) or is terminated by us without cause (as defined in the agreement), Mr. Levy would be entitled to receive (i) his then base salary (in accordance with our general payroll policy) commencing on the first payroll period following the fifteenth day after termination of employment and (ii) substantially similar coverage under our then-current medical, health and vision insurance coverage for a period of one year.

Pursuant to Mr. Levy's agreement and subsequent to the initial six months of the term of the agreement, if Mr. Levy resigns for good reason or is terminated by us without cause or if we fail to enter into a new employment agreement with Mr. Levy at the end of term of the agreement after bona fide and good faith negotiation between us and Mr. Levy, Mr. Levy would be entitled to receive Severance Benefits for a period of one year less one month for each month (on a pro-rated basis) such termination or resignation occurs subsequent to the initial six month anniversary of the term (the "Adjusted Severance Period"). For example, in the event Mr. Levy is terminated without cause or resigns for good reason at the end of the eight month anniversary of the effective date, Mr. Levy would be entitled to an Adjusted Severance Period of ten months.

If we terminate Mr. Levy's employment for cause or employment terminates as a result of Mr. Levy's resignation (without good reason) or death, Mr. Levy would only be entitled to any salary earned but unpaid prior to termination, all accrued but unused personal time, and any business expenses that were incurred but not reimbursed as of the date of the termination. Vesting of any option grants would immediately cease.

Mr. Levy's agreement also contains certain non-competition, non-solicitation, confidentiality, and assignment of inventions provisions whereby Mr. Levy is subject to non-competition and non-solicitation restrictions for a period of one year and two years following termination of his employment respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed financial statements and related notes above.

Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 conditions and/or intense competition;
- loss of a key customer or supplier;
- entry of new competitors;
- adverse federal, state and local government regulation;
- technological obsolescence of our manufacturing process and equipment;
- technical problems with our research and products;
- risks of mergers and acquisitions including the time and cost of implementing transactions and the potential failure to achieve expected gains, revenue growth or expense savings;
- price increases for supplies and components; and
- the inability to carry out our business plans.

For a discussion of these and other risks that relate to our business and investing in shares of our common stock, you should carefully review the risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q. The forward-looking statements contained in this Quarterly Report on Form 10-Q 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.

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.

Results of Operations

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

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

Revenue

Revenues, net. For the three months ended September 30, 2021, revenues increased by \$93,000 to \$335,000 when compared to \$242,000 for the three months ended September 30, 2020. The increase in our overall revenues was predominantly due to growth of consumer product sales and finished good custom white-label sales. The branded product sales increased growth, however, there was a decrease in our historical legacy revenue due to certain customers experiencing supply chain packaging delays related to COVID-19 in 2021.

Gross profit (loss). Our gross loss was \$57,000 for the three months ended September 30, 2021, compared to a gross loss of \$27,000 for the three months ended September 30, 2020. The gross loss recorded for the three months ended September 30, 2021, as compared to a gross profit recorded for the three months ended September 30, 2020, was primarily due to a significant cost associated with the supplemental staffing requirements in the current quarter. On a percentage basis, our gross loss was approximately (17)% for the three months ended September 30, 2021. Gross loss for the three months ended September 30, 2020 was approximately (11)%.

The components of cost of revenues are as follows for the three months ended September 30, 2021 and 2020 (\$ in thousands):

	Three Months Ended September 30,	
	2021	2020
Cost of revenues		
Materials and finished products	\$ 121	\$ 83
Share-based compensation	—	—
Compensation and benefits	157	115
Depreciation and amortization	22	7
Equipment, production and other expenses	92	64
Total cost of revenues	<u>\$ 392</u>	<u>\$ 269</u>

Cost of revenues increased by \$123 thousand to \$392 thousand for the three months ended September 30, 2021, as compared to \$269 thousand for the three months ended September 30, 2020. The increase in cost of revenues was primarily due to a significant cost associated with restart of the plant accelerator post upgrade and increased material and finished products associated with increased revenue. The Company anticipates increased utilization of the facility in the current year, which we believe will increase our gross margins as the fixed cost of the facilities will not increase on a proportional basis.

