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

**FORM 10-K/A**
**(Amendment No. 1)**

**(Mark One)**

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

**For the fiscal year ended: December 31, 2019**

**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**<br>**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.

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

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

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☑ | | |
| Smaller reporting company | ☑ | Emerging growth company | ☑ |

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

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

As of April 3, 2020, the registrant had 73,005,208 shares of common stock outstanding.

## EXPLANATORY NOTE

The purpose of this Amendment No. 1 to the NexGel, Inc. (the "Company") Annual Report on Form 10-K for the year ended December 31, 2019 (this "Amendment No. 1"), filed with the Securities and Exchange Commission on March 30, 2020 (the "Form 10-K"), is to correct a typographical error in the Report of Independent Registered Public Accounting Firm to the Shareholders and Board of Directors of Turner, Stone & Company, L.L.P. ("Turner Stone") included on page F-3 of the Company's Financial Statements for the years ended December 31, 2019 and 2018 (the "Report"). In the second paragraph under the heading "Opinion on the Financial Statements," the Report in the original Form 10-K incorrectly referenced Notes 1 and 9 rather than Notes 1 and 8 relating to adjustments to the 2018 financial statements to include weighted average shares outstanding in order to compute net loss per share common share during the year ended December 31, 2018. Pursuant to Rule 12b-15 promulgated under the Securities Exchange Act of 1934, as amended, the Company has repeated the entire text of Item 8 and Item 15 of the Form 10-K in this Amendment No. 1, however, there have been no changes to such items other than to replace the audit report of Turner Stone to correct the error described above.

Other than these correction to the Report, no other changes have been made to the Form 10-K. This Amendment No. 1 does not reflect subsequent events occurring after the original filing date of the Form 10-K or otherwise modify or update in any way disclosures made in the Form 10-K. This Amendment No. 1 should be read in conjunction with the Form 10-K.

**Item 8. Financial Statements and Supplementary Data**

**FINANCIAL STATEMENTS - TABLE OF CONTENTS**
**For the Years Ended December 31, 2019 and 2018**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

**Opinion on the Financial Statements**

We have audited, before the effects of the adjustment to retrospectively apply the effects of net loss per common share, as described in Note 8b, the accompanying balance sheet of NexGel, Inc., formerly known as AquaMed Technologies, Inc. (a segment of Alliqua BioMedical, Inc.) (the "Company"), as of December 31, 2018, the related statements of operations, changes in parent's net investment and cash flows for the year ended December 31, 2018, and the related notes (collectively referred to as the "financial statements") (the 2018 financial statements before the effects of the adjustment discussed in Note 8b are not presented herein). In our opinion, the 2018 financial statements, before the effects of the adjustment to retrospectively apply the effects of net loss per common share, as described in Note 8b, present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

**Explanatory Paragraph — Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

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

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

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

We were not engaged to audit, review, or apply any procedures to the adjustment to retrospectively apply the effects of net loss per common share as described in Note 8b and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by Turner, Stone & Company, L.L.P.

/s/ Marcum llp

Marcum LLP

We have served as the Company's auditor from 2010 to 2019.

New York, NY
March 11, 2019

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

**Opinion on the Financial Statements**

We have audited the accompanying balance sheet of NexGel, Inc. and its subsidiaries (the "Company") as of December 31, 2019 and the related statements of operations, stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

As part of our audit of the 2019 financial statements, we also audited the adjustments to the 2018 financial statements to include weighted average shares outstanding in order to compute net loss per share common share during the year ended December 31, 2018 as described in Notes 1 and 8. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to NexGel's 2018 financial statements other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2018 financial statements as whole.

**Explanatory Paragraph – Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

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

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

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

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

Dallas, Texas
March 30, 2020

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

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

| | Year Ended December 31, 2019 | Year Ended December 31, 2018 |
|---|---|---|
| **ASSETS:** | | |
| Current Assets: | | |
| Cash | $ 261 | $ - |
| Accounts receivable, net | 102 | 34 |
| Inventory | 113 | 101 |
| Prepaid expenses and other current assets | 37 | 226 |
| Total current assets | 513 | 361 |
| Property and equipment, net | 282 | 200 |
| Operating lease - right of use asset | 917 | - |
| Other assets | 178 | 178 |
| Total assets | $ 1,890 | $ 739 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable | $ 510 | $ 157 |
| Accrued expenses and other current liabilities | 28 | 250 |
| Warrant liability | 56 | - |
| Operating lease liability, current portion | 207 | - |
| Total current liabilities | 801 | 407 |
| Operating lease liability, net of current portion | 710 | - |
| Other long-term liabilities | - | 51 |
| Total liabilities | 1,511 | 458 |
| | | |
| Commitments and Contingencies | | |
| | | |
| Parent's net investment | - | 281 |
| 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, 100,000,000 shares authorized; 57,505,208 shares issued and outstanding as of December 31, 2019 | 57 | - |
| Additional paid-in capital | 561 | - |
| Accumulated deficit | (238) | - |
| Total stockholders' equity | 380 | 281 |
| Total liabilities and stockholders' equity | $ 1,890 | $ 739 |

