

RenovaCare, Inc.  
Form 10-K  
April 12, 2019

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

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

For the fiscal year ended **December 31, 2018**

**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 **000-30156**

**RENOVACARE, INC.**

(Exact name of registrant as specified in its charter)

**Nevada** **98-0170247**  
(State or other jurisdiction of incorporation) (I.R.S. Employer Identification No.)

**9375 East Shea Blvd., Suite 107-A**

**Scottsdale, AZ 85260**

(Address of principal executive offices)

**(888) 398-0202**

(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if 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 and posted on its corporate Web site, if any, every Interactive Data file required to be submitted and posted pursuant to Rule 405 of Regulations S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer   Accelerated filer  
Non-accelerated filer   Smaller reporting company  
   Emerging Growth Company

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price of the registrant's common stock on June 30, 2018, as reported on the OTCQB was \$72,159,018. Common stock held by each officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of April 9, 2019, there were 87,175,522 shares of the registrant's common stock outstanding.

Documents incorporated by reference: None.

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**RENOVACARE, INC.**

**FORM 10-K**

**For The Fiscal Year Ended December 31, 2018**

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## PART I

### Forward-Looking Statements

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, as well as information relating to RenovaCare, Inc. and its subsidiaries that is based on management's exercise of business judgment and assumptions made by and information currently available to management. Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. When used in this document and other documents, releases and reports released by us, the words "anticipate," "believe," "estimate," "expect," "intend," "the facts suggest" and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements and unknown, unidentified or unpredictable factors could materially and adversely impact our future results. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to our forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events. Several of these factors include, without limitation:

- our ability to meet requisite regulations or receive regulatory approvals in the United States, and our ability to retain any regulatory approvals that we may obtain; and the absence of adverse regulatory developments in the United States and abroad;
- new entrance of competitive products or further penetration of existing products in our markets;
- the effect on us from adverse publicity related to our products or the company itself; and
- any adverse claims relating to our intellectual property.

The safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, apply to forward-looking statements made by the Company. The reader is cautioned that no statements contained in this Form 10-K should be construed as a guarantee or assurance of future performance or results. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks described in this report and matters described in this report generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur.

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We file reports with the Securities and Exchange Commission. We make available on our website free of charge our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Information appearing at our website is not a part of this Annual Report on Form 10-K. You can also read and copy any materials we file with the SEC at its Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. In addition, the SEC maintains an Internet site ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

## Item 1. Business

### Overview

RenovaCare, Inc. (formerly Janus Resources, Inc.) (together with its wholly owned subsidiary, “**RenovaCare**” the “**Company**” “**we**” “**us**” and “**our**”) was incorporated under the laws of the State of Nevada and has an authorized capital of 500,000,000 shares of \$0.00001 par value common stock, of which 87,175,522 shares are outstanding as of December 31, 2018, and 10,000,000 shares of \$0.0001 par value preferred stock, of which none are outstanding.

On January 7, 2014, we filed a Certificate of Amendment to Articles of Incorporation changing our name from “Janus Resources, Inc.” to “RenovaCare, Inc.” so as to more fully reflect our operations. The Financial Industry Regulatory Authority (“**FINRA**”) declared the name change effective as of January 9, 2014. In conjunction with the name change, we changed our stock symbol on the OTCQB from “JANI” to “RCAR”.

Our principal executive offices are located at 9375 East Shea Blvd., Suite 107-A, , Scottsdale, AZ 85260. Our telephone number is (888) 398-0202.

As we are a smaller reporting company, we are not required to make certain disclosures otherwise required to be made in a Form 10-K.

### Description of Business

We are a development-stage company focusing on the acquisition, development and commercialization of autologous (using a patient’s own cells) cellular therapies for medical and aesthetic applications. On July 12, 2013, we, through our wholly owned subsidiary, RenovaCare Sciences Corp., completed the acquisition of our flagship CellMist™ System along with associated United States patent applications and two foreign patent applications, the first of which was filed on August 23, 2007 (DE 10 2007 040 252.1) and the second of which was filed on April 27, 2011 (DE 10 2011 100 450.9), both of which have been granted. One of the US patent applications was granted to us on November 29, 2016 (Patent No. US 9,505,000) and the other patent application was granted to us on April 4, 2017 (Patent No. US 9,610,430). Two additional patent applications are pending.

On or about April 11, 2017, we received from Avita Medical a Petition for Inter Partes Review purporting to challenge the validity of the claims in U.S. Patent No. 9,610,430 before the PTAB of the U.S. Patent & Trademark Office. Upon consideration of the arguments and evidence set forth by us and Avita, on December 18, 2017, the PTAB rendered a Final Written Decision dismissing the Petition in its entirety and, accordingly, confirming all such



claims. Avita Medical's right to file an appeal expired on February 21, 2018.

In the case of U.S. patents, a typical utility patent term is 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications, from the date on which the earliest such application was filed. Patents filed outside of the U.S. have a patent term typically running 20 years from the date of first filing, but which are determined by the law of the country in which they issue. Patent term may be affected by events such as maintenance (or annuity) fee payment, terminal or statutory disclaimer, post-grant proceedings, patent term adjustment, and/or patent term extension.

The development of our CellMist™ System is in the early stage and we anticipate that we will be required to expend significant time and resources to further develop our technology and determine whether a commercially viable product can be developed. Research and development of new technologies involves a high degree of risk and there is no assurance that our development activities will result in a commercially viable product. The long-term profitability of our operations will be, in part, directly related to the cost and success of our development programs, which may be affected by a number of factors.

The average adult human has a skin surface area of between 16 - 21 square feet, which protects all other organs against the external environment. When a person's skin is assailed by trauma or exposed to extreme heat, the skin's various layers may be destroyed and depending on the severity of the injury, might cause life-threatening conditions. Currently, severe trauma to the skin, such as second or third degree burns, requires surgical mesh-grafting of skin, whereby healthy skin is removed from one area of the patient's body (a "donor site") and implanted on the damaged area.

While mesh grafting is often the method of choice, there are significant deficiencies with this method. The surgical procedure to remove healthy skin from the donor site can be painful and leaves the patient with a new wound that must also be attended to. In many instances the aesthetic results are not satisfying, as the color of the skin from the donor site may not match the skin color of the damaged skin. Additionally, the size of the donor skin removed must be substantially equal in size to the damaged skin area. These donor and injury sites can take weeks to heal, requiring expensive hospital stays, ongoing wound dressing management, and in some cases, complex anti-infection strategies.

We are currently evaluating the potential of our CellMist™ System in the treatment of tissue that has been subject to severe trauma such as second degree burns. The CellMist™ System utilizes the patient's own skin stem cells, reduces the size of the donor site, and has shown to significantly decrease scarring. Furthermore, we believe the CellMist™ System could enable treatment of other skin disorders with minimal scarring.

### **Our Market Opportunity**

According to medical market research firm, Kalorama Information, the global market for wound care products is projected to grow to approximately \$18.3 billion by 2019.

### ***Burn Wounds***

Burns are one of the most common and devastating forms of trauma. Patients with serious thermal injury require immediate specialized care in order to minimize morbidity and mortality. Data from the National Center for Injury Prevention and Control in the U.S. show that approximately 2 million fires are reported each year which result in 1.2 million people with burn injuries (see American Burn Association *Burn Incidence and Treatment in the US: 2000 Fact Sheet*, available at: <http://www.ameriburn.org>). Moderate to severe burn injuries requiring hospitalization account for approximately 100,000 of these cases, and about 5,000 patients die each year from burn-related complications (see Church D, Elsayed S, Reid O, Winston B, Lindsay R “*Burn wound infections*” *Clinical Microbiology Reviews* 2006;19(2):403–34, available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1471990>).

The prevalence of patients with severe burns is even higher in emerging economies. For example, according to the World Health Organization over 1,000,000 people in India are moderately to severely burnt every year and approximately 265,000 people worldwide die from burn related injuries (see World Health Organization “*Burns: Fact Sheet No. 365*,” reviewed September 2016, available at: <http://www.who.int/mediacentre/factsheets/fs365/en/>). According to *Critical Care*, an international clinical medical journal, burns are also among the most expensive traumatic injuries because of long and costly hospitalization, rehabilitation and wound and scar treatment (see Brusselsaers, N., Monstrey, et al, “*Severe Burn Injury in Europe: A systematic Review of the Incidence, Etiology, Morbidity, and Mortality*” available at: <http://ccforum.com/content/14/5/R188>).

Burn injuries account for a significant cost to the health care system in North America and worldwide. In the U.S. there are currently 127 centers specializing in burn care. Recent estimates in the U.S. show that 40,000 patients are admitted annually for treatment with burn injuries, over 60% of the estimated U.S. acute hospitalizations related to burn injury were admitted to burn centers. Such centers now average over 200 annual admissions for burn injury and skin disorders requiring similar treatment. The other 4,500 U.S. acute care hospitals average less than 3 burn admissions per year (see American Burn Association *Burn Incidence and Treatment in the US: 2013 Fact Sheet*, available at: <http://www.ameriburn.org>).

Initial hospitalization costs and physicians' fees for specialized care of a patient with a major burn injury are currently estimated to be \$200,000. Overall, costs escalate for major burn cases because of repeated admissions for reconstruction and rehabilitation therapy. In the U.S., current annual estimates show that more than \$18 billion is spent on specialized care of patients with major burn injuries (see Church D, Elsayed S, Reid O, Winston B, Lindsay R “*Burn wound infections*” *Clinical Microbiology Reviews* 2006;19(2):403–34, available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1471990>).

Most burn injuries involve layers of the upper skin, the epidermis. Severe major trauma involves a complete loss of the entire thickness of the skin and often requires major surgery involving split-skin mesh-grafting. Skin grafting is a procedure where healthy skin is removed from one area of the body and transplanted to a wound site.

### ***Our Technology***

Our cell isolation methodology is referred to as the CellMist™ process, and our cell deposition device is referred to as the SkinGun™. We isolate a patient's stem cells from a small biopsy of the patient's skin. The stem cells are placed into a liquid solution, which is then filled into a sterile syringe. The syringe is inserted into the SkinGun™, which then sprays the stem cell-loaded liquid solution into the wound.

The first phase of gathering the patient's stem cells, creating a liquid solution, and applying the stem cells takes approximately 1.5–2 hours. Within two weeks following the wound treatment procedure, the skin cells fully generate a normal upper skin layer (re-epithelialization), and within months the skin regains its color and texture.

Our cell isolation procedure and the cell spraying are performed on the same day, in an on-site setting. Because the skin cells sprayed using the SkinGun™ are actually the patient's own cells, the skin that is regenerated looks more natural than artificial skin replacements. During recovery, the skin cells grow into fully functional layers of the skin and the regenerated skin leaves minimal scarring. Additionally, our methods require substantially smaller donor areas than skin grafting, reducing donor area burden such as pain and the risk of complications.

*The CellMist™ System remains an experimental, unproven methodology and we continue to evaluate its efficacy. There is no guarantee that we will be able to develop a commercially viable product based upon the CellMist™ System and its underlying technology.*

### ***Domestic Regulation***

Governmental authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products or devices such as those we are attempting to develop. Our device candidates, to the extent they are developed, will be subject to pre-market approval by the FDA prior to their marketing for commercial use in the U.S., and to any approvals required by foreign governmental entities prior to their marketing outside the U.S. In addition, any changes or modifications to a device that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application in the U.S. for pre-market approval, or for

foreign regulatory approvals outside the U.S.. The process of obtaining foreign approvals, can be expensive, time consuming and uncertain.

### **Premarket Approval**

We will be required to file for premarket approval (“PMA”) for the SkinGum™ or any other device that we commercialize if it is deemed a Class III medical device. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, the FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a PMA application under section 515 of the Federal Food, Drug and Cosmetic Act in order to obtain marketing clearance.

PMA is the most stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device.

### **Investigational Device Exemption (“IDE”)**

Among the data required in a PMA application is human clinical test data. The FDA’s regulation that governs the human testing is the IDE and other patient protection regulations. For devices that are considered Significant Risk, an IDE application is required. It consists of the proposed clinical protocol and all supporting study documentation and must be submitted and approved by FDA and an Institutional Review Board (IRB) prior to initiation of the human testing. Since the CellMist™ System employs the use of stem cells taken from the patient, it is considered Significant Risk by the FDA; therefore, we will be required to file an IDE application prior to conducting a clinical study for any application, such as for treatment of severe burns. The FDA has a specified review timeline and process for IDE reviews - each review phase takes 30 days and if the FDA has questions or concerns about the study design, there may be multiple review rounds until FDA either: (a) conditionally approves, (b) approves or (c) denies approval of the clinical study conduct under the submitted IDE. There is no guarantee that any IDE application we submit will be approved by the FDA.

### *HIPAA Requirements*

Other federal legislation may affect our ability to obtain certain health information in conjunction with any research activities we conduct. The Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”), mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services (“**HHS**”), has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research.

### *Other U.S. Regulatory Requirements*

In the U.S., the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users

of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

### *International Regulation*

The regulation of any potential product candidates we may produce outside of the U.S. varies by country. Certain countries regulate human tissue products as a biological product, which would require us to make extensive filings and obtain regulatory approvals before selling our product candidates. Certain other countries may classify our product candidates as human tissue for transplantation but may restrict its import or sale. Other countries have no application regulations regarding the import or sale of products similar to potential product candidates, creating uncertainty as to what standards we may be required to meet.