Selling, general and administrative expenses. The following table highlights selling, general and administrative expenses by type for the three months ended September 30, 2021 and 2020 (\$ in thousands):

	Three Months Ended	
	September 30,	
	2021	2020
Selling, general and administrative expenses		
Compensation and benefits	\$ 87	\$ 132
Share-based compensation	45	83
Depreciation and amortization	3	42
Other expenses and professional fees	418	251
Total selling, general and administrative expenses	<u>\$ 553</u>	<u>\$ 508</u>

Selling, general and administrative expenses increased by \$45,000 to \$553,000 for the three months ended September 30, 2021, as compared to \$508,000 for the three months ended September 30, 2020. The increase in selling, general and administrative expenses is primarily attributable to our decrease in compensation and benefits and our share-based compensation offset by higher costs for professional fees and other administrative expenses.

Compensation and benefits declined by \$45,000 to \$87,000 for the three months ended September 30, 2021, as compared to \$132,000 for the three months ended September 30, 2020. The company's adjustments to staffing resulted in a compensation decrease compared to the prior year period.

Share-based compensation was \$45,000 for the three months ended September 30, 2021, which is related to stock option expense of \$24,000 to a director and a strategic advisor and \$21,000 related to the vesting of restricted awards to our Chief Executive Officer. Share-based compensation was \$83,000 for the three months ended September 30, 2020, which is related to the issuance of 5,714,282 stock options and the issuance of restricted awards to our Chief Executive Officer.

Other Expenses and professional fees increased by \$167,000 to \$418,000 for the three months ended September 30, 2021 from \$251,000 for the three months ended September 30, 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 result of professional fees incurred in preparation for a planned exchange listing.

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

Revenue

Revenues, net. For the nine months ended September 30, 2021 revenues were \$1,018,000 and increased by \$445,000 when compared to \$573,000 for the nine months ended September 30, 2020. The increase in our overall revenues was predominantly due to initiation of consumer product sales and finished good custom white-label and branded product sales. There was a decrease in our historical legacy revenue due to certain customers experiencing supply chain delays related to Covid-19 during 2020.

Gross profit (loss). Our gross loss was (\$95,000) for the nine months ended September 30, 2021 compared to a gross loss of (\$153,000) for the nine months ended September 30, 2020. The loss recorded for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to the higher volume of contract manufacturing sales and lower manufacturing labor costs. Gross loss was approximately -9% for the nine months ended September 30, 2021. Gross profit was (26.7)% for the nine months ended September 30, 2020.

The components of cost of revenues are as follows for the nine months ended September 30, 2021 and 2020 (\$ in thousands):

	Nine Months Ended September 30,	
	2021	2020
Cost of revenues		
Materials and finished products	\$ 351	\$ 167
Share-based compensation	—	1
Compensation and benefits	419	355
Depreciation and amortization	65	21
Equipment, production and other expenses	278	182
Total cost of revenues	<u>\$ 1,113</u>	<u>\$ 726</u>

Selling, general and administrative expenses. The following table highlights selling, general and administrative expenses by type for the nine months ended September 30, 2021 and 2020 (\$ in thousands):

	Nine Months Ended September 30,	
	2021	2020
Selling, general and administrative expenses		
Compensation and benefits	\$ 259	\$ 350
Share-based compensation	230	186
Depreciation and amortization	10	49
Other expenses and professional fees	1,089	846
Total selling, general and administrative expenses	<u>\$ 1,588</u>	<u>\$ 1,431</u>

Selling, general and administrative expenses increased by \$157,000 to \$1,588,000 for the nine months ended September 30, 2021, as compared to \$1,431,000 for the nine months ended September 30, 2020. The increase in selling, general and administrative expenses is primarily attributable to a decrease in compensation and benefits as well as other expenses and professional fees offset by an increase in share-based compensation as compared to the prior year period.

Compensation and benefits decreased by \$91,000 to \$259,000 for the nine months ended September 30, 2021, as compared to \$350,000 for the nine months ended September 30, 2020. The number of employees increased compared to the prior period, however, adjustments to staffing compensation resulted in a decrease compared to the prior year period.