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

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

| | Year Ended December 31, 2019 | Year Ended December 31, 2018 |
|---|---|---|
| Revenues, net | $ 717 | $ 2,213 |
| Cost of revenues | 854 | 1,699 |
| Gross (loss)/profit | (137) | 514 |
| Operating expenses | | |
| Selling, general and administrative | 1,787 | 2,402 |
| Total operating expenses | 1,787 | 2,402 |
| Loss from operations | (1,924) | (1,888) |
| Changes in fair value of warrant liability | (1) | - |
| Net loss | $ (1,923) | $ (1,888) |
| Net loss per common share - basic | $ (0.14) | $ (0.38) |
| Net loss per common share - diluted | $ (0.14) | $ (0.38) |
| Weighted average shares used in computing net loss per common share - basic | 13,570,585 | 5,005,211 |
| Weighted average shares used in computing net loss per common share – diluted | 13,570,585 | 5,005,211 |

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

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

| | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Parent's Net Investment | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| Balance, January 1, 2018 | - | $ - | $ - | $ 625 | $ - | $ 625 |
| Net loss | - | - | - | (1,888) | - | (1,888) |
| Advances from parent | - | - | - | 1,544 | - | 1,544 |
| Balance, December 31, 2018 | - | - | - | 281 | - | 281 |
| Net loss | - | - | | (1,685) | (238) | (1,923) |
| Transfers from parent | - | - | - | 1,345 | - | 1,345 |
| Reclassification of parent's net investment in connection with spin-off, June 21, 2019 | - | - | (59) | 59 | - | - |
| Common stock distributed in connection with spin-off, June 21, 2019 | 5,005,211 | 5 | (5) | - | - | - |
| Issuance of common stock, net of issuance costs | 52,499,997 | 52 | 621 | - | - | 673 |
| Share-based compensation | - | - | 4 | - | - | 4 |
| Balance, December 31, 2019 | 57,505,208 | $ 57 | $ 561 | $ - | $ (238) | $ 380 |

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

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

| | Year Ended December 31, | |
|---|---|---|
| | **2019** | **2018** |
| **Operating Activities** | | |
| Net loss | $ (1,923) | $ (1,888) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 67 | 322 |
| Amortization of deferred lease incentive | - | (8) |
| Provision for doubtful accounts | - | (1) |
| Provision for excess and slow moving inventory | - | (5) |
| Share-based compensation | 4 | - |
| Changes in fair value of warrant liability | (1) | |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (68) | 66 |
| Inventory | (12) | (3) |
| Prepaid expenses and other assets | 189 | (224) |
| Accounts payable | 203 | 94 |
| Accrued expenses and other liabilities | (273) | 103 |
| **Net Cash Used in Operating Activities** | (1,814) | (1,544) |
| **Financing Activities** | | |
| Issuance of common stock, net of issuance costs | 730 | - |
| Net distributions from Former Parent | 1,345 | 1,544 |
| **Net Cash Provided by Financing Activities** | 2,075 | 1,544 |
| **Net Increase in Cash** | 261 | - |
| Cash – Beginning of period | - | - |
| Cash – End of period | $ 261 | $ - |
| **Supplemental Disclosure of Cash Flows Information** | | |
| **Non Cash Transactions:** | | |
| Accrued construction in progress | $ 150 | $ - |
| Warrants issued as equity issuance cost | 56 | - |

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

**NEXGEL, INC.**
**NOTES TO 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. The Company specializes in custom gels by capitalizing on proprietary manufacturing technologies. The Company has historically served as a contract manufacturer supplying its gels to third parties who incorporate them into their own products. NexGel was previously known as AquaMed Technologies, Inc. ("AquaMed") before changing its name to NexGel, Inc. on November 14, 2019. The Company is implementing a new strategy to become a consumer products business focused on proprietary branded products and white label opportunities.