## **Competition**

The biotechnology, medical device, and wound care industries are characterized by intense competition, rapid product development and technological change. Our CellMist™ System competes with a variety of companies in the wound care markets, many of which offer substantially different treatments for similar problems. Currently Avita Medical Limited is evaluating the efficacy of ReCell, a cell spray device and a cell isolation procedure for autologous cells. Integra Lifesciences Holding Corp. sells Integra Dermal Regeneration Template, which does not use autologous cells, but instead uses an animal-derived intercellular matrix with an artificial waterproof barrier. Other competitors include: MiMedx Group, Inc.; Kinetic Concepts Inc.; Fibrocell Science, Inc.; Shire Plc and Organogenesis, Inc.

Many of our competitors are large, well-established companies with considerably greater financial, marketing, sales and technical resources than those available to us. Additionally, many of our present and potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors.

## **Intellectual Property**

### *General*

In the course of conducting our business, we from time to time create inventions. Obtaining, maintaining and protecting our inventions, including seeking patent protection, might be important depending on the nature of the invention. To that end, we seek to implement patent and other intellectual property strategies to appropriately protect our intellectual property. While we file and prosecute patent applications to protect our inventions, our pending patent applications might not result in the issuance of patents or issued patents might not provide competitive advantages. Also, our patent protection might not prevent others from developing competitive products using related or other technology.

The scope, enforceability and effective term of issued patents can be highly uncertain and often involve complex legal and factual questions. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. The patents we obtain and the unpatented proprietary technology we hold might not afford us significant commercial protection or advantage.



In addition to issued patents describe above, we plan to file additional patent applications that, if issued, would provide further protection for The CellMist™ System. Although we believe the bases for these patents and patent applications are sound, they are untested; and there is no assurance that they will not be successfully challenged. There can be no assurance that any patent previously issued will be of commercial value, that any patent applications will result in issued patents of commercial value, or that our technology will not be held to infringe patents held by others.

## **Strategy**

Our ultimate goal is to leverage the potential of our CellMist™ System, together with our cell isolation method, as cutting edge treatments in skin therapy. Before we can do so, however, there are a number of steps we must first take, including:

- initiating a series of clinical trials to determine the CellMist™ System's safety and efficacy for treating wounds and burns;
- formalizing collaborations with universities and scientific partners;
- creating a network of clinical and research partners;
- achieving FDA and other regulatory clearance; and
- expanding the range of possible applications.

Additionally, we will likely be continue to raise significant capital in order to fund our ongoing research and development operations, and there is no guarantee that we will be able to continue to raise capital on acceptable terms, if at all.

## **Operations**

We expect to be engaged in research and development activities for the foreseeable future.

## **Employees**

We currently have one full time employee, Mr. Andrew Danielson, Director of Operations, and two consultants, one of whom provides service as officers: Ms. Patsy Trisler, Vice-President Clinical & Regulatory Affairs; and Dr. Roger Esteban-Vives, Director of Cell Sciences. From time to time we use additional independent contractors to provide us with services. None of the consultants are required to expend all of their time and efforts on our behalf and may engage in other activities.

## **Item 1A. Risk Factors**

Smaller reporting companies are not required to provide the information required by this item.

Our business operations are subject to numerous risks, including the risk of delays in, or discontinuation of, our research and development due to lack of financing, poor results, inability to commercialize our technologies or to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks associated with the Company please review our registration statements on Form S-1 filed with the SEC, along with any amendments thereto.

## **Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

We do not own any properties. Our corporate offices are located at 9375 East Shea Blvd., Suite 107-A, Scottsdale, AZ 85260.

**Item 3. Legal proceedings**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities****Market Information**

The following table sets forth the high and low bid prices for our common stock for the calendar quarters indicated as reported by the OTCQB for the last two years. These prices represent quotations between dealers without adjustment for retail mark-up, markdown or commission and may not represent actual transactions.

	<b>1<sup>st</sup></b>	<b>2<sup>nd</sup></b>	<b>3<sup>rd</sup></b>	<b>4<sup>th</sup></b>
	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>
2018 – High	\$ 10.65	\$ 6.92	\$ 4.73	\$ 2.65
2018 – Low	\$ 4.60	\$ 2.90	\$ 1.41	\$ 1.29
2017 – High	\$ 5.50	\$ 2.49	\$ 3.95	\$ 4.95
2017 – Low	\$ 2.10	\$ 1.75	\$ 2.87	\$ 2.99

The closing price of our common stock on April 9, 2019, was \$1.53. As of April 9, 2019, there were approximately 361 stockholders of record (this number does not include stockholders who hold their stock through brokers, banks and other nominees).

**Transfer Agent**

The transfer agent of our common stock is Worldwide Stock Transfer, LLC, having an office at One University Plaza, Suite 505, Hackensack, NJ, USA 07601; their phone number is (201) 820-2008.

**Penny Stock**

The Securities and Exchange Commission has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system.

The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document prepared by the Commission, which: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation of such duties or other requirements of Securities' laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form as the Commission shall require by rule or regulation. The broker-dealer also must provide to the customer, prior to effecting any transaction in a penny stock: (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our stock if it becomes subject to these penny stock rules.

## Rule 144

There were 87,175,522 shares of our common stock issued and outstanding at April 5, 2019, of which 51,513,687 shares are deemed “restricted securities” or “control securities” within the meaning of Rule 144. Absent registration under the Securities Act, the sale of such shares is subject to Rule 144, as promulgated under the Securities Act.

In general, under Rule 144, subject to the satisfaction of certain other conditions, a person deemed to be one of our affiliates, who has beneficially owned restricted shares of our common stock for at least one year is permitted to sell in a brokerage transaction, within any three-month period, a number of shares that does not exceed the greater of 1% of the total number of outstanding shares of the same class, or, if our common stock is quoted on a stock exchange, the average weekly trading volume during the four calendar weeks preceding the sale, if greater.

Rule 144 also permits a person who presently is not and who has not been an affiliate of ours for at least three months immediately preceding the sale and who has beneficially owned the shares of common stock for at least six months to sell such shares without restriction other than the requirement that there be current public information as set forth in Rule 144. To the extent that Rule 144 is otherwise available, this provision is currently applicable to all of the restricted shares. If a non-affiliate has held the shares for more than one year, such person may make unlimited sales pursuant to Rule 144 without restriction. The possibility that substantial amounts of our common stock may be sold under Rule 144 into the public market may adversely affect prevailing market prices for the common stock and could impair our ability to raise capital in the future through the sale of equity securities.

## Dividend Policy

We have not paid any dividends on our common stock and our Board of Directors (the “**Board**”) presently intends to continue a policy of retaining earnings, if any, for use in our operations. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by the Board in light of conditions then existing, including earnings, financial condition, capital requirements and other factors. The Nevada Revised Statutes prohibit us from declaring dividends where, if after giving effect to the distribution of the dividend:

- we would not be able to pay our debts as they become due in the usual course of business; or
- our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

Except as set forth above, there are no restrictions that currently materially limit our ability to pay dividends or which we reasonably believe are likely to limit materially the future payment of dividends on common stock.

**Item 6. Selected Financial Data**

Smaller reporting companies are not required to provide the information required by this item.

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

*The following discussion and analysis is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, and should be read in conjunction with our financial statements and related notes. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In addition, the following discussion and analysis contains forward-looking statements that involve risks and uncertainties, including, but not limited to, those discussed in “**Forward Looking Statements**,” and elsewhere in this Form 10-K.*

**Results of Operations*****Year Ended December 31, 2018 versus December 31, 2017***

	Year Ended December 31,		Increase / (Decrease)	Percentage Change
	2018	2017		
Operating expenses:				
Research and development	\$ 340,988	\$ 473,461	\$ (132,473)	-28
General and administrative	1,496,518	1,318,357	178,161	14
Stock compensation	170,516	904,004	(733,488)	-81
Total operating expenses	\$ 2,008,022	\$ 2,695,822	\$ 687,800	-26

***Research and Development***



Research and development (“**R&D**”) costs represent costs incurred to develop our CellMist™ System and are incurred pursuant to agreements with third party providers and certain internal R&D cost allocations. Payments under these agreements include salaries and benefits for R&D personnel, allocated overhead, contract services and other costs. R&D costs are expensed when incurred. R&D costs, excluding stock based compensation, decreased during the year ended December 31, 2018 compared to 2017, as a result of the timing of our R&D expenses.

### ***General and Administrative***

General and administrative (“**G&A**”) costs include all expenditures incurred other than research and development related costs, including costs related to personnel, professional fees, travel and entertainment, public company costs, insurance and other office related costs. 2018 G&A costs, excluding stock based compensation, increased compared to 2017 and included an increase of \$349,000 related to professional fees offset by a \$77,000 decrease in investor communications costs.

### ***Stock Compensation***

Expense associated with equity based transactions is calculated and expensed in our financial statements as required pursuant to various accounting rules and is non-cash in nature. Stock compensation represents the expense associated with the amortization of our stock options. Stock compensation expense decreased during 2018 compared to 2017 due to the May 11, 2017 grant of 310,000 stock options with a weighted average grant date fair value of \$3.38 per share of which 160,000 vested on the date of grant whereas in 2018, no stock options were granted.

***Other Income (Expense)***

Other income relates to interest earned on bank account deposits. Other expense related to our convertible promissory notes. Interest expense related to the stated interest of the convertible promissory notes. Accretion of debt discount represents the accretion of the discount applied to the notes as a result of the issuance of detachable warrants and the beneficial conversion feature contained in the promissory notes.

**Liquidity and Capital Resources**

The Company does not have any commercialized products, has not generated any revenue since inception and has sustained recurring losses and negative cash flows since inception. The Company has incurred recurring operating losses of \$2,120,841 and \$3,689,338 for the years ended December 31, 2018 and 2017. The Company expects to incur losses as it continues development of its products and technologies. Over the past year, the Company has been funded through the sale of equity securities. As of December 31, 2018, the Company had \$15,397,524 of cash. The Company believes that it currently has sufficient cash to meet its funding requirements over the next year.

Net cash used in operating activities was \$2,026,213 during the year ended December 31, 2018, compared to net cash used in operating activities of \$1,674,028 during the year ended December 31, 2017. The increase in cash used in operating activities is primarily due to an increase in prepaid expenses and deposits .

There was no net cash used in investing activities during the years ended December 31, 2018 and 2017.

Net cash provided by financing activities was \$14,517,500 during the year ended December 31, 2018, compared to \$4,162,234 during the year ended December 31, 2017.

On November 26, 2018, the Company issued 9,605,000 units of the Company's equity securities at a price of \$1.50 per unit, pursuant to a private placement offering conducted by the Company resulting in \$14,407,500 of proceeds to the Company.

On November 26, 2018, the Company issued 730,000 units of the Company's equity securities at a price of \$1.50 per unit, pursuant to a private placement offering conducted by the Company resulting in conversion of \$1,095,000 principal amount of loan indebtedness.

On February 13, 2018, the Company issued 100,000 shares of common stock upon the exercise of a Series D Warrant at an exercise price of \$1.10 per share resulting in \$110,000 of proceeds to the Company.

On October 16, 2017, the Company received proceeds of \$2,300,000 from the October 2017 Private Placement in exchange for the issuance of Units with each unit consisting of one share of common stock and one Series H Warrant.

On July 21, 2017, the Company received proceeds of \$1,122,610 from the July 2017 Private Placement in exchange for the issuance of Units with each unit consisting of one share of common stock and one Series G Warrant.

On June 28, 2017, KCC exercised 114,493 Series F Warrants for \$3.01 per share resulting in the issuance of 114,493 shares of common stock and proceeds of \$344,624.

On February 23, 2017 and March 9, 2017, we entered into loan agreements with KCC, Sierchio and an Investor whereby KCC, Sierchio and an Investor loaned the Company \$395,000, \$25,000 and \$25,000, respectively.

## **Dividends**

We have neither declared nor paid any dividends on our common stock. We intend to retain our earnings to finance growth and expand our operations and do not anticipate paying any dividends on our common stock in the foreseeable future.

## **Fair Value of Financial Instruments and Risks**

The carrying value of cash and cash equivalents, accounts payable, and contract and contribution payable, approximate their fair value because of the short-term nature of these instruments and their liquidity. It is not practical to determine the fair value of the Company's notes payable and accrued interest due to the complex terms. Management is of the opinion that the Company is not exposed to significant interest or credit risks arising from these financial instruments.

## **Plans for Next Twelve Months**

During the next twelve months we intend to continue our research and development efforts on the CellMist™ System. As part of these efforts we intend to make certain filings with regulatory bodies, including, but not limited to, the FDA, in order to obtain regulatory approval for the clinical use of the CellMist™ System.

## **Share Capital**

At December 31, 2018, we had:

- Authorized share capital of 10,000,000 preferred shares with par value of \$0.0001.
- Authorized share capital of 500,000,000 common shares with par value of \$0.00001 each.
- 87,175,522 common shares were issued and outstanding.

## **Market Risk Disclosures**

We have not entered into derivative contracts either to hedge existing risks or for speculative purposes during the years ended December 31, 2018 and 2017, and the subsequent period through the date of this annual report.

### **Off-balance Sheet Arrangements and Contractual Obligations**

We do not have any off-balance sheet arrangements or contractual obligations at December 31, 2018, and the subsequent period through the date of this annual report, that are likely to have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that have not been disclosed in our consolidated financial statements.

### **Critical Accounting Policies**

See “**Note 2. Significant Accounting Policies**” in the Notes to the Consolidated Financial Statements in this Form 10-K.

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Smaller reporting companies are not required to provide the information required by this item.

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

**INDEX TO FINANCIAL STATEMENTS**

The following audited consolidated financial statements are filed as part of this annual report:

<u>Report of Independent Registered Public Accounting Firm</u>	14
<u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u>	16
<u>Consolidated Statements of Operations for the years ended December 31, 2018 and 2017</u>	17
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017</u>	18
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017</u>	19
<u>Notes to the Consolidated Financial Statements</u>	20

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders and Board of Directors of

**RenovaCare, Inc. and Subsidiary**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of RenovaCare, Inc. and Subsidiary (the “Company”) as of December 31, 2018, the related consolidated 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, 2018, 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.