Share-based compensation was \$230,000 for the nine months ended September 30, 2021, which is related to stock option expense of \$167,000 to a director and a strategic advisor and \$63,000 related to the vesting of restricted awards to our Chief Executive Officer.

Other Expenses and Professional fees increased by \$243,000 to \$1,089,000 for the nine months ended September 30, 2021 from \$846,000 for the nine months ended September 30, 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 decrease in professional fees compared to the prior year period was the primary result in the cost reduction, offset by professional fees incurred in preparation for a planned exchange listing.

Liquidity and Capital Resources

As of September 30, 2021, we had \$1.3 million of cash, compared to \$32 thousand of cash at December 31, 2020. Net cash used in operating activities was \$1.5 million and \$1.4 million for the nine months ended September 30, 2021 and 2020, respectively.

Net cash used in investing activities during the nine months ended September 30, 2021 was \$390 thousand related to facility upgrade costs. Net cash used in investing activities was \$152 thousand for the nine months ended September 30, 2020 related to equipment purchases.

Net cash provided by financing activities for the nine months ended September 30, 2021 was \$3.2 million which is attributable to the issuance of common stock of \$285 thousand and proceeds of notes payable of \$15 thousand and proceeds from the PPP loan of \$128 thousand and convertible notes payable of \$2.8 million. Net cash provided by financing activities for the nine months ended September 30, 2020 was \$1.4 million which is attributable to the issuance of common stock of \$1.0 million and proceeds of a notes payable of \$408,000.

At September 30, 2021, current assets totaled \$1,810,000 and current liabilities totaled \$2,409,000, as compared to current assets totaling \$363,000 and current liabilities totaling \$1,331,000 at December 31, 2020. As a result, we had working capital deficit of \$599,000 at September 30, 2021, compared to a working capital deficit of \$887,000 at December 31, 2020. The decrease in the working capital deficit as of September 30, 2021 is primarily attributable to the capital raised and additional convertible notes payable due in March 2022 and September 2022.

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 \$1,814,000, including Original Issue Discount (OID) of \$194,400, which is convertible into shares of the Company's common stock at a price per share of \$0.15. The net proceeds received by the Company were \$1,504,400 after deducting fees and expenses related to the transaction.

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 \$1,680,000, including Original Issue Discount (OID) of \$180,000, which is convertible into shares of the Company's common stock at a price per share of \$0.10. The net proceeds received by the Company were \$1,337,000 after deducting fees and expenses related to the transaction.

On March 4, 2021, the Company received a second PPP Loan in the amount of \$128 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.

On January 19, 2021, 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 \$0.03. The note was due on or before March 19, 2021 and fully-repaid (including all accrued but unpaid interest) on March 14, 2021.

From January 1, 2021 through March 31, 2021, the Company entered into securities purchase agreements with certain accredited investors whereby we sold 3,563,000 shares of our common stock at a price per share equal to \$0.08 for an aggregate purchase price of \$285,000.

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

The Company is in the process of expanding its customer base to increase revenue in order to alleviate the current going concern. 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.

Moving forward, the Company will potentially be raising additional capital and focusing on increasing revenues for the business to stabilize and become profitable. The Company will maintain and attempt to grow the existing contract manufacturing business. The Company plans to continue building and developing its catalog of consumer products for sale to branding partners. Thirdly, we will 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 market places.

We expect to continue incurring losses for the near-term future and may need to raise additional capital to support ongoing operations. Our ability to continue to operate as a going concern is dependent upon our ability to raise additional capital and to ultimately achieve profitable operations. Management is evaluating various options to raise capital to fund the Company's working capital requirements through equity offerings. There can be no assurances, however, that management will be able to obtain sufficient additional funds when needed, or that such funds, if available, will be obtained on terms satisfactory to us. These factors raise substantial doubt as to our ability to continue as a going concern. 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.