***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 ("Capitalization"), all existing operations were distributed to NexGel with the exception of a corporate lease for property in Yardley, Pennsylvania which was retained by Adynxx, Inc.

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

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

***Basis of Presentation***

The balance sheet as of December 31, 2019 consists of the balances of NexGel as prepared on a stand-alone basis. The balance sheet as of December 31, 2018, and the statements of operations, stockholders' equity, and cash flows were prepared on a "carve-out" basis for the periods and dates prior to the Spin-Off and include stand-alone results for the period subsequent to the date of Spin-Off. 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.

## 2. Going Concern

As of December 31, 2019, the Company had a cash balance of $261 thousand. For the year ended December 31, 2019, the Company incurred a net loss of $1.92 million and had a net usage of cash in operating activities of $1.81 million. In addition, the Company had a working capital deficit of $288 thousand as of December 31, 2019. Year over year revenue decreased by $1.5 million which was driven by the loss of a key customer, which had over $1 million in sales in the year ended December 31, 2018. The reminder of the decline in the year ended December 31, 2019 was attributable to decreased orders from our contract manufacturing customers.

On September 10, 2019, we entered into a Stock Purchase Agreement and issued 3,269,500 of the our common stock, par value $0.001 per share, in a private placement offering that sold the shares to two accredited investors at $0.053525 per share and raised $175 thousand. 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. Proceeds from this offering are expected to be used for working capital and general business operations.

From February through March, 2020, the Company initiated another round of financing to issue an additional 15,500,000 shares of its common stock, par value $0.001 per share, in a private placement offering to accredited investors valued at $0.04 per share for a total raise of $620 thousand. Proceeds from this offering are expected to be used for working capital, new product development and testing, and general business operations.

During the fourth quarter of 2019, the Company focused on stabilizing the internal structure and functions as a standalone company. 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 adjacent industries, such as cosmetics and athletic products. The Company has increased focused on sales and developing a sales pipeline for potential customers. This customer base expansion will enable us to provide financial stability for the foreseeable future, expand our current processes, and position us for long-term shareholder value creation.

Moving forward, the Company we will 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 on building and developing a catalog of consumer products for sale to branding partners. The Company products have the ability to deliver a wide range of compounds. Thirdly, we will use our in house capabilities to create and test market some of our own branded products. These products will be target marketed and sold online through social media, television and online market places.

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 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.

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.

## 3. Significant Accounting Policies and Estimates

*Use of Estimates*

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

*Cash*

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

*Accounts receivable, net*

Trade accounts receivable are stated at the amount the Company expects to collect and do not bear interest. The Company evaluates the collectability of accounts receivable and records a provision to the allowance for doubtful accounts based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowances for doubtful accounts are recorded in selling, general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered. The allowance for doubtful accounts was $2 thousand as of December 31, 2019 and nominal as of December 31, 2018,

*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 solely of raw materials and was $113 thousand and $101 thousand on December 31, 2019 and December 31, 2018 respectively.

As a contract manufacturer, the Company builds its products based on customer orders and immediately ships the products upon completion of the production process. There were no work in progress or finished goods inventories as of December 31, 2019 and December 31, 2018.

*Property and equipment, net*

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

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

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

*Impairment of Long-Lived Assets*

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.

Based on the Company's financial performance in 2019, it was determined that there was a triggering event causing an impairment review requiring an assessment of the recoverability of the Company's single asset group. As a result, the Company evaluated the recoverability of the Company's asset group and determined with the investment of $150 thousand in upgrading the equipment within the leased facility, the expected return on this investment based on management's plans as discussed in Note 2 will be sufficient to recover the carrying value of the asset group such that there was no impairment to measure and recognize.

*Prepaid expenses and other current assets*

Prepaid expenses and other current assets is recorded at historical cost and is primarily made up of $18 thousand and $223 thousand of prepaid insurance, and $17 thousand and $3 thousand general prepaid expenses in the years ended December 31, 2019 and 2018 respectively.

*Other Assets*

Other Assets is recorded at historical costs, and as of December 31, 2019, 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 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 one type of revenue, contract manufacturing. Revenue from contract manufacturing is recognized at the point where the customer obtains control of the goods and the Company satisfies its performance obligation, which generally is at the time 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.

As of December 31, 2019 and December 31, 2018, the Company did not have any contract assets or contract liabilities from contracts with customers. As of December 31, 2019 and December 31, 2018, there were no remaining performance obligations that the Company had not satisfied.