**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.

/s/ Marcum llp

Marcum llp

We have served as the Company's auditor since 2018.

Melville, NY

April 12, 2019

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and the Board of Directors

RenovaCare, Inc.

Scottsdale, Arizona

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of RenovaCare, Inc. and Subsidiaries ("the Company") as of December 31, 2017, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, 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.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/S/ PETERSON SULLIVAN LLP

We had served as the Company's auditor since 2006 and our tenure ended on October 22, 2018.

Seattle, Washington

March 13, 2018

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RENOVACARE, INC AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS  
AS OF DECEMBER 31, 2018 AND 2017

	December 31,	
	2018	2017
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$15,397,524	\$2,906,237
Prepaid expenses	168,707	750
Total current assets	15,566,231	2,906,987
Equipment, net of accumulated depreciation of \$687 and \$370, respectively	264	581
Intangible assets	152,854	152,854
Total assets	\$15,719,349	\$3,060,422
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$222,163	\$107,336
Accounts payable - related parties	3,000	61,333
Interest payable to related parties	167,497	90,678
Contract payable	—	100,000
Total current liabilities	392,660	359,347
Convertible promissory notes payable to related party, net of discount of \$534,519	—	1,036,562
Total liabilities	392,660	1,395,909
Commitments and contingencies		
Stockholders' equity		
Preferred stock: \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock: \$0.00001 par value; 500,000,000 shares authorized, 87,175,522 and 76,145,418 shares issued and outstanding at December 31, 2018 and 2017, respectively	872	762
Additional paid-in capital	32,187,580	16,404,673
Retained deficit	(16,861,763)	(14,740,922)
Total stockholders' equity	15,326,689	1,664,513
Total liabilities and stockholders' equity	\$15,719,349	\$3,060,422

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

**RENOVACARE, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

Years Ended

	December 31, 2018		2017
Revenue	\$ —		\$ —
Operating expenses			
Research and development	368,954		574,091
General and administrative	1,639,068		2,121,732
Total operating expenses	2,008,022		2,695,823
Loss from operations	(2,008,022 )		(2,695,823 )
Other income (expense)			
Interest income	22,450		3,136
Interest expense	(76,831 )		(77,284 )
Accretion of debt discount	(58,438 )		(919,367 )
Total other income (expense)	(112,819 )		(993,515 )
Net loss	\$ (2,120,841 )		\$ (3,689,338 )
Basic and Diluted Loss per Common Share	\$ (0.03 )		\$ (0.05 )
Weighted average number of common shares outstanding - basic and diluted	77,748,437		74,386,340

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

**RENOVACARE, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017**

	<b>Common Stock</b>		<b>Additional</b>		<b>Retained</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>-in Capital</b>		<b>Deficit</b>	<b>Stockholders'</b>
						<b>Equity</b>
Balance, December 31, 2016	70,069,693	\$ 702	\$ 11,290,209		\$(11,051,584)	\$ 239,327
						—
Issuance of common stock from the exercise of warrants	4,592,895	46	344,578		—	344,624
Issuance of common stock from the exercise of stock options	102,580	1	(1 )		—	—
October 2017 Private Placement units issued	920,000	9	2,299,991		—	2,300,000
July 2017 Private Placement units issued	460,250	4	1,122,606		—	1,122,610
Stock based compensation due to common stock purchase options	—	—	904,004		—	904,004
Discount on convertible promissory note due to detachable warrants and beneficial conversion feature	—	—	443,286		—	443,286
Net loss for the year ended December 31, 2017	—	—	—		(3,689,338 )	(3,689,338 )
Balance, December 31, 2017	76,145,418	762	16,404,673		(14,740,922)	1,664,513
Issuance of common stock from the exercise of warrants	569,797	6	109,994		—	110,000
Issuance of common stock from the exercise of stock options	125,307	1	(1 )		—	—
November 2018 Private Placement units issued	9,605,000	96	14,407,404		—	14,407,500
November 2018 Private Placement units issued for debt conversion	730,000	7	1,094,993		—	1,095,000
Stock based compensation due to common stock purchase options	—	—	170,517		—	170,517
Discount on convertible promissory note due to detachable warrants and beneficial conversion feature	—	—	—		—	—
Net loss for the year ended December 31, 2018	—	—	—		(2,120,841 )	(2,120,841 )
Balance, December 31, 2018	87,175,522	\$ 872	\$ 32,187,580		\$(16,861,763)	\$ 15,326,689

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

**RENOVACARE, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Years Ended</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities</b>		
Net loss	\$(2,120,841 )	\$(3,689,338)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation	317	317
Stock based compensation expense	170,517	904,004
Accretion of debt discount	58,438	919,367
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses	(167,957 )	30,785
Increase (decrease) in accounts payable	114,827	107,336
Increase (decrease) in accounts payable - related parties	(58,333 )	28,043
Increase (decrease) in interest payable - related parties	76,819	75,458
Increase (decrease) in contract payable	(100,000 )	(50,000 )
Net cash flows from operating activities	(2,026,213 )	(1,674,028)
<b>Cash flows from investing activity</b>		
Net cash flows from investing activity	—	—
<b>Cash flows from financing activities</b>		
Proceeds from exercise of warrants and issuance of common stock	14,517,500	3,767,234
Proceeds from the issuance of convertible promissory notes	—	445,000
Payments of convertible promissory notes	—	(50,000 )
Net cash flows from financing activities	14,517,500	4,162,234
<b>Increase in cash and cash equivalents</b>	12,491,287	2,488,206
<b>Cash and cash equivalents at beginning of period</b>	2,906,237	418,031
<b>Cash and cash equivalents at end of period</b>	\$15,397,524	\$2,906,237
<b>Supplemental disclosure of cash flow information:</b>		
Interest paid in cash	\$—	\$1,825
Income taxes paid in cash	\$—	\$—
<b>Supplemental disclosure of non-cash transactions:</b>		
Discount on convertible promissory note due to detachable warrants and beneficial conversion feature	\$—	\$443,286
Debt conversion	\$1,095,000	\$—

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



**RENOVACARE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Organization, Nature and Continuance of Operations**

*Organization*

RenovaCare, Inc., together with its wholly owned subsidiary, focuses on the acquisition, research, development and, if warranted, commercialization of autologous (using a patient's own cells) cellular therapies that can be used for medical and aesthetic applications.

On July 12, 2013, the Company, through its wholly owned subsidiary, RenovaCare Sciences Corp., completed the acquisition of its flagship technologies (collectively, the “**CellMist™ System**”) along with associated United States patent applications and two foreign patent applications, the first of which was filed on August 23, 2007 (DE 10 2007 040 252.1) and the second of which was filed on April 27, 2011 (DE 10 2011 100 450.9), both of which have been granted. One of the US patent applications was granted on November 29, 2016 (Patent No. US 9,505,000) and the other patent application was granted on April 4, 2017 (Patent No. US 9,610,430).

The CellMist™ System is comprised of (a) a treatment methodology for cell isolation for the regeneration of human skin cells (the “**CellMist™ Solution**”) and (b) a solution sprayer device (the “**SkinGun™**”) for delivering the cells to the treatment area. The Company has filed additional patent applications related to the CellMist™ Solution and SkinGun™ technologies.

*Nature and Continuance of Operations*

The Company does not have any commercialized products. The Company's activities have consisted principally of performing research and development activities and raising capital. These development activities are subject to significant risks and uncertainties, including possible failure of preclinical testing. The Company has not generated any revenue since inception and has sustained recurring losses and negative cash flows from operations since inception. The Company expects to incur losses as it continues development of its products and technologies and expects that it will need to raise additional capital through the sale of its securities to accomplish its business plan and failing to secure such additional funding before achieving sustainable revenue and profit from operations poses a significant risk. The Company's ability to fund the development of its cellular therapies will depend on the amount and timing of cash receipts from future financing activities. There can be no assurance as to the availability or terms upon



which such financing and capital might be available.

As of December 31, 2018, the Company had \$15,397,524 of cash on hand. On January 26, 2018, the Company entered into the first amendment to the convertible promissory note dated September 9, 2016 and the Company entered into the first amendment to the convertible promissory note dated February 23, 2017 both with KCC pursuant to which both notes were amended (with a combined principal balance of \$1,095,000) to extend the maturity date to December 31, 2019. On February 13, 2018, the Company received \$110,000 upon the exercise of 100,000 Series D Warrants. On November 26, 2018, the Company completed a private placement, whereby the Company received proceeds of \$14,407,500 from the sale of common stock and warrants and settled the principal balance of \$1,095,000 of the convertible promissory notes. The Company believes that, as a result of the financings, it currently has sufficient cash to meet its funding requirements over the next twelve months following the issuance of this Annual Report on Form 10-K. However, the Company has experienced and continues to experience negative cash flows from operations, as well as an ongoing requirement for substantial additional capital investment. The Company expects that it may need to raise additional capital to accomplish its business plan over the next several years. If additional funding is required, the Company expects to seek to obtain that funding through private equity or convertible debt. There can be no assurance as to the availability or terms upon which such financing and capital might be available.

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (“US GAAP”), which contemplates continuation of the Company as a going concern, which is dependent upon the Company’s ability to establish itself as a profitable business.

## **Note 2. Significant Accounting Policies**

### ***Principles of Consolidation***

These consolidated financial statements have been prepared in accordance with US GAAP and include the accounts of the Company and its wholly owned subsidiary, RenovaCare Sciences. All significant intercompany transactions and balances have been eliminated. RenovaCare Sciences was incorporated under the laws of the State of Nevada on June 12, 2013.

### ***New Accounting Standards***

Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative non-governmental US GAAP as found in the Financial Accounting Standards Board's Accounting Standards Codification.

In July 2017, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)*. The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments

in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Management has assessed that there is no impact upon the adoption of ASU 2017-11 to the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for public business entities for reporting periods for which financial statements have not yet been issued. Management has assessed that there is no impact upon the adoption of ASU 2017-09 to the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)", which supersedes ASC Topic 840, Leases, and creates a new topic, ASC Topic 842, Leases. ASU 2016-02 requires lessees to recognize a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months on its balance sheet. ASU 2016-02 also expands the required quantitative and qualitative disclosures surrounding leases. ASU 2016-02 is effective for the Company beginning January 1, 2019. Early adoption is permitted. The Company has determined that the adoption of ASU 2016-02 will currently have no impact on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes” (“ASU 2015-17”). The standard requires that deferred tax assets and liabilities be classified as noncurrent on the balance sheet rather than being separated into current and noncurrent. The Company adopted the guidance under ASU 2015-17 with no material impact on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606)”, to clarify the principles used to recognize revenue for all entities. In March 2016, the FASB issued ASU 2016-08 to further clarify the implementation guidance on principal versus agent considerations. The guidance is effective for annual and interim periods beginning after December 15, 2017, and early adoption is permitted. The Company has determined that the adoption of ASU 2014-09 will currently have no impact on its consolidated financial statements.

The Company reviews new accounting standards as issued. Although some of these accounting standards issued or effective after the end of the Company’s previous fiscal year may be applicable, the Company has not identified any standards that the Company believes merit further discussion other than as discussed above. The Company believes that none of the new standards will have a significant impact on the financial statements.

#### *Accounting Estimates*

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. Actual results, as determined by future events, may differ from these estimates. Management utilizes various other estimates, including but not limited to, determining the estimated lives of long-lived assets, determining the potential impairment of intangibles, the fair value of warrants issued, the fair value of stock options and other legal claims and contingencies.

#### *Cash and Cash Equivalents*

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents may at times exceed federally insured limits.

#### *Fair Value Measurement*

The Company measures fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The Company utilizes a three-tier hierarchy which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1. Valuations based on quoted prices in active markets for identical assets or liabilities that an entity has the ability to access. The Company has no assets or liabilities valued with Level 1 inputs.

Level 2. Valuations based on quoted prices for similar assets or liabilities, quoted prices for identical assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities. The Company has no assets or liabilities valued with Level 2 inputs.

Level 3. Valuations based on inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company has no assets or liabilities valued with Level 3 inputs.

*Fair Value of Financial Instruments*

The carrying value of cash and cash equivalents, accounts payable, and contract payable, approximate their fair value because of the short-term nature of these instruments and their liquidity. It is not practical to determine the fair value of the Company's notes payable and accrued interest due to the complex terms. Management is of the opinion that the Company is not exposed to significant interest or credit risks arising from these financial instruments.

*Research and Development Costs*

The Company intends to outsource its research and development efforts and expense related costs as incurred, including the cost of manufacturing product for testing, licensing fees and costs associated with planning and conducting clinical trials. The value ascribed to patents and other intellectual property acquired will be capitalized as it relates to particular research and development projects that may have alternative future uses.

*Equipment*

Equipment is carried at cost, less accumulated depreciation and amortization. Major improvements are capitalized, while repair and maintenance are expensed when incurred. Renewals and betterments that materially extend the life of the assets are capitalized. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is reflected in income for the period.

Depreciation is computed on a straight-line basis over estimated useful lives of the related assets. The estimated useful lives of depreciable assets are:

	<b>Estimated</b>
	<b>Useful</b>
	<b>Lives</b>
Office equipment	3-5 years
Furniture & equipment	5 - 7 years

*Intangible Assets*

The Company's intangible asset consists primarily of the CellMist™ System technology that the Company acquired during 2013 and is recorded at cost. At the time of acquisition, the technology had not reached technological feasibility. The amount capitalized is accounted for as an indefinite-lived intangible asset, subject to impairment testing until completion or abandonment. Upon successful completion, a determination will be made as to the then useful life of the intangible asset, generally determined by the period in which substantially all of the cash flows are expected to be generated, and begin amortization. The Company tests the intangible asset for impairment at least annually or more frequently if impairment indicators exist after performing a qualitative analysis. Management has multiple criteria that it considers when performing the qualitative analysis. The results of this review are then weighed and prioritized. If the totality of the relevant events and circumstances indicate that the intangible asset is not impaired, additional impairment tests are not necessary.