On January 30, 2020, the World Health Organization declared the coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. While it is unknown how long these conditions will last and what the complete financial effect will be to the Company, to date, the Company could experience declining revenue, labor and supply shortages, or difficulty in raising additional capital. Our concentrations with a few customers and one supplier make it reasonably possible that we are vulnerable to the risk of a near-term severe impact.

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 September 30, 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 Financial Statements in accordance with generally accepted accounting principles is based on the selection and application of accounting policies that require us to make significant estimates and assumptions about the effects of matters that are inherently uncertain. We consider the accounting policies discussed below to be critical to the understanding of our Financial Statements. Actual results could differ from our estimates and assumptions, and any such differences could be material to our Financial Statements.

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 the 3 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 (v) the period of time employees are expected to hold the award prior to exercise (referred to as the expected term). Under the Black-Scholes option-valuation model, entities typically estimate the expected volatility based on historical volatilities of the entity’s own common stock. Based on the lack of historical data of volatility for the Company’s common stock, the Company based its estimate of expected volatility on a weighted average of the historical volatility of comparable public companies that manufacture similar products and are similar in size, stage of life cycle, and financial leverage. The fair value of the common stock that underlies the stock option is estimated by the Company considering the price of the most recent issuance of the Company’s common stock. The dividend yield is based upon the assumption that the Company will not declare a dividend over the life of the options. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for bonds with maturities consistent with the expected term of the related award.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures.

As of September 30, 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 September 30, 2021 at a reasonable level of assurance.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, the Company may become involved in lawsuits, investigations and claims that arise in the ordinary course of business. The Company believes it has meritorious defenses against all pending claims and intends to vigorously pursue them. While it is not possible to predict or determine the outcomes of any pending actions, the Company believes the amount of liability, if any, with respect to such actions, would not materially affect its financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

Not required for smaller reporting companies.

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

(a) Unregistered Sales of Equity Securities

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 \$0.15 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 of 10,800,000 shares of the Company's common stock at an exercise price of \$0.15 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 770,667 shares of the Company's common stock, with a term of five years, at a per share exercise price of \$0.15.

All of the shares issued and sold (including those underlying the Auctus Note and Auctus Warrants) 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).

(b) Issuer Purchases of Equity Securities

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

See “Index to Exhibits” for a description of our exhibits.

Index to Exhibits

Exhibit No.	Description
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)
3.6	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 August 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).
10.1	Second Amendment to the Senior Secured Promissory Note, Warrants, and Securities Purchase Agreement (March 11, 2021) dated October 28, 2021 by and between NexGel, Inc. and Auctus Fund, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on November 3, 2021).
10.2	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).
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Company’s Quarterly Report on Form 10-Q for the fiscal quarter June 30, 2021, formatted in iXBRL (Inline eXtensible Business Reporting Language), (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders’ Equity, (iv) Statements of Cash Flows, and (v) Notes to the Financial Statements.
104*	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit).

* Filed herewith.

** Certain exhibits and schedules have been omitted and the Company agrees to furnish supplementary to the Securities and Exchange Commission a copy of any omitted exhibits upon request.

SIGNATURES

Pursuant to the requirements 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.

Date: November 10, 2021

NEXGEL, INC.

By: /s/ Adam Levy

Name: Adam Levy

Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Adam E. Drapczuk III

Name: Adam E. Drapczuk III

Title: Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(A) AND 15d-14(A)
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Adam Levy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NexGel, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 10, 2021

By: /s/ Adam Levy
Adam Levy
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(A) AND 15d-14(A)
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Adam E. Drapczuk III, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

By: /s/ Adam E. Drapczuk III
Adam E. Drapczuk III
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the nine months ended September 30, 2021, of NexGel, Inc. (the "Company"). I, Adam Levy, the Chief Executive Officer and Principal Executive Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 10, 2021

By: /s/ Adam Levy
Name: Adam Levy
Title: Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the nine months ended September 30, 2021 of NexGel, Inc. (the "Company"). I, Adam E. Drapczuk III, the Chief Financial Officer and Principal Financial Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 10, 2021

By: /s/ Adam E. Drapczuk III
Name: Adam E. Drapczuk III
Title: Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