*Share-based compensation*

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 financial statements ended December 31, 2019.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718)*: *Improvements to Employee Share-Based Payment Accounting*. Amendments of this Update change the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid-in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis, as is currently required. The Company adopted this standard in the third quarter of 2019 and it did not have material impact to its financial statements ended December 31, 2019.

*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 February 2016, the FASB established ASC Topic 842, *Leases*, by issuing Accounting Standards Update ("ASU") No. 2016-02, which requires lessees to recognize operating leases on the balance sheet and disclose key information about leasing arrangements. ASC Topic 842 was subsequently amended by ASU No. 2018-01, *Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases. Leases will be classified as either finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. Lessor accounting under the new standard is substantially unchanged. Additional qualitative and quantitative disclosures are also required.

The Company adopted the new standard on leases on January 1, 2019 using the optional transition method to the modified retrospective approach, which eliminates the requirement to restate the prior period financial statements. The Company currently recognizes an operating lease right-of-use asset and a corresponding lease liability on its balance sheet. The Company also applies the following accounting policies related to this standard:

- The Company does not recognize ROU assets and liabilities for leases with a term of 12 months or less; and
- The Company does not separate lease and non-lease components in the Company's lease contracts.

Adoption of the new lease standard resulted in the recording of additional operating lease ROU assets and operating lease liabilities of approximately $1.026 million and $1.026 million, respectively, at January 1, 2019, and additional operating lease ROU assets and operating lease liabilities of approximately $917 thousand and $917 thousand, respectively, at December 31, 2019.

***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.

*Financial* Instruments—*Credit Losses*

In June 2016, the FASB issued *ASU No. 2016-13, Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* which introduces a model based on expected losses to estimate credit losses for most financial assets and certain other instruments. In November 2019, the FASB issued ASU No. 2019-10 Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842). The update allows the extension of the initial effective date for entities which have not yet adopted ASU No. 2016-02. The standard is effective for annual reporting periods beginning after December 15, 2022, with early adoption permitted for annual reporting periods beginning after December 15, 2018. Entities will apply the standard's provisions by recording a cumulative effect adjustment to retained earnings. The Company has not yet adopted ASU 2016-13 and currently assessing the impact of this new standard on its financial statements.

*Collaborative Arrangements*

In November 2018, the FASB issued *ASU 2018-18, Collaborative Arrangements (Topic 808). This update clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers* ("ASU 2018-18"). The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This update will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 and early adoption is permitted. The adoption of this standard will not have a material impact on the Company's financial statements as the Company does not have any collaborative agreements. However, there is a potential for the Company to enter into collaborative agreements in the future, as it expands into consumer markets.

*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.

***Impact on Previously Issued Financial Statements for the Correction of an Error***

In the Quarterly Report on Form 10-Q filed on January 28, 2019 ("Q3 Form 10-Q"), the September 10, 2019 an issuance of warrants to purchase common stock was not recognized in the financial statements, including the related impact to the balance sheet. Accordingly, the accompanying financial statements as of December 31, 2019 reflect the issuance of the warrants and the financial statement implications thereto.

These issued warrants impact the additional paid-in capital for the period ending September 30, 2019 by decreasing $14 thousand, and increasing warrant liability by the fair value of the warrants as of September 30, 2019, by $14 thousand. The warrants did not impact net loss during the interim period ended September 30, 2019.

**4. Leases**

The Company has one operating lease for a commercial manufacturing facility and administrative offices located in Langhorne, Pennsylvania that runs through January 2026.

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 December 31, 2019 ($ in thousands):

| **Maturity of Lease Liability** | | **Operating Lease Liability** |
|---|---|---|
| 2020 | $ | 207 |
| 2021 | | 207 |
| 2022 | | 207 |
| 2023 | | 207 |
| 2024 | | 207 |
| Thereafter | $ | 226 |
| Total undiscounted operating lease payments | $ | 1,261 |
| Less: Imputed interest | | (344) |
| Present value of operating lease liability | $ | 917 |
| Weighted average remaining lease term | | 6.0 years |
| Weighted average discount rate | | 11.0% |

Total operating lease expense for the year ended December 31, 2019 was $207 thousand, and is recorded in cost of goods sold and selling, general and administrative expenses on the statement of operations. For the year ended December 31, 2018, the Company recorded lease expense under Accounting Standards Codification Topic 840, *Leases*, and recognized $207 thousand, which was recorded in cost of goods sold and selling, general and administrative expenses.