The Company assessed the following qualitative factors that could affect any change in the fair value of the intangible asset: analysis of the technology's current phase, additional testing necessary to bring the technology to market, development of competing products, changes in projections caused by delays, changes in regulations, changes in the market for the technology and changes in cost projections to bring the technology to market. Based on a qualitative assessment, management concluded that a positive assertion can be made from the qualitative assessment that it is more likely than not that the intangible asset related to the CellMist™ System is not impaired.

#### *Stock Options*

The Company measures all stock-based compensation awards using a fair value method on the date of grant and recognizes such expense in its consolidated financial statements over the requisite service period. The Company uses the Black-Scholes pricing model to determine the fair value of stock-based compensation awards on the date of grant. The Black-Scholes pricing model requires management to make assumptions regarding option lives, expected volatility, and risk free interest rates. Forfeitures are recognized as they occur. The Company's policy is to issue new shares upon exercise of options.

*Financial Instruments, Convertible Instruments, Warrants and Derivatives*

The Company reviews its convertible instruments for the existence of embedded conversion features that may require bifurcation. If certain criteria are met, the bifurcated derivative financial instrument is required to be recorded at fair value. The Company also reviews and re-assesses, at each reporting date, any common stock purchase warrants and other freestanding derivative financial instruments and classifies them on the consolidated balance sheet as equity, assets or liabilities based upon the nature of the instruments.

*Income Taxes*

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributed to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences and carry-forwards are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred tax assets to amounts expected to be realized. The Company reports a liability for unrecognized tax benefits resulting from uncertain income tax positions, if any, taken or expected to be taken in an income tax return. Estimated interest and penalties are recorded as a component of interest expense or other expense, respectively.

*Earnings (Loss) Per Share*

The Company presents both basic and diluted earnings per share ("EPS") amounts. Basic EPS is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period presented. Diluted EPS amounts are based upon the weighted average number of common and common equivalent shares outstanding during the period presented. The Company has not included the effects of warrants, stock options and convertible debt on net loss per share because to do so would be antidilutive.

Following is the computation of basic and diluted net loss per share for the years ended December 31, 2018 and 2017:

**Years Ended**



	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Basic and Diluted EPS Computation</b>		
Numerator:		
Loss available to common stockholders	\$(2,120,841 )	\$(3,689,338 )
Denominator:		
Weighted average number of common shares outstanding	77,748,437	74,386,340
Basic and diluted EPS	\$(0.03 )	\$(0.05 )

The shares listed below were not included in the computation of diluted losses per share because to do so would have been antidilutive for the periods presented:

Stock options	317,500	545,000
Warrants	13,346,912	3,609,158
Convertible debt	—	619,266
Total shares not included in the computation of diluted losses per share	13,664,412	4,773,424

*Related Party Transactions*

A related party is generally defined as (i) any person who holds 10% or more of the Company's securities and their immediate families; (ii) the Company's management; (iii) someone who directly or indirectly controls, is controlled by or is under common control with the Company; or (iv) anyone who can significantly influence the financial and operating decisions of the Company. A transaction is considered to be a related party transaction when there is a transfer of resources or obligations between related parties. See "Note 9. Related Party Transactions" for further discussion.

**Note 3. Assets – Intellectual Property**

On July 12, 2013, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an asset purchase agreement ("APA") with Dr. Jörg Gerlach, MD, PhD, pursuant to which RenovaCare Sciences purchased all of Dr. Gerlach's rights, title and interest in the CellMist™ System. Acquisition related costs amounted to \$52,852 and were capitalized together with the cash payment upon the closing of the transaction in July 2013 of \$100,002. Intangible assets amounted to \$152,854 at December 31, 2018 and 2017.

**Note 4. Contract Payable**

On June 9, 2014, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an amended asset purchase agreement (the "Amended APA") with Dr. Jörg Gerlach, MD, PhD, pursuant to which RenovaCare Sciences purchased all of Dr. Gerlach's rights, title and interest in the CellMist™ System. The Amended APA provided for cash payments of \$300,000 as partial consideration for the purchase which are payable as follows: (a) \$100,000 on December 31, 2014; (b) \$50,000 on December 31, 2015; (c) \$50,000 on December 31, 2017; and (d) \$100,000 on December 31, 2017. At December 31, 2017, \$100,000 of the amount payable to Dr. Gerlach was recorded as current liabilities in the accompanying consolidated balance sheet and was paid on January 24, 2018.

See also "Note 9. Related Party Transactions."

**Note 5. Debt**

As of December 31, 2018 and 2017, the Company had the following outstanding debt balances:

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	Issue Date	Maturity Date	Principal	Debt Discount	Balance	Interest Payable
As of December 31, 2018:						
February 2017 Note as amended	2/23/2017	11/26/2018	\$—	\$—	\$—	\$51,225
September 2016 Note as amended	9/9/2016	11/26/2018	—	—	—	116,272
			\$—	\$—	\$—	\$167,497
<b>As of December 31, 2017:</b>						
February 2017 Note as amended	2/23/2017	12/31/2019	\$395,000	\$(58,438)	\$336,562	\$24,074
September 2016 Note as amended	9/9/2016	12/31/2019	700,000	—	700,000	66,604
			\$1,095,000	\$(58,438)	\$1,036,562	\$90,678

**February 2017 Convertible Promissory Notes**

Between February 23, 2017 and March 9, 2017, the Company entered into three separate loan agreements containing identical terms (the “**February 2017 Loan Agreements**”) with Joseph Sierchio (“**Sierchio**”), an investor (the “**Investor**”), Paul Barbiero, a related party, and Kalen Capital Corporation (“**KCC**”); KCC is wholly owned by Mr. Harmel S. Rayat, the Company's majority shareholder (collectively, the “**Holders**”). Pursuant to the terms of the February 2017 Loan Agreements, Sierchio and the Investor each agreed to loan the Company \$25,000 (\$50,000 total) and KCC agreed to loan the Company \$395,000 at an annual interest rate of 7% per year, compounded quarterly. Each loan was evidenced by a convertible promissory note (collectively, the “**February 2017 Notes**”). The February 2017 Notes, including any interest due thereon, may not be prepaid without the consent of the Holders. The February 2017 Notes were initially due on February 23, 2018, and, beginning on the one month anniversary, can be converted, at the Holders’ sole discretion, into shares of the Company’s common stock at conversion rate equal to the lesser of: (i) \$3.45, the closing price of the Company’s common stock on the day prior to the issuance of the February 2017 Notes or (ii) a 20% discount to the average closing price of the Company’s common stock for the five days prior to the date on which the Holder(s) elect to convert the February 2017 Note(s), subject to a floor price of \$2.76.

Per the February 2017 Loan Agreement, the Company issued Sierchio, the Investor and KCC a Series F Stock Purchase Warrant (the “**Series F Warrant**”) to purchase up to 7,246 shares, 7,246 shares and 114,493 shares, respectively, of the Company’s common stock at an exercise price per share equal to the lesser of: (i) \$3.45, the closing price of the Company’s common stock on the day prior to issuance of the Series F Warrant; or (ii) a 20% discount to the average closing price of the Company’s common stock for the five days prior to the date on which the Holder elects to exercise their Series F Warrant. The Series F Warrant is exercisable for a period of five years from the date of issuance and may be exercised on a cashless basis.

The Company calculated the debt discount related to the February 2017 Notes and Series F Warrants by first allocating the respective fair value of the February 2017 Notes and Series F Warrants based upon their relative fair values to the total February 2017 Notes proceeds. The fair value of the Series F Warrant issued with the February 2017 Notes was calculated using the Black-Scholes option pricing model and the following assumptions: exercise price - \$3.45 per share as to \$420,000 of February 2017 Note principal and \$2.90 per share as to \$25,000 of February 2017 Note principal; market price of common stock - \$3.53 as to \$420,000 of February 2017 Note principal and \$3.80 per share as to \$25,000 of February 2017 Note principal; estimated volatility – 110.0% as to \$420,000 of February 2017 Note principal and 116.0% as to \$25,000 of February 2017 Note principal; risk free interest rate – 2.13% as to \$420,000 of February 2017 Note principal and 1.87% as to \$25,000 of February 2017 Note principal; expected dividend rate - 0% and expected life - 5.0 years. The resulting fair value of \$211,073 was allocated to the Series F Warrant. The intrinsic value of the beneficial conversion feature amounted to \$232,213. The resulting \$443,286 discount to the February 2017 Notes is being accreted over their 1.25 year term.

The February 2017 Loan Agreements provide the Holders with registration rights for all of the shares issuable upon conversion of the February 2017 Notes, including exercise of the Series F Warrants, beginning on the first anniversary of the February 2017 Loan Agreements.

On July 27, 2017, the Company repaid the Investor in full, including \$25,000 of note principal and \$676 of accrued interest.

On October 19, 2017, the Company repaid Sierchio in full, including \$25,000 of note principal and \$1,149 of accrued interest.

On January 29, 2018, KCC and the Company entered into an Amendment No. 1 to the February 2017 Note whereby the maturity date of the KCC February Note was extended from February 23, 2018 to December 31, 2019. On November 26, 2018, KCC and the Company entered into an Amendment No. 2 to the February 2017 Note whereby the principal amount was settled by the issuance of 296,667 units of the Company's equity securities (the "**Units**") at a price of \$1.50 per Unit. Each Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series I Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$2.00 per share for a period of seven (7) years commencing on the date the Warrants are first issued. (the "**Series I Warrants**").

The Series I Warrants do not have a cashless exercise provision. KCC does not have any registration rights with respect to the shares comprising a part of the Units or issuable upon exercise of the Series I Warrants.

During the year ended December 31, 2018, the Company recognized \$27,151 of interest expense and \$58,438 of accretion related to the debt discount.

### *September 9, 2016 Convertible Promissory Note*

On September 9, 2016, the Company entered into a loan agreement (the “**Loan Agreement**”) with KCC. Pursuant to the terms of the Loan Agreement, KCC agreed to loan the Company up to \$900,000 at an annual interest rate of 7% per year, compounded quarterly. KCC provided the Company with an initial loan in the amount of \$700,000, which was evidenced by a convertible promissory note (the “**Note**”); the remaining \$200,000 needed to be loaned prior to December 31, 2018. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matured on December 31, 2017, but was extended to December 31, 2019 pursuant to the Amendment No. 1, dated as of January 29, 2018, to the Note. Beginning on September 9, 2017, the Note became convertible, at KCC’s sole discretion, into shares of our common stock at conversion rate equal to the lesser of: (i) \$1.54, the closing price of our common stock on the day prior to the issuance of the Note or (ii) a 20% discount to the average closing price of our common stock for the five days prior to the date on which KCC elects to convert the Note, subject to a floor price of \$1.23 per share. On November 26, 2018, KCC and the Company entered into an Amendment No. 2 to the February 2017 Note whereby the principal amount was settled by the issuance of 463,333 units of the Company’s equity securities (the “**Units**”) at a price of \$1.50 per Unit. The Unit price represents a discount of \$0.03 from the closing price on November 23, 2018 and a \$0.05 discount to the 20-day lookback of the closing price of the Company’s common stock as quoted on the OTC Markets Pink Sheets for the 20 trading days prior to the Closing Date. Each Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series I Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$2.00 per share for a period of seven (7) years commencing on the date the Warrants are first issued. (the “**Series I Warrants**”).

The Series I Warrants do not have a cashless exercise provision. KCC does not have any registration rights with respect to the shares comprising a part of the Units or issuable upon exercise of the Series I Warrants.

Per the Loan Agreement, the Company issued KCC a Series E Stock Purchase Warrant (the “**Series E Warrant**”) to purchase up to 584,416 shares of the Company’s common stock at a purchase price of the lesser of: (i) \$1.54, the closing price of the Company’s common stock on the day prior to issuance of the Series E Warrant; or (ii) a 20% discount to the average closing price of the Company’s common stock for the five days prior to the date on which KCC elects to exercise the Series E Warrant. The Series E Warrant is exercisable for a period of five years from the date of issuance and may be exercised on a cashless basis.

The Company calculated the debt discount related to the Note and Series E Warrant by first allocating the respective fair value of the Note and Series E Warrant based upon their relative fair values to the total Note proceeds. The fair value of the Series E Warrant issued with the Note was calculated using the Black-Scholes option pricing model and the following assumptions: exercise price - \$1.25 per share; market price of common stock - \$1.54 per share; estimated volatility – 92.3%; risk free interest rate - 1.23%; expected dividend rate - 0% and expected life - 5.0 years. The resulting fair value of \$340,735 was allocated to the Series E Warrant. The intrinsic value of the beneficial conversion feature amounted to \$359,265. The resulting \$700,000 discount to the Note is being accreted over their 1.25 year term.

During the years ended December 31, 2018 and 2017, the Company recognized \$49,680 and \$51,385, respectively, of interest expense and \$0 and \$534,519, respectively, of accretion related to the debt discount.

## **Note 6. Common Stock and Warrants**

### ***Common Stock***

At December 31, 2018, the Company had 500,000,000 authorized shares of common stock with a par value of \$0.00001 per share, 87,175,522 shares of common stock outstanding and 19,440,765 shares reserved for issuance under the Company's 2013 Long-Term Incentive Plan (the "2013 Plan") as adopted and approved by the Company's Board of Directors (the "Board") on June 20, 2013 that provides for the grant of stock options to employees, directors, officers and consultants. See "Note 7. Stock Options" for further discussion.