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

| | | **December 31, 2019** |
|---|---|---|
| Cash paid for amounts included in the measurement of lease liability: | | |
| Operating cash flows from operating lease | $ | 207 |
| | | |
| Right-of-use asset obtained in exchange for lease obligation: | | |
| Operating lease | $ | 917 |

## 5. Property and Equipment, Net

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

| | Useful Life (Years) | December 31, 2019 | December 31, 2018 |
|---|---|---|---|
| Machinery and equipment | 3 - 10 | $ 2,893 | $ 2,893 |
| Office furniture and equipment | 3 - 10 | 49 | 49 |
| Leasehold improvements | 6 | 228 | 228 |
| Construction in progress | N/A | 150 | - |
| | | 3,320 | 3,170 |
| Less: accumulated depreciation and amortization | | (3,038) | (2,970) |
| Property and equipment, net | | $ 282 | $ 200 |

Depreciation and amortization expense for the year ended December 31, 2019 was $67 thousand. For the year ended December 31, 2018, depreciation and amortization expense was $322 thousand.

## 6. Accrued Expenses and Other Current Liabilities

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

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Salaries, benefits and incentive compensation | $ 14 | $ 108 |
| Professional fees | - | 95 |
| Other | 14 | 47 |
| Total accrued expenses and other current liabilities | $ 28 | $ 250 |

## 7. Common Stock

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 10– Warrant Liability.

At December 31, 2019, the Company has reserved common stock for issuance in relation to the following:

| | |
|---|---|
| Share-based compensation plan | 2,000,000 |
| Warrants to purchase common stock | 5,250,000 |

**8. Net Loss Per Common Share**

a. 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 year ended December 31, 2019, to the extent they are issued and outstanding, because their effect would be anti-dilutive.

b. On June 21, 2019, the date of consummation of the Spin-Off, 5,005,211 shares of the Company's Common Stock, par value $0.001 per share, was distributed to Adynxx shareholders of record as of April 22, 2019. This share amount is being utilized for the calculation of basic and diluted earnings per share for all periods presented prior to the Spin-Off as no common stock was outstanding prior to the date of the Spin-Off. For the 2018 year to date calculations, these shares are treated as issued and outstanding from January 1, 2018 for purposes of calculating historical basic and diluted earnings per share. The financial statements for 2018 were adjusted herein to reflect the subsequent consummation of the spinout and the inclusion of basic and diluted earnings per share, as described above, consistent with that of 2019.

**9. 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 has reserved a total of 2,000,000 shares of the Company's common stock for awards under the 2019 Plan, 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*

In August 2019, pursuant to the terms of the 2019 Plan, the Company awarded options to purchase an aggregate of 1,000,000 shares of common stock to two of its employees and one contractor. Pursuant to the terms of the option agreements, 50% of such options vested on the date of grant, and the remaining 50% of such options will vest on the first anniversary of the date of grant. The term of the options is ten years.

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

| | Awards Reserved for Issuance | Awards Issued | Awards Available for Grant |
|---|---|---|---|
| 2019 Plan | 2,000,000 | 1,000,000 | 1,000,000 |

The following table summarizes the Company's incentive stock option activity and related information for the period ended December 31, 2019:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Contractual Term in Years |
|---|---|---|---|
| Outstanding at June 21, 2019 | - | - | - |
| Granted | 1,000,000 | $ 0.053525 | 10.0 |
| Exercised | - | - | - |
| Forfeited | - | - | - |
| Cancelled | - | - | - |
| Expired | - | - | - |
| Outstanding at December 31, 2019 | 1,000,000 | $ 0.053525 | 10.0 |

As of December 31, 2019, vested outstanding stock options had no intrinsic value as the exercise price is greater than the estimated fair value of the underlying common stock. As of December 31, 2019, there was approximately $4 thousand of total unrecognized share-based compensation related to unvested stock options, which the Company expects to recognize over the next 12 months.

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period. The following assumptions were used to calculate share-based compensation expense for year ended December 31, 2019:

| | |
|---|---|
| Volatility | 88.42% |
| Risk-free interest rate | 1.37% - 1.39% |
| Dividend yield | 0.0% |
| Expected term | 5.25 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.

**10. Warrant Liability**

On September 10, 2019 and November 6, 2019, the Company issued 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 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:

| ***Black-Scholes Assumptions*** | | **Issuance date(1) September 10, 2019** | | **Issuance date(2) November 6, 2019** |
|---|---|---|---|---|
| Exercise Price(1)(2) | $ | 0.014 | $ | 0.014 |
| Warrant Expiration Date (1)(2) | | September 10, 2022 | | November 6, 2022 |
| Stock Price (3) | $ | 0.014 | $ | 0.014 |
| Interest Rate (annual) (4) | | 1.61% | | 1.60% |
| Volatility (annual) (5) | | 139.84% | | 138.48% |
| Time to Maturity (Years) | | 3.0 | | 3.0 |
| Calculated fair value per share | $ | 0.01091 | $ | 0.1095 |
| Future Estimated Quarterly Dividend per share(6) | $ | — | $ | — |

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

| ***Black-Scholes Assumptions*** | | **Year ending(1) December 31, 2019** | | **Year ending(2) December 31, 2019** |
|---|---|---|---|---|
| Exercise Price(1)(2) | | $0.014 | | $0.014 |
| Warrant Expiration Date (1)(2) | | September 10, 2022 | | November 6, 2022 |
| Stock Price (3) | $ | 0.014 | $ | 0.014 |
| Interest Rate (annual) (4) | | 1.62% | | 1.62% |
| Volatility (annual) (5) | | 137.47% | | 137.47% |
| Time to Maturity (Years) | | 2.70 | | 2.85 |
| Calculated fair value per share | $ | 0.01045 | $ | 0.01064 |
| Future Estimated Quarterly Dividend per share(6) | $ | — | $ | — |

*(1) Based on the terms provided in the warrant agreement related to the issuance of common stock of on September 10th, 2019*

*(2) Based on the terms provided in the warrant agreement related to the issuance of common stock of on November 6th, 2019*

*(3) Based on the observable transaction value of common stock of per the most recent stock issuance financing agreements.*

*(4) 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.*

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

*(6) 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 at initial measurement date of 9/10/2019** | **1,250,000** | **$** | **0.01091** | **$** | **14** |
| | | | | | |
| | | | | | |
| **Fair Value at initial measurement date of 11/6/2019** | **4,000,000** | **$** | **0.01085** | **$** | **43** |
| Change in fair value of warrant liability | | | | | (1) |
| **Fair Value as of period ending 12/31/2019** | **5,250,000** | | | **$** | **56** |

The warrant liabilities are considered Level 3 liabilities on the fair value hierarchy as the determination of fair value includes various assumptions about of future activities and the Company's stock prices and historical volatility of Guideline Public Companies as inputs. As of December 31, 2019, none of the warrants have been exercised.

**11. Related Party Transactions**

While the Company was owned by Adynxx, the Company was included within the consolidation process of Adynxx. The Company's operating losses of $1.89 million in the year ending December 31, 2018 were included within Adynxx's financial results.

All significant intercompany transactions and related party transactions between the Company and Adynxx have been included in these financial statements, as these statements were prepared on a "carve-out basis" prior to the Spin-Off. Net cash provided by Adynxx for operations during the year ended December 31, 2019 was $1.35 million of cash advances. For the year ended December 31, 2018, cash flows from our Adynxx was $1.54 million, all of which were cash advances. The total net effect of the settlement of these transactions detailed above is reflected in the Statements of Cash Flows as a financing activity and in the Balance Sheets as parent's net investment of $0 and $281 thousand as of December 31, 2019 and 2018, respectively.

**12. Income Taxes**

Prior to the consummation of the Spin-Off, NexGel's operating results were included in Adynxx consolidated U.S. federal and state income tax returns. For the purposes of the Company's Consolidated and Combined Financial Statements for periods prior to the Separation, income tax expense and deferred tax balances have been recorded as if the Company filed tax returns on a standalone basis separate from Adynxx. The Separate Return Method applies the accounting guidance for income taxes to the standalone financial statements as if the Company was a separate taxpayer and a standalone enterprise prior to the separation from Adynxx.

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

| | For The Years Ended December 31 | |
|---|---|---|
| | 2019 | 2018 |
| Federal: | | |
| Current | $ - | $ - |
| Deferred | - | - |
| State and local: | | |
| Current | - | - |
| Deferred | - | - |
| Income tax provision | $ - | $ - |

Company has established a full valuation allowance for its deferred tax assets based on management's belief that it is not more likely than not that the related deferred tax assets will be realized. For the years ended December 31, 2019 and 2018, the expected tax benefit based on the statutory rate reconciled with the actual benefit is as follows:

| | For The Years Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| U.S. federal statutory rate | 21.0% | 21.0% |
| State tax rate, net of federal benefit | 5.3% | 1.1% |
| Permanent differences | | |
| Non-deductible expenses | (0.7%) | 0.0% |
| State tax change | 0.0% | 4.2% |
| Change in valuation allowance | (25.6%) | (26.3)% |
| Income tax provision | 0.0% | 0.0% |

For the years ended December 31, 2019 and 2018, differences between the expected tax expense based on the federal statutory rate and the actual tax expense is primarily attributable to losses for which no benefit is recognized.