During the year ended December 31, 2018, the Company had the following common stock related transactions:

- On February 3, 2018, Thomas Bold, the Company's President, CEO and Interim Chief Financial Officer exercised options to purchase up to 60,000 shares, on a cashless basis, resulting in the issuance of 44,083 shares of common stock.

- On February 11, 2018, a consultant exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 17,480 shares of common stock.

- On February 12, 2018, Dr. Gerlach exercised a Series A Warrant to purchase up to 480,000 shares, on a cashless basis, resulting in the issuance of 457,480 shares of common stock.

- On February 13, 2018, the Company issued 100,000 shares of common stock, upon the exercise of a Series D Warrant at an exercise price of \$1.10 per share resulting in \$110,000 of proceeds to the Company.

- On February 22, 2018, Kenneth Kirkland, a member of the Company's board of directors, exercised options to purchase up to 50,000 shares, on a cashless basis, resulting in the issuance of 41,033 shares of common stock.

On February 22, 2018, Joseph Sierchio, a member of the Company's board of directors 1) exercised options to purchase up to 37,500 shares, on a cashless basis, resulting in the issuance of 22,711 shares of common stock; 2) exercised a Series F Warrant to purchase up to 7,246 shares, on a cashless basis, resulting in the issuance of 4,899 shares of common stock; and 3) exercised a Series H Warrant to purchase up to 10,000 shares, on a cashless basis, resulting in the issuance of 7,418 shares of common stock.

On November 26, 2018, the Company entered into Subscription Agreements (each, a "**Subscription Agreement**") with KCC, a private corporation owning in excess of 10% of the Company's issued and outstanding common stock, for the purchase and sale of 10,335,000 units of the Company's equity securities (the "**Units**") at a price of \$1.50 per Unit, pursuant to a private placement offering conducted by the Company (the "**Offering**") for (i) aggregate cash proceeds of \$14,407,500 and (ii) conversion of \$1,095,000 principal amount of outstanding loan indebtedness. The Each Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series I Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$2.00 per share for a period of seven (7) years commencing on the date the Warrants are first issued. (the "**Series I Warrants**"). The Series I Warrants do not have a cashless exercise provision. KCC does not have any registration rights with respect to the shares comprising a part of the Units or issuable upon exercise of the Series I Warrants. A deemed dividend of \$180,000 was incurred with respect to the difference between the floor price of the conversion feature of \$395,000 of outstanding loan indebtedness. This amount is a reclassification within equity only.

During the year ended December 31, 2017, the Company had the following common stock related transactions:

- On October 16, 2017, the Company completed a self-directed offering of 920,000 shares of the Company common stock at a price of \$2.50 per share for \$2,300,000 in aggregate proceeds (the "**October 2017 Private Placement**").



Additionally, each purchaser, in a concurrent private placement, received one stock purchase warrant for each share of stock purchased for no additional consideration (the "**Series H Warrant**"). Each Series H Warrant is exercisable at a price of \$2.75 per share for a period of five years. The warrants may be exercised on a cashless basis. The relative fair value of the common stock was estimated to be \$1,309,458. The relative fair value of the Series H Warrants was estimated to be \$990,542 as determined based on the relative fair value allocation of the proceeds received. The Series H Warrants were valued using the Black-Scholes option pricing model using the following variables: market price of common stock - \$3.10 per share; exercise price of \$2.75; estimated volatility – 98.25%; 5-year risk free interest rate – 1.95%; expected dividend rate - 0% and expected life - 5 years.

On July 21, 2017, the Company completed a self-directed offering of 460,250 units of the Company's equity securities (the "Units") at a price of \$2.44 per unit for \$1,122,610 in aggregate proceeds (the "**July 2017 Private Placement**"). Each unit consists of (a) one share of common stock and one Series G Stock Purchase Warrant (the "**Series G Warrants**") allowing the holder to purchase one share of the Company's common stock at a price of \$2.68 per share for a period of five years. The warrants may be exercised on a cashless basis. The relative fair value of the common stock was estimated to be \$634,782. The relative fair value of the Series G Warrants was estimated to be \$487,828 as determined based on the relative fair value allocation of the proceeds received. The Series G Warrants were valued using the Black-Scholes option pricing model using the following variables: market price of common stock - \$2.92 per share; estimated volatility – 102.23%; 5-year risk free interest rate – 1.81%; expected dividend rate - 0% and expected life - 5 years.

On June 28, 2017, KCC exercised 114,493 Series F Warrants for \$3.01 per share resulting in the issuance of 114,493 shares of common stock and proceeds of \$344,624.

March 1, 2017, KCC exercised 1,326,087 Series B Warrants and 3,500,000 Series C Warrants, on a cashless basis, resulting in the issuance of 4,273,831 shares of common stock.

On February 17, 2017, Thomas Bold, the Company's former President exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 34,296 shares of common stock. Mr. Bold resigned as President and Director on March 30, 2019.

On February 10, 2017, Joseph Sierchio, a former member of the Company's board of directors, exercised options to purchase up to 70,000 shares, on a cashless basis, resulting in the issuance of 38,642 shares of common stock.

On February 2, 2017, Kenneth Kirkland, a member of the Company's board of directors, exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 29,642 shares of common stock.

On January 10, 2017, Dr. Gerlach exercised a Series A Warrant to purchase up to 240,000 shares, on a cashless basis, resulting in the issuance of 204,571 shares of common stock.

## Warrants

The following table summarizes information about warrants outstanding at December 31, 2018 and 2017:

Description	Shares of Common Stock Issuable from Warrants Outstanding as of		Weighted Average Exercise Price	Expiration
	December 31, 2018	December 31, 2017		
Series A	240,000	720,000	\$ 0.35	July 12, 2019
Series D	810,000	910,000	\$ 1.10	June 5, 2020
Series E	584,416	584,416	\$ 1.54	September 8, 2021

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Series F	7,246	14,492	\$	3.45	February 23, 2022 & March 9, 2022
Series G	460,250	460,250	\$	2.68	July 21, 2022
Series H	910,000	920,000	\$	2.75	October 16, 2022
Series I	10,335,000	-	\$	2.00	November 26, 2025
Total	13,346,912	3,609,158			

As consideration for the CellMist™ System and services performed in connection therewith, the Company issued to Dr. Gerlach a Series A Stock Purchase Warrant entitling him to purchase 1,200,000 shares of the Company's common stock at an exercise price of \$0.35 per share. Pursuant to the terms of the Amended APA, the Series A Warrant will vest in five equal installments of 240,000 shares on each of July 12, 2014, July 12, 2015, July 12, 2016, July 12, 2017 and July 12, 2018. On August 5, 2015, Dr. Gerlach exercised a Series A Warrant to purchase up to 240,000 shares on a cashless basis and the Company issued him 196,812 shares of common stock. On January 10, 2017, Dr. Gerlach exercised a Series A Warrant to purchase up to 240,000 shares on a cashless basis and the Company issued him 204,571 shares of common stock. On February 3, 2018, Dr. Gerlach exercised a Series A Warrant to purchase up to 480,000 shares on a cashless basis and the Company issued him 457,480 shares of common stock.

A Series B Warrant with an exercise price of \$0.46 to purchase 3,500,000 shares of common stock was issued on November 29, 2013 to KCC in connection with the November 29, 2013 financing. On February 2, 2016, KCC exercised a portion of its Series B Warrant for 2,173,913 shares of the Company's common stock resulting in proceeds of \$1,000,000. On March 1, 2017, KCC exercised, in full, on a cashless basis, the remaining 1,326,087 Series B Warrants resulting in the issuance of 1,181,194 shares of common stock.

A Series C Warrant with an exercise price of \$0.49, to purchase 3,500,000 shares of common stock was issued on November 29, 2013 to KCC in connection with a financing. On March 1, 2017, KCC exercised, in full, on a cashless basis, the 3,500,000 Series C Warrants resulting in the issuance of 3,092,637 shares of common stock.

Series D Warrants with an exercise price of \$1.10 to purchase 1,010,000 shares of common stock were issued on June 5, 2015 in connection with the sale of units pursuant to a private placement. On December 6, 2016, 100,000 Series D Warrants were exercised resulting in the Company receiving \$110,000 of proceeds. On February 13, 2018, an additional 100,000 Series D Warrants were exercised resulting in the Company receiving \$110,000 of proceeds

A Series E Warrant to purchase 584,416 shares of common stock was issued on September 9, 2016 in connection with the Loan Agreement. See "Note 5. Debt" for further discussion.

Three Series F Warrants to purchase 128,985 shares of common stock were issued between February 22, 2017 and March 9, 2017 in connection with the February 2017 Loan Agreements. On June 28, 2017, KCC exercised 114,493 Series F Warrants for \$3.01 per share resulting in the issuance of 114,493 shares of common stock and proceeds of \$344,624. See "Note 5. Debt" for further discussion. On February 22, 2018, Joe Sierchio exercised a Series F Warrant to purchase up to 7,246 shares on a cashless basis and the Company issued him 4,899 shares of common stock.

The Series G Warrants to purchase 460,250 shares of common stock were issued on July 21, 2017 in connection with the sale of units pursuant to the July 2017 Private Placement. See above for further discussion.

The Series H Warrants to purchase 920,000 shares of common stock were issued on October 16, 2017 in connection with the sale of units pursuant to the October 2017 Private Placement. See “Note 6. Common Stock and Warrants” for further discussion. On February 22, 2018, Joe Sierchio exercised a Series F Warrant to purchase up to 10,000 shares on a cashless basis and the Company issued him 7,418 shares of common stock.

#### **Note 7. Stock Options**

On June 20, 2013, the Company’s Board adopted the 2013 Long-Term Incentive Plan and on November 15, 2013, a stockholder owning a majority of the Company’s issued and outstanding stock approved adoption to the 2013 Plan. Pursuant to the terms of the 2013 Plan, an aggregate of 20,000,000 shares of the Company’s common stock are reserved for issuance to the Company’s officers, directors, employees and consultants in order to attract and hire key technical personnel and management. Options granted to employees under the 2013 Plan, including directors and officers who are employees, may be incentive stock options or non-qualified stock options; options granted to others under the 2013 Plan are limited to non-qualified stock options. As of December 31, 2018, there were 19,440,765 shares available for grant.

The 2013 Plan is administered by the Board or a committee designated by the Board. Subject to the provisions of the 2013 Plan, the Board has the authority to determine the officers, employees and consultants to whom options will be granted, the number of shares covered by each option, vesting rights and the terms and conditions of each option that is granted to them; however, no person may be granted in any of the Company's fiscal year, options to purchase more than 2,000,000 shares under the 2013 Plan, and the aggregate fair market value (determined at the time the option is granted) of the shares with respect to which incentive stock options are exercisable for the first time by an optionee during any calendar year cannot exceed \$100,000. Options granted pursuant to the 2013 Plan are exercisable no later than ten years after the date of grant.

The exercise price per share of common stock for options granted under the 2013 Plan will be the fair market value of the Company's common stock on the date of grant, using the closing price of the Company's common stock on the last trading day prior to the date of grant, except for incentive stock options granted to a holder of ten percent or more of the Company's common stock, for whom the exercise price per share will not be less than 110% of the fair market value. No option can be granted under the 2013 Plan after June 20, 2023. The Company adopted ASU 2017-09 (Compensation – Stock Compensation (Topic 718)) effective January 1, 2017 with no effect on retained deficit or other components of equity as of the beginning of the period.

### *Stock Option Activity*

The following table summarizes stock option activity for the period ended December 31, 2018 :

	Number of Options	Weighted Average Exercise Price (\$)	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (\$)
Outstanding at December 31, 2016	385,000	1.42		
Grants	310,000	4.20		
Exercises	(150,000 )	1.12		
Outstanding at December 31, 2017	545,000	3.09		
Forfeited	(40,000 )	4.20		
Exercises	(187,500 )	1.12		
Outstanding at December 31, 2018	317,500	3.41	7.68 years	70,000
Exercisable at December 31, 2018	307,500	3.49	7.76 years	60,000
Available for grant at December 31, 2018	19,440,765			

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. There were 310,000 stock options granted during the year ended December 31, 2017 with a weighted-average grant date fair value of \$3.38. During the year ended December 31, 2017, there were 150,000 options exercised on a cashless basis resulting in the issuance of 102,582 shares of common stock, with an aggregate intrinsic value of

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\$397,100. Non-employee options are remeasured each reporting period and adjusted to reflect the remeasurement. Final remeasurement was done during the year ended December 31, 2018 when the options fully vested. Assumptions regarding volatility, expected term, dividend yield and risk-free interest rate are required for the Black-Scholes model. The volatility assumption is based on the Company's historical experience. The risk-free interest rate is based on a U.S. treasury note with maturity similar to the option award's expected life. The expected life represents the average period of time that options granted are expected to be outstanding. The assumptions for volatility, expected life, dividend yield and risk-free interest rate for options granted are presented in the table below:

	Years Ended December	
	31, 2018	2017
Risk-free interest rate	2.97%	1.93% - 2.39 %
Expected life in years	9.0	5.5 – 10.0
Weighted Avg. Expected Volatility	108 %	98% - 106 %
Expected dividend yield	0	0

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The share-based compensation cost resulting from stock option grants, including those previously granted and vesting over time is expensed ratably over the respective vesting periods. During the years December 31, 2018 and 2017, the Company recognized \$170,517 and \$904,004, respectively, in share-based compensation. As of December 31, 2018, the Company had \$416 unrecognized compensation cost related to unvested stock options. Stock-based compensation has been included in the consolidated statement of operations as follows:

	Years Ended	
	December 31, 2018	2017
Research and development	\$27,967	\$100,630
General and administrative	142,550	803,374
Total	\$170,517	\$904,004

The following table summarizes information about stock options outstanding and exercisable at December 31, 2018:

Range of Exercise Prices	Stock Options Outstanding			Stock Options Exercisable		
	Number of Shares Subject to Outstanding Options	Weighted Average Contractual Life (years)	Weighted Average Exercise Price	Number of Shares Subject To Options Exercise	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
1.05	55,000	5.25	1.05	45,000	5.25	1.05
1.25	7,500	6.46	1.25	7,500	6.46	1.25
1.34	7,500	6.50	1.34	7,500	6.50	1.34
1.70	7,500	6.79	1.70	7,500	6.79	1.70
2.28	7,500	7.55	2.28	7,500	7.55	2.28
4.20	232,500	8.36	4.20	232,500	8.36	4.20
Total	317,500	7.68	\$ 3.41	307,500	7.68	\$ 3.49

#### **Note 8. Commitments**

Effective March 1, 2015, the Company entered into a lease agreement (the "Lease") in the Pittsburgh Life Sciences Greenhouse at a monthly rate of \$750. The Lease was renewed effective March 1, 2016 at a monthly rate of \$800 through August 30, 2018. Rent expense for the years ended December 31, 2018 and 2017 was \$6,400 and \$9,600, respectively.



In connection with the Company's anticipated regulatory filings, the Company has engaged StemCell Systems GmbH ("StemCell Systems") to provide it with prototypes and related documents under various agreements. Pursuant to these engagements the Company incurred expenses of \$80,229 and \$219,806 in during the years ended December 31, 2018 and 2017, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

On August 1, 2017, the Company and the University of Pittsburgh entered into a Corporate Research Agreement whereby the University of Pittsburgh will perform academic research related to the Company's technologies in exchange for \$171,595 with \$42,899 due on August 1, 2017; \$42,899 due on November 1, 2017; \$42,899 due on February 1, 2018 and \$42,898 due on May 31, 2018. As of December 31, 2018, the Company has paid the amounts in full.

See also "Note 9. Related Party Transactions."

**Note 9. Related Party Transactions**

As compensation for their service on the Board, Dr. Kirkland and Mr. Sierchio receive an annual retainer of \$6,000, payable in equal quarterly installments in arrears. Additionally, on March 15, 2016, the Company granted to each of Dr. Kirkland and Mr. Sierchio an incentive stock option to purchase up to 50,000 shares of the Company's common stock at an exercise price of \$1.91 per share; and on May 11, 2017, the Company granted to each of Dr. Kirkland and Mr. Sierchio an incentive stock option to purchase up to 75,000 shares of the Company's common stock at an exercise price of \$4.20 per share. The 50,000 options became fully vested upon grant and the 75,000 options vested 50% on the date of grant and 50% one year hence. The options may be exercised on a "cashless basis" using the formula contained therein. Compensation expense of \$86,325 and \$394,725 with respect to these options was recorded during the years ended December 31, 2018 and 2017 respectively.

Effective July 1, 2018, Joseph Sierchio resigned his position as a Company director. The law firm of Satterlee Stephens LLP ("Satterlee"), of which Joseph Sierchio is a partner, provides counsel to the Company. Mr. Sierchio will continue to be the Company's primary attorney. During the years ended December 31, 2018 and 2017, the Company recognized \$577,718 and \$277,933 of fees for legal services billed by Satterlee. At December 31, 2018 and 2017, accounts payable to Satterlee amounted to \$171,828 and \$30,000, respectively.

In connection with the Company's anticipated FDA and other regulatory filings, the Company engaged StemCell Systems to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$80,229 and \$219,806 during the years ended December 31, 2018 and 2017, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems. Thomas Bold is a business consultant and economic advisor to StemCell Systems.

Dr. Gerlach is entitled to payments for consulting services. During the years ended December 31, 2018 and 2017, the Company recognized expenses related to Dr. Gerlach services of \$7,020 and \$38,540, respectively. Accounts payable to Dr. Gerlach amounted to \$0 and \$17,640 at December 31, 2018 and 2017, respectively.

On August 1, 2013, the Company entered into a consulting agreement, as amended on May 1, 2016, with Jatinder Bhogal, an individual owning in excess of 5% of our issued and outstanding shares of common stock, to provide consulting services to the Company through his wholly owned company, Vector Asset Management, Inc. ("VAM"). Pursuant to the consulting agreement Vector assisted the Company with identifying subject matter experts in the medical device and biotechnology industries and assisted the Company with its ongoing research, development and eventual commercialization of its Regeneration Technology. Pursuant to the amendment the monthly consulting fee was increased to \$6,800 from \$5,000. On June 22, 2018, the Company and VAM entered into an Executive Consulting Agreement ("ECA") whereby Mr. Bhogal will serve as the Company's Chief Operating Officer. The ECA supersedes the prior consulting agreement. Pursuant to the ECA, VAM will receive compensation of \$120,000 per year. During the year ended December 31, 2018 and 2017, the Company recognized expenses of \$103,467 and \$81,600, respectively for consulting services provided by VAM.

On September 9, 2016, the Company entered into the Loan Agreement with KCC whereby KCC loaned the Company \$700,000 at an interest rate of 7%. The Note was amended on January 29, 2018 to extend the maturity date to December 31, 2019. Per the Loan Agreement, the Company issued KCC a Series E Warrant to purchase up to 584,416 shares of the Company's common stock. See "Note 5. Debt" for further discussion.

On January 10, 2017, Dr. Gerlach exercised a Series A Warrant to purchase up to 240,000 shares, on a cashless basis, resulting in the issuance of 204,571 shares of common stock.

On February 2, 2017, Kenneth Kirkland, a member of the Company's board of directors, exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 29,642 shares of common stock.

On February 10, 2017, Joseph Sierchio, a former member of the Company's board of directors, exercised options to purchase up to 70,000 shares, on a cashless basis, resulting in the issuance of 38,642 shares of common stock.

On February 17, 2017, Thomas Bold, the Company's former President exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 34,296 shares of common stock.

On February 23, 2017, the Company entered into two of the February 2017 Loan Agreements with Sierchio and KCC pursuant to which Sierchio loaned the Company \$25,000 and KCC loaned \$395,000 at an interest rate of 7%. On October 19, 2017, the Company repaid the Sierchio in full, including \$25,000 of note principal and \$1,149 of accrued interest. The remaining note with KCC was amended on January 29, 2018 to extend the maturity date to December 31, 2019. Per the February 2017 Loan Agreement, the Company issued Sierchio, and KCC a Series F Warrant to purchase up to 7,246 shares and 114,493 shares, respectively, of the Company's common stock. See "Note 5, Debt" for further discussion.

March 1, 2017, KCC exercised 1,326,087 Series B Warrants and 3,092,637 Series C Warrants, on a cashless basis, resulting in the issuance of 4,273,831 shares of common stock.

On June 28, 2017, KCC exercised 114,493 Series F Warrants for \$3.01 per share resulting in the issuance of 114,493 shares of common stock and proceeds of \$344,624.

On July 21, 2017, the Company entered into the July 2017 Private Placement with KCC for the sale of 410,000 units at a price of \$2.44 per unit for \$1,000,400 in aggregate proceeds. Each unit consisted of one share of common stock and one Series G Warrant to purchase one (1) share of common stock at an exercise price of \$2.68 per share through July 21, 2022. The warrants may be exercised on a cashless basis. See "Note 6. Common Stock and Warrants" for further discussion.

On August 1, 2017, the Company and the University of Pittsburgh entered into a Corporate Research Agreement whereby the University of Pittsburgh will perform academic research related to the Company's technologies in exchange for \$171,595. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a professor at the University.

On October 16, 2017, the Company entered into the October 2017 Private Placement with Joseph Sierchio for the sale of 10,000 shares of common stock at a price of \$2.50 per share for \$25,000 in aggregate proceeds. Additionally, Mr. Sierchio, in a concurrent private placement, received one Series H Warrant for each share of stock purchased for no additional consideration. Each Series H Warrant has an exercise price of \$2.75 per share through October 16, 2022. The warrants may be exercised on a cashless basis. See "Note 6. Common Stock and Warrants" for further discussion.

On February 12, 2018, Dr. Gerlach exercised a Series A Warrant to purchase up to 480,000 shares, on a cashless basis, resulting in the issuance of 457,480 shares of common stock.

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On February 22, 2018, Kenneth Kirkland, a member of the Company's board of directors, exercised options to purchase up to 50,000 shares, on a cashless basis, resulting in the issuance of 41,033 shares of common stock.

On February 22, 2018, Mr. Sierchio, a member of the Company's board of directors until his resignation effective July 1, 2018, 1) exercised options to purchase up to 37,500 shares, on a cashless basis, resulting in the issuance of 22,711 shares of common stock; 2) exercised a Series F Warrant to purchase up to 7,246 shares, on a cashless basis, resulting in the issuance of 4,899 shares of common stock; and 3) exercised a Series H Warrant to purchase up to 10,000 shares, on a cashless basis, resulting in the issuance of 7,418 shares of common stock.

On February 3, 2018, Thomas Bold, the Company's former President, exercised options to purchase up to 60,000 shares, on a cashless basis, resulting in the issuance of 44,086 shares of common stock.

On August 1, 2017, the Company and the University of Pittsburgh entered into a Corporate Research Agreement whereby the University of Pittsburgh will perform academic research related to the Company's technologies in exchange for \$171,595. During the years ended December 31, 2018 and 2017, the Company paid the University of Pittsburgh \$nil and \$171,595, respectively, pursuant to the Corporate Research Agreement. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a professor at the University.

During the year ended December 31, 2018, the Company was offered executive office space located at 9375 E. Shea Blvd., Suite 107-A, Scottsdale, AZ 85260 for consideration of \$1 per year. The executive office space is owned indirectly by Harmel S. Rayat, the Company's majority shareholder and Chairman and CEO.

**Note 10. 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 events that have been recognized in the Company's financial statements or tax returns. A valuation allowance is established to reduce deferred tax assets if all, or some portion, of such assets will more than likely not be realized.

On December 22, 2017, the President of the United States signed into law H.R. 1, "An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for Fiscal Year 2018" (the "Tax Cuts and Jobs Act"). ASC Topic 740, Accounting for Income Taxes, requires companies to recognize the effect of tax law changes in the period of enactment. The Tax Cuts and Jobs Act made significant changes to existing U.S. tax law, including, but not limited to, a permanent reduction to the U.S. federal corporate income tax rate from 35% to 21%, imposition of a one-time tax on deferred foreign income ("Repatriation Transition Tax"), adoption of a participation exemption system with respect to the taxation of future dividends received from foreign corporations, and repeal of the corporate alternative minimum tax system. Other significant changes in the Tax Cuts and Jobs Act include taxing payments made to foreign related parties that are deemed to be excessive, imposing a minimum tax on certain foreign earnings, requiring (beginning after December 31, 2021) the capitalization and subsequent amortization of certain research and development related expenses, and placing additional limits on the use of net operating losses and the deductibility of certain executive compensation. The reduction of the Company's deferred tax assets resulting from the Tax Cuts and Jobs Act's reduction in the U.S. federal corporate income tax rate from 35% to 21% amounted to \$1,831,000 during 2017 with an offsetting decrease to the valuation allowance with no effect on the Statement of Operations. There has been no change to the amount determined in 2017.

There is no current or deferred tax expense for 2018 and 2017, due to the Company's loss position. Realization of the future tax benefits related to the deferred tax assets is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Management has considered these factors in reaching its conclusion as to the valuation allowance for financial reporting purposes and has recorded a full valuation allowance against the deferred tax asset. The income tax effect of temporary differences comprising the deferred tax assets and deferred tax liabilities is a result of the following at December 31:

	2018	2017
Deferred tax assets:		
Net operating loss and contribution carryforwards	\$3,068,000	\$2,480,000
Intangible asset	85,000	85,000
Capital loss carryforward	—	146,000
Stock-based compensation	208,000	247,000
	3,361,000	2,958,000
Valuation allowance	(3,361,000)	(2,958,000)
Net deferred tax assets	\$—	\$—

The 2018 increase in the valuation allowance was \$403,000 compared to a decrease of \$792,000 in 2017.

The Company has available net operating loss and contribution carryforwards of approximately \$14,612,000 for tax purposes to offset future taxable income which \$11,592,000 incurred prior to 2018 expire commencing 2019 through to the year 2037 while \$3,020,000 incurred in 2018 do not expire. The capital loss carryforward expired during 2018. Pursuant to the Tax Reform Act of 1986, annual utilization of the Company's net operating loss and contribution carryforwards may be limited if a cumulative change in ownership of more than 50% is deemed to occur within any three-year period. The tax years 2015 through 2018 remain open to examination by federal agencies and other jurisdictions in which it operates.

A reconciliation between the statutory federal income tax rate and the effective rate of income tax expense for the years ended December 31 follows:

	2018	2017
Statutory federal income tax rate	21 %	34 %
Permanent differences and other	(2 %)	(5 %)
Deferred tax impact from tax rate change	0 %	(50%)
Valuation allowance	(19%)	21 %
	0 %	0 %

**Note 11. Subsequent Events**

Management has reviewed material events subsequent of the period ended December 31, 2018 and prior to the filing of financial statements in accordance with FASB ASC 855 “Subsequent Events”.



## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures**

None.

## **Item 9A. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

As of the end of the period covered by this Annual Report on Form 10-K, we performed an evaluation under the supervision of and with the participation of management, including our Principal Executive Officer and Principal Financial Officer, of the design and effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934 as amended (the “Exchange Act”). Based upon that evaluation, our Principal Executive Officer and Acting Principal Financial Officer concluded, as of the end of the period covered by this Annual Report that our disclosure controls and procedures were not effective due to material weaknesses in internal control over financial reporting as discussed and defined in Management’s Report on Internal Control over Financial Reporting referred to below.

Our management has concluded that our consolidated financial statements for the periods covered by and included in this Annual Report are prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) and fairly present, in all material respects, our financial position, results of operations and cash flows for each of the periods presented herein.

### **Evaluation of and Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers, or persons performing similar functions, and effected by our Board of Directors, management and other personnel, 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management conducted an evaluation of the effectiveness of the Company's internal control over financial reporting based on the framework in "Internal Control — Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that our internal control over financial reporting was not effective at December 31, 2018 because of the material weaknesses described below.

Based on the COSO criteria, management identified control deficiencies that constitute material weaknesses. A "material weakness", as defined by COSO, is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is more than a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has identified the following material weaknesses in our internal control over financial reporting:

- Ineffective control environment due to an insufficient number of independent board members, insufficient oversight of work performed, and the lack of compensating controls over financial reporting due to limited personnel;
- Ineffective design, implementation, and documentation of internal controls impacting financial statement accounts and general controls over technology pertaining to user access and segregation of duties, banking and disbursements, and financial accounting system applications; and
- Ineffective monitoring controls related to the financial close and reporting process, including management's risk assessment process and its identification, evaluation, and timely remediation of control deficiencies

We have not had sufficient time to fully remediate the aforementioned deficiencies and/or there was insufficient passage of time to evidence that the controls that were implemented during 2019 were effective. Therefore, the aforementioned control deficiencies continued to exist as of December 31, 2018. We believe the control deficiencies described herein, individually and when aggregated, represent material weakness in our internal control over financial reporting at December 31, 2018 since such deficiencies result in a reasonable possibility that a material misstatement in our annual or interim consolidated financial statements may not be prevented or detected on a timely basis by our internal controls. As a result of our assessment, we have therefore concluded that our internal control over financial reporting was not effective at December 31, 2018.

### **Changes in Internal Control over Financial Reporting**

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to the permanent exemption from section 404(b) of the Sarbanes-Oxley Act of 2002 for non-accelerated filers.

There were no changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), or in factors that could materially affect internal controls, during the quarter ended December 31, 2018, or subsequent to the date that management completed their evaluation, that materially affected, or are reasonably likely to materially affect, our internal control over financing reporting.

### ***Item 9B. Other Information***

None.

**PART III****Item 10. Directors, Executive Officers and Corporate Governance****Directors and Executive Officers**

The following table and text set forth the names and ages of all directors and executive officers of our company as of April 9, 2019. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships between or among the directors, executive officers or persons nominated or charged by our company to become directors or executive officers. Executive officers serve at the discretion of the Board, and are appointed to serve by the Board.

<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Director / Officer Since</b>
Patsy Trisler	69	Vice-President, Regulatory & Clinical Affairs	April 1, 2014
Harmel S. Rayat	58	Chief Executive Officer	March 2018
Kenneth Kirkland	75	Director	August 2013

Set forth below are the names of all directors and executive officers, all positions and offices with us held by each person, the period during which each has served as such, the principal occupations and employment of such persons during at least the last five years, and other director positions held currently or during the last five years:

**Thomas Bold.** Since 2013 Mr. Bold has been serving as a Business Consultant and Economic Advisor for StemCell Systems, GmbH. In this position he serves as a member of the steering committee of a multinational research project sponsored by the European Commission. From 2004 through 2012 Mr. Bold served as the CEO of StemCell Systems GmbH, a Berlin-based biomedical company engaged in the development and commercialization of advanced cell culture bioreactors. During his time in this position Mr. Bold managed several national and international research and development projects for the company. Mr. Bold has more than 15 years of professional business experience in the field of medical biotechnology device manufacturing, stem cell culture technology platform development and regenerative medicine research project management and product development. Mr. Bold has co-founded several start-up companies in Germany and specializes in structuring and management of new ventures and organizations. He initiated and managed successful business/R&D collaborations between many company and university partners and has been involved in successful patent application processes and IP portfolio management. Mr. Bold has assisted companies in securing millions of dollars of funding from local and national German research organizations and the European Commission and managed national and international life science R&D projects for Hybrid Organ GmbH, StemCell Systems GmbH and the Charité Medical Faculty of the Berlin Universities, Germany. He initiated and managed several skin therapy project consortia on wound dressing development, skin cell isolation technologies and skin cell spray deposition devices. Mr. Bold received his Bachelor's degree in Business Management from the University of Cologne, Germany and his Diplom-Kaufmann (Masters') degree in Business Management, Economic Journalism and American Economy from the Freie Universität Berlin. On March 30, 2019, Mr. Bold resigned his

position as the Company's President and as a member of the Board of Directors. Mr. Bold will continue to provide consulting services to the company pursuant to an at will consulting agreement.

**Patsy Trisler, JD, RAC.** For over 20 years Ms. Trisler has provided strategic regulatory guidance and clinical compliance consulting services to medical device companies, including advising on non-clinical and clinical testing requirements for a variety of product types; preparing FDA submissions; facilitating FDA meetings; training on compliance with GCPs & FDA regulatory requirements. Ms. Trisler has been a regulatory consultant since 1991 and has held senior level positions where she provided consulting services for pharmaceutical, biotechnology and medical device clients and was most recently an independent consultant for a number of clients within the medical products industry. Prior to that Ms. Trisler served for nearly seven years at the FDA as a scientific reviewer and special assistant to the Director of the Office of Device Evaluation in developing medical device policies and guidances. She began her career as a biologist in a molecular biology laboratory at the National Cancer Institute (NCI). Ms. Trisler received her B.S. in biology and psychology from American University in Washington, DC, and her juris doctorate from the Potomac School of Law/Antioch Law School in Washington, DC. Ms. Trisler is regulatory affairs certified (RAC) and a member of several professional groups including the Association of Clinical Research Professionals (ACRP) and Regulatory Affairs Professional Society (RAPS). Ms. Trisler was appointed to serve as our Vice-President, Regulatory & Clinical Affairs due to her extensive regulatory guidance and clinical compliance experience.

**Harmel S. Rayat.** Mr. Rayat is the president and sole stockholder of Kalen Capital Corporation. Mr. Rayat is also a director of SolarWindow Technologies, Inc. Mr. Rayat established, and is the majority stockholder of, Talia Jevan Properties, Inc. in 2006 to acquire and manage high-quality, relatively low-risk commercial real estate properties, with an emphasis on Class-A properties in prominent cities qualified by size, economic strength, growth potential, social and cultural diversity, geographical appeal, and most importantly, a superior risk adjusted return on investment. Starting with no legacy assets, a personal equity investment of \$20 million and following a risk-adjusted acquisition strategy and a proactive managerial mindset heavily focused on providing exceptional service to tenants, Mr. Rayat has since built a commercial real estate portfolio valued at almost \$200 million, using modest leverage.

**Dr. Kenneth Kirkland.** From August 1998 through July 2010, Dr. Kirkland worked as an Executive Director at Iowa State University and most recently served as the University's Executive Director of the Research Foundation and Director of the Office of Intellectual Property and Technology Transfer. While there, he was successful in increasing the licensing of the University's technologies to companies to achieve number one ranking among U.S. universities in the number of licenses executed. Dr. Kirkland also spearheaded successful litigation against infringers of the Research Foundation's intellectual property resulting in total settlements of \$20 million. Dr. Kirkland completed his undergraduate studies in the U.K., and obtained his M.S. and Ph.D. degrees in Agronomic Crop Science from Oregon State University. Dr. Kirkland was invited to join the Board due to his extensive experience in licensing intellectual property.

**Stephen Yan-Klassen.** Mr. Yan-Klassen is a Chartered Professional Accountant (“CPA”), a Certified Management Accountant (“CMA”). Mr. Yan-Klassen was a senior manager at Wolrige Mahon Collins Barrow LLP and at BDO Canada LLP, and a practicing CPA at Amisano Hanson Chartered Accountants. Mr. Yan-Klassen’s public company accounting experience includes over fifteen years of auditing financial statements for SEC, Canadian Securities Exchange and TSX Venture Exchange reporting issuers. Areas of expertise include companies with operations in technology, energy, manufacturing and mining in North and South America, Africa, and Southeast Asia.

### **Certain Relationships**

There are no family relationships among or between any of our officers and directors.

### **Consideration of Director Nominees**

### **Director Qualifications**

We believe that our Board, to the extent that our limited resources permit, should encompass a diverse range of talent, skill and expertise sufficient to provide sound and prudent guidance with respect to our operations and interests. Each director also is expected to: exhibit high standards of integrity, commitment and independence of thought and

judgment; use his or her skills and experiences to provide independent oversight to our business; participate in a constructive and collegial manner; be willing to devote sufficient time to carrying out their duties and responsibilities effectively; devote the time and effort necessary to learn our business; and, represent the long-term interests of all shareholders.

The Board has determined that the Board as a whole must have the right diversity, mix of characteristics and skills for the optimal functioning of the Board in its oversight of our affairs. The Board believes it should be comprised of persons with skills in areas such as: finance; real estate; banking; strategic planning; human resources and diversity; leadership of business organizations; and legal matters. The Board may also consider in its assessment of the Board's diversity, in its broadest sense, reflecting, but not limited to, age, geography, gender and ethnicity.

In addition to the targeted skill areas, the Board looks for a strong record of achievement in key knowledge areas that it believes are critical for directors to add value to the Board, including:

- **Strategy**—knowledge of our business model, the formulation of corporate strategies, knowledge of key competitors and markets;

- **Leadership**—skills in coaching and working with senior executives and the ability to assist the Chief Executive Officer;

• **Organizational Issues**—understanding of strategy implementation, change management processes, group effectiveness and organizational design;

• **Relationships**—understanding how to interact with investors, accountants, attorneys, management companies, analysts, and communities in which we operate;

• **Functional**—understanding of finance matters, financial statements and auditing procedures, technical expertise, legal issues, information technology and marketing; and

• **Ethics**—the ability to identify and raise key ethical issues concerning our activities and those of senior management as they affect the business community and society.

### **Board of Directors Meetings, Committees of the Board of Directors, and Annual Meeting Attendance**

We do not currently have any standing committees of the Board. The full Board is responsible for performing the functions of: (i) the Audit Committee, (ii) the Compensation Committee and (iii) the Nominating Committee.

Our Bylaws provide that the number of Directors shall be fixed from time to time by the Board, but in no event shall be less than the minimum required by law. The Board should be large enough to maintain our required expertise but not too large so as not to function efficiently. Director nominees are recommended, reviewed and approved by the entire Board. The Board believes that this process is appropriate due to the relatively small number of directors on the Board and the opportunity to benefit from a variety of opinions and perspectives in determining director nominees by involving the full Board.

While the Board is solely responsible for the selection and nomination of directors, the Board may consider nominees recommended by stockholders as it deems appropriate. The Board evaluates each potential nominee in the same manner regardless of the source of the potential nominee's recommendation. Although we do not have a policy regarding diversity, the Board does take into consideration the value of diversity among Board members in background, experience, education and perspective in considering potential nominees for recommendation to the Board for selection. Stockholders who wish to recommend a nominee should send nominations to our Chief Executive Officer, Harmel S. Rayat, 9375 East Shea Blvd., Suite 107-A, , Scottsdale, AZ 85260, and include all information relating to such person that is required to be disclosed in solicitations of proxies for the election of directors. The recommendation must be accompanied by a written consent of the individual to stand for election if nominated by the Board and to serve if elected.

### **Directors' and Officers' Liability Insurance**

We currently maintain directors' and officers' liability insurance coverage.



## **Legal Proceedings**

None of our directors or officers are involved in any legal proceedings as described in Regulation S-K (§229.401(f)).

## **Compliance with Section 16(a) of the Exchange Act**

Because we do not have a class of equity securities registered pursuant to section 12 of the Exchange Act we are not required to make the disclosures required by Item 405 of Regulation S-K.

## **Code of Ethics**

We have adopted a Code of Ethics that applies to all our officers, directors and employees, including our Chief Executive Officer and Chief Financial Officer, which complies with the requirements of the Sarbanes-Oxley Act of 2002 and applicable FINRA listing standards. Accordingly, the Code of Ethics is designed to deter wrongdoing, and to promote, among other things, honest and ethical conduct, full, timely, accurate and clear public disclosures, compliance with all applicable laws, rules and regulations, the prompt internal reporting of violations of the Code of Ethics, and accountability. Our Code of Ethics is available on our website at <http://www.renovacareinc.com>. To access our Code of Ethics, click on “Investors”, and then click on “Investor Briefcase” and then click on “Code of Ethics”.

A copy of our Code of Ethics may be obtained at no charge by sending a written request to our Chief Executive Officer, Harmel S. Rayat, 9375 East Shea Blvd., Suite 107-A, Scottsdale, AZ 85260.

## **Corporate Governance**

We have adopted Corporate Governance Principles applicable to our Board. Our Corporate Governance Principles are available on our website at <http://www.renovacareinc.com>. To access our Corporate Governance Principles, click on “Investors”, and then click on “Investor Briefcase” and then click on “Corporate Governance Principles”.

## **Board Leadership Structure**

We currently have three executive officers and two directors. Our Board has reviewed our current Board leadership structure in light of the composition of the Board, our size, the nature of our business, the regulatory framework under which we operate, our stockholder base, our peer group and other relevant factors, and has determined that this structure is currently the most appropriate Board leadership structure for our company. Nevertheless, the Board intends to carefully evaluate from time to time to determine what the Board believes is best for us and our stockholders.

## **Board Role in Risk Oversight**

Risk is inherent in every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including strategic risks, enterprise risks, financial risks, and regulatory risks. While our management is responsible for day to day management of various risks we face, the Board, as a whole, is responsible for evaluating our exposure to risk and to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed. The Board reviews and discusses policies with respect to risk assessment and risk management. The Board also has oversight responsibility with respect to the integrity of our financial reporting process and systems of internal control regarding finance and accounting, as well as its financial statements.

## **Director Independence**

Our securities are not listed on a U.S. securities exchange and, therefore, are not subject to the corporate governance requirements of any such exchange, including those related to the independence of directors. However, at this time,

after considering all of the relevant facts and circumstances, the Board has determined that Dr. Kirkland is independent from our management and qualifies as an “**Independent Director**” under the standards of independence under the applicable FINRA listing standards. This means that, in the judgment of the Board, Dr. Kirkland (1) is not an officer or employee of the Company or its subsidiaries, or (2) has not had any direct or indirect relationship with the Company that would interfere with the exercise of his independent judgment in carrying out the responsibilities of a director. Upon our listing on any national securities exchange or any inter-dealer quotation system, we will elect such independent directors as is necessary under the rules of any such securities exchange.

### **Communications with the Board of Directors**

Stockholders who wish to communicate with the Board may do so by addressing their correspondence to the Board at RenovaCare, Inc. 9375 East Shea Blvd., Suite 107-A, Scottsdale, AZ 85260. The Board has approved a process pursuant to which the CEO reviews and forwards correspondence to the appropriate director or group of directors for response.

### **Item 11. Executive Compensation**

Our Board is responsible for establishing the compensation and benefits for our executive officers. The Board reviews the performance and total compensation package for our executive officers, and considers the modification of existing compensation and the adoption of new compensation plans. The board has not retained any compensation consultants.

The goals of our executive compensation program are to attract, motivate and retain individuals with the skills and qualities necessary to support and develop our business within the framework of our small size and available resources. We designed our executive compensation program to achieve the following objectives:

- attract and retain executives experienced in developing and delivering products such as our own;
- motivate and reward executives whose experience and skills are critical to our success; reward performance; and
- align the interests of our executive officers and stockholders by motivating executive officers to increase stockholder value.

The following table and descriptive materials set forth information concerning compensation earned for services rendered to us by: the President; the Chief Financial Officer (“CFO”); and the three other most highly-compensated executive officers other than the CEO and CFO who were serving as our executive officers during the last two fiscal years (“**Named Executive Officers**”).

Name and principal position	Year	Salary/	Bonus	Stock	Option	All other	Total
		consulting fee		awards	awards	compensation	
	December 31,	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Thomas Bold <sup>(1)</sup>	2018	100,000	—	—	—	—	100,000
former President and interim CFO	2017	100,000	—	—	248,700	—	348,700
Patsy Trisler <sup>(2)</sup>	2018	60,000	—	—	—	—	60,000
VP – Clinical & Regulatory	2017	60,000	—	—	—	—	60,000
Jatinder Bhogal <sup>(3)</sup>	2018	103,467	—	—	—	—	103,467
Chief Operating Officer	2017	81,600	—	—	—	—	81,600
Stephen Yan-Klassen <sup>(4)</sup>	2018	5,000	—	—	—	—	5,000
CFO	2017	—	—	—	—	—	—

<sup>(1)</sup> On December 1, 2013, the Company appointed Mr. Bold as our President & CEO. On October 8, 2016, Mr. Bold assumed the role of Chief Financial Officer commensurate with the resignation of Rhonda Rosen. On December 1, 2013 we entered into the Consulting Agreement with Mr. Bold. Pursuant to the terms of the Consulting Agreement, Mr. Bold is expected to serve on a part-time basis and will receive an annual fee of \$100,000, payable in 12 equal installments, which is prorated for any partial months during the term of the Consulting Agreement. In addition to Mr. Bold’s fee, he was issued a stock option to purchase up to 40,000 shares of common stock at an exercise price of \$0.75 per share, the closing price of our common stock as quoted on the OTCQB on November 29, 2013, a stock option to purchase up to 60,000 shares of common stock at an exercise price of \$1.91 per share, the closing price on March 15, 2016, and a stock option to purchase up to 75,000 shares of common stock at an exercise price of \$4.20 per share, the closing price on May 11, 2017. The options may be exercised on a “cashless basis” using the formula contained therein

and vest as follows: (a) 20,000 vested on December 1, 2014; (b) 20,000 vested on December 1, 2015; (c) 60,000 vested on March 16, 2016; (d) 37,500 vested on May 11, 2017; and (e) 37,500 vested on May 11, 2018. On March 30, 2019 Mr. Bold resigned as President.

<sup>(2)</sup> On April 1, 2014, the Company appointed Ms. Patsy Trisler as our Vice President – Clinical & Regulatory Affairs and entered into an at-will consulting agreement with Ms. Trisler pursuant to which we granted Ms. Trisler an option to purchase up to 50,000 shares of the Company’s common stock at a price of \$1.05 per share, the closing price of the Company’s common stock as quoted on the OTCQB on April 1, 2014 and receives an annual fee of \$60,000, payable in 12 equal installments. The options may be exercised on a “cashless basis” using the formula contained therein and, subject to Ms. Trisler’s continued service, the options vest(ed) as follows, 10,000 on: (a) April 1, 2015; (b) April 1, 2016; (c) April 1, 2017; (d) April 1, 2018; and (e) April 1, 2019.

(1) On June 11, 2018, the Company appointed Mr. Jatinder S. Bhogal as Chief Operating Officer.

(4) On October 22, 2018, the Company appointed Mr. Stephen Yan-Klassen as Chief Financial Officer.

## Outstanding Equity Awards at Fiscal-Year End

The following table sets forth information regarding equity awards that have been previously awarded to each of the Named Executives and which remained outstanding as of December 31, 2018.

### Option Awards

Name	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Option Exercise Price (\$)	Option Expiration Date
Thomas Bold	60,000	-	1.91	March 15, 2026
(former President)	37,500	37,500	4.20	May 11, 2028
Patsy Trisler	30,000	20,000	1.05	March 31, 2025

### Long-Term Incentive Plans

On June 20, 2013, our Board adopted our 2013 Long-Term Incentive Plan and on November 15, 2013, a stockholder owning a majority of our issued and outstanding stock approved adoption to the 2013 Plan. Pursuant to the terms of the 2013 Plan, an aggregate of 20,000,000 shares of our common stock are reserved for issuance to our officers, directors, employees and consultants in order to attract and hire key technical personnel and management. Options granted to employees under the 2013 Plan, including directors and officers who are employees, may be incentive stock options or non-qualified stock options; options granted to others under the Incentive Plan are limited to non-qualified stock options. As of December 31, 2018, there were 19,338,572 shares available for grant.

The 2013 Plan is administered by the Board or a committee designated by the Board. Subject to the provisions of the 2013 Plan, the Board has the authority to determine the officers, employees and consultants to whom options will be granted, the number of shares covered by each option, vesting rights and the terms and conditions of each option that is granted to them; however, no person may be granted in any of the Company's fiscal year, options to purchase more than 2,000,000 shares under the 2013 Plan, and the aggregate fair market value (determined at the time the option is

granted) of the shares with respect to which incentive stock options are exercisable for the first time by an optionee during any calendar year cannot exceed \$100,000. Options granted pursuant to the 2013 Plan are exercisable no later than ten years after the date of grant.

The exercise price per share of common stock for options granted under the 2013 Plan will be the fair market value of the Company's common stock on the date of grant, using the closing price of the Company's common stock on the last trading day prior to the date of grant, except for incentive stock options granted to a holder of ten percent or more of the Company's common stock, for whom the exercise price per share will not be less than 110% of the fair market value. No option can be granted under the 2013 Plan after June 20, 2023.

There are no arrangements or plans in which we provide pension, retirement or similar benefits for directors or executive officers, except that our directors and executive officers may receive stock options at the discretion of our Board. We do not have any material bonus or profit sharing plans pursuant to which cash or non-cash compensation is or may be paid to our directors or executive officers, except that stock options may be granted at the discretion of our Board.

#### **Employment Contracts**

On March 30, 2019, Mr. Thomas Bold and the Company entered into a termination agreement (the "Agreement") pursuant to which Mr. Bold resigned his position as (i) the Company's President and (ii) a member of the Company's Board of Directors.

We have no plans or arrangements in respect of remuneration received or that may be received by our executive officers to compensate such officers in the event of termination of employment (as a result of resignation, retirement, change of control) or a change of responsibilities following a change of control, where the value of such compensation exceeds \$60,000 per executive officer.

## Change of Control Agreements

There are no understandings or agreements known by management at this time which would result in a change in control. We do not have any change of control or severance agreements with any of its executive officers or directors. In the event of the termination of employment of the Named Executive Officers any and all unexercised stock options shall expire and no longer be exercisable after a specified time following the date of the termination.

## Compensation of Directors

Our Board determines the non-employee directors' compensation for serving on the Board and its committees. In establishing director compensation, the Board is guided by the following goals:

- compensation should consist of a combination of cash and equity awards that are designed to fairly pay the directors for work required for a company of our size and scope;
- compensation should align the directors' interests with the long-term interests of stockholders; and
- compensation should assist with attracting and retaining qualified directors.

We reimburse our directors for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our Board. We do not pay director compensation to directors who are also employees. All non-employee directors are paid a director's fee. Our Board may award special remuneration to any director undertaking any special services on our behalf other than services ordinarily required of a director. Effective as of August 1, 2013, we agreed to pay non-employee directors an annual fee of \$6,000 for their services, paid quarterly. Directors are entitled to participate in, and have been issued options under, our 2013 Long-Term Stock Incentive Plan.

The following table reports all compensation we paid to non-employee directors during the last two fiscal years.

Name	Fees earned or		Option awards Aggregate Grant Date Fair Value (\$) <sup>(2)</sup>	Total (\$)
	paid in cash <sup>(1)</sup> (\$)			
Joseph Sierchio <sup>(3)</sup>	2018	3,000	-	3,000
	2017	6,000	248,700	254,700
Kenneth Kirkland	2018	6,000	-	6,000
	2017	6,000	248,700	254,700

<sup>(1)</sup> The amounts in this column represent the quarterly compensation.



(2) The amounts in this column represent the total fair value assigned to options granted in 2018 and 2017 to Messrs. Kirkland and Sierchio.

(3) The amounts set forth in this table do not include fees paid to legal firms associated with Mr. Sierchio.

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

<b>Name and Address of Beneficial Owner <sup>(1)</sup></b>	<b>Number of shares Beneficially Owned <sup>(2)</sup></b>	<b>% of Class Owned <sup>(2)</sup></b>
<b><u>Directors and Officers</u></b>		
Thomas Bold, former President <sup>(3)</sup>	163,379	*
Patsy Trisler <sup>(4)</sup>	40,000	*
Kenneth Kirkland <sup>(5)</sup>	145,675	*
		*
All Directors and Officers as a Group (4 people)	349,054	

**5% Shareholders**

Kalen Capital Corporation <sup>(7)</sup>

The Kalen Capital Building

688 West Hastings St. 53,872,037 75.44

Suite 700

Vancouver, BC V6B 1P1

Jatinder Singh Bhogal <sup>(8)</sup>

1962 Knox Road 5,029,425 5.96

Vancouver, BC V6T1S6

\* less than 1%

- (1) Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Each of the beneficial owners listed above has direct ownership of and sole voting power and investment power with respect to the shares of our common stock and except as indicated the address of each beneficial owner is 9375 East Shea Blvd., Suite 107-A, Scottsdale, AZ 85260.
- (2) Calculated pursuant to Rule 13d-3(d) of the Exchange Act. Beneficial ownership is calculated based on 76,840,522 shares of common stock issued and outstanding on a fully diluted basis as of February 23, 2018. Under Rule 13d-3(d) of the Exchange Act, shares not outstanding which are subject to options, warrants, rights or conversion privileges exercisable within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person, but are not deemed outstanding for the purpose of calculating the percentage owned by each other person listed.
- (3) Consists of 5,000 shares of common stock and a Series D Warrant to purchase 5,000 shares of common stock purchased by Mr. Bold in a private placement we conducted in 2015; 78,379 shares received upon the cashless exercise of 100,000 options and vested options to purchase up to 75,000 shares of common stock.
- (4) Ms. Trisler was appointed as our Vice President – Clinical & Regulatory Affairs on April 1, 2014; as part of her appointment she was granted a stock option to purchase up to 50,000 shares of common stock. The option vests in five equal installments of 10,000 on April 1, 2015-2019, subject to her continued service with the Company.
- (5) Consists of 70,675 shares issued upon the cashless exercise of options and vested options to purchase 75,000 shares of common stock.
- (6) Includes (a) 550,000 shares of common stock owned by Mr. Sierchio; (b) 75,199 shares of common stock issued upon the cashless exercise of vested stock options; (c) 10,000 shares of common stock purchased pursuant to the October 2017 private placement; (d) 4,899 shares of common stock issued upon the cashless exercise of a Series F Warrant; and (e) 7,418 shares of common stock issued upon the cashless exercise of a Series H Warrant. Does not include 37,500 shares issuable upon exercise of issued warrants scheduled to vest on May 11, 2018.
- (7) Kalen Capital Corporation is a private Alberta corporation wholly owned by Mr. Harmel Rayat. In such capacity, Mr. Rayat may be deemed to have beneficial ownership of these shares. Consists of (a) 49,449,037 shares of common stock; (b) a Series D Warrant to purchase up to 800,000 shares of common stock at an exercise price of \$1.10 per share through June 5, 2020; (c) a Series E Warrant to purchase up to 584,416 shares of common stock at an exercise price of the lesser of \$1.54, or a 20% discount to the average closing price of our common stock for the five days prior to the date on which the Series E Warrant is exercised, through September 9, 2021; (d) a Series G Warrant to purchase up to 410,000 shares of common stock at an exercise price of \$2.68 per share through July 21, 2022; (e) a Series I Warrant