As of December 31, 2019 and 2018, the Company's deferred tax assets consisted of the effects of temporary differences attributable to the following:

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 2,110 | $ 3,110 |
| Intangible Assets | - | 28 |
| Other | 2 | 30 |
| Total deferred tax assets | 2,112 | 3,168 |
| Valuation allowance | (2,072) | (3,151) |
| Deferred tax assets, net of valuation allowance | $ 40 | $ 17 |
| Deferred tax liabilities: | | |
| Property and equipment, net | (40) | (17) |
| Total deferred tax liabilities | (40) | (17) |
| Net deferred tax liabilities | $ - | $ - |

The deferred tax assets associated with net operating losses included in the table above reflect proforma net operating losses as if the Company were a separate taxpayer during the periods presented. As of December 31, 2019 and 2018, reported approximately $8.0 million and $7.8 million of federal NOL carryovers, respectively, which begin to expire in 2028 and through 2035. Similarly, the subsidiary's Pennsylvania state returns reported state NOL carryovers of approximately $7.9 million and $7.7 million, as of December 31, 2019 and December 31, 2018, respectively. However, these loss carryforwards on a separate company basis may be subject to limitations on the amounts that may be utilized pursuant to Internal Revenue Code section 382 and applicable state law. Section 382 imposes significant limitations on the utilization of net operating losses after certain changes of corporate ownership. The Company will need to determine the amount of loss carryforwards that may be utilized in the future as necessary.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of the deferred tax assets is dependent upon the future generation of taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all the evidence, both positive and negative, management has recorded a full valuation allowance against net deferred tax assets at December 31, 2019 and December 31, 2018 because management has determined that it is more likely than not that these deferred tax assets will not be realized.

The Company is subject to taxation in the U.S. and various states. Based on the history of net operating losses all jurisdictions and tax years are open for examination until the operating losses are utilized or the statute of limitations expires. As of December 31, 2019 and 2018, the Company does not have any significant uncertain tax positions.

**13. 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 four customers that exceeded 10% of total revenues for the year ended December 31, 2019 were 38%, 17%, 13% and 10%. Accounts receivable from these same four customers were 0%, 13%, 0% and 34% of the total accounts receivable as of December 31, 2019. For the year ended December 31, 2018, two customers exceeded 10% of revenues and were 63% and 14% of total revenues. Accounts receivable from these same two customers were 0% and 0% of the total accounts receivable as of December 31, 2018.

Our customer revenue decreased from the year ended December 31, 2018 to December 31, 2019 by $1.5 million, which was driven by the loss of a key customer, which had over $1 million in sales in the year ended December 31, 2018.

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.

**14. Subsequent Events**

From February through March, 2020, the Company initiated another round of financing to issue an additional 15,500,000 shares of its common stock, par value $0.001 per share, in a private placement offering to accredited investors valued at $0.04 per share for a total raise of $620 thousand. Proceeds from this offering are expected to be used for working capital, new product development and testing, and general business operations.

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 with one-fourth of such option vesting on each of December 31, 2020, March 31, 2021, June 30, 2021 and September 30, 2021, respectively, and with an acceleration of any unvested options upon the departure of applicable Board member from the Board for any reason.

On February 17, 2020, the Company granted a restricted stock award of 5,928,571 shares of the Company's common stock to the Company's Chief Executive Officer and Chief Financial Officer, Adam Levy, with the following vesting terms: (i) 3/12 $^{th}$ of such shares vested as of February 17, 2020; (ii) 1/12$^{th}$ of such shares vest on each of the eight months following February 17, 2020 and (iii) all remaining shares vest on September 10, 2020.

**Item 15. Exhibits and Financial Statement Schedules**

The following documents are filed as part of this report:

(1) Financial Statements

The following financial statements are included herein:

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2019 and 2018
Consolidated Statements of Operations for the years ended December 31, 2019 and 2018
Consolidated Statement of Stockholders' Equity (Deficit) for the two years ended December 31, 2019
Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

None.

(3) Exhibits

| | |
|---|---|
| 2.1 | Form of Asset Contribution and Separation Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc. |
| 2.2 | Form of Tax Matters Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc. |
| 2.3 | Form of Bill of Sale and Assignment and Assumption Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc. |
| 2.4 | Amendment No. 2, dated April 19, 2019, to Agreement and Plan of Merger |
| 3.1 | Certificate of Incorporation of AquaMed Technologies, Inc. (as currently in effect) |
| 3.2 | Certificate of Amendment to Certificate of Incorporation of AquaMed Technologies, Inc. |
| 3.3 | Form of Amended and Restated Certificate of Incorporation of AquaMed Technologies, Inc. |
| 3.4 | Bylaws of AquaMed Technologies, Inc. (as currently in effect) |
| 3.5 | Form of Amended and Restated Bylaws of AquaMed Technologies, Inc. |
| 10.1 | Assignment and Amended and Restated Lease, dated as of January 25, 2002, by and between 2150 Cabot LLC, Embryo Development Corporation and Hydrogel Design Systems, Inc. |
| 10.2 | Amendment to Lease, dated as of February 23, 2007, by and between 2150 Cabot LLC and Hydrogel Design Systems, Inc. |
| 10.3 | Third Amendment to Lease, dated as of February 27, 2009, by and between Exeter 2150 Cabot, L.P and Hydrogel Design Systems, Inc. |
| 10.4 | Assignment and Assumption of Lease Agreement, dated as of February 27, 2009, by and among Exeter 2150 Cabot, L.P, Hydrogel Design Systems, Inc. and Aquamed Technologies, Inc. |
| 10.5 | Fourth Amendment to Lease, dated as of July 24, 2013, by and between Exeter 2150 Cabot, L.P and Aquamed Technologies, Inc. |
| 10.6 | Warrant, dated March 9, 2016 issued to Sidney Taubenfeld |
| 10.7 | Warrant, dated November 1, 2018, issued to Bernard Sucher, exercisable at $15.11 per Class A Unit |
| 10.8 | Warrant, dated November 1, 2018, issued to Bernard Sucher, exercisable at $45.32 per Class A Unit |
| 10.9 | Form of 2019 Incentive Plan |
| 10.10 | Form of Incentive Option Agreement under 2019 Incentive Plan |
| 10.11 | Form of Nonqualified Stock Option Agreement under 2019 Incentive Plan |
| 10.12 | Form of Restricted Stock Award Agreement under 2019 Incentive Plan |
| 21.1 | Subsidiaries of Registrant* |
| 31.1 | Rule 13a-14(a) Certification of Principal Executive Officer* |
| 31.2 | Rule 13a-14(a) Certification of Principal Financial Officer* |
| 32.1 | Section 1350 Certification of Principal Executive Officer** |
| 32.2 | Section 1350 Certification of Principal Financial Officer** |
| 101 INS* | XBRL Instance Document |
| 101 SCH* | XBRL Taxonomy Extension Schema Document |
| 101 CAL* | XBRL Taxonomy Calculation Linkbase Document |
| 101 LAB* | XBRL Taxonomy Labels Linkbase Document |
| 101 PRE* | XBRL Taxonomy Presentation Linkbase Document |
| 101 DEF* | XBRL Taxonomy Extension Definition Linkbase Document |

* Filed herewith.

** Furnished herewith.

## SIGNATURES

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

**NexGel, Inc.**

April 3, 2020

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

By: /s/ Adam Levy
Adam Levy
Chief Financial Officer (Principal Financial and Accounting Officer)

**Exhibit 21.1**

**Subsidiaries of the Registrant**

**None.**

**Exhibit 31.1**

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

I, Adam Levy, certify that:

1. I have reviewed this Annual Report on Form 10-K/A, Amendment No. 1, 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 consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 3, 2020

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

**Exhibit 31.2**

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

I, Adam Levy, certify that:

1. I have reviewed this Annual Report on Form 10-K/A, Amendment No. 1, 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 consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 3, 2020

/s/ Adam Levy
Adam Levy
Chief Financial Officer
(Principal Financial and Accounting Officer)

**Exhibit 32.1**

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

In connection with the Annual Report of NexGel, Inc. (the "Company") on Form 10-K/A, Amendment No. 1, for the period ending December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam Levy, Chief Executive Officer, certify to my knowledge and in my capacity as an officer of the Company, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and,

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: April 3, 2020

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

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

**Exhibit 32.2**

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

In connection with the Annual Report of NexGel, Inc. (the “Company”) on Form 10-K/A, Amendment No. 1, for the period ending December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Adam Levy, Chief Financial Officer, certify to my knowledge and in my capacity as an officer of the Company, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and,

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: April 3, 2020

/s/ Adam Levy
Adam Levy
Chief Financial Officer
(Principal Financial and Accounting Officer)

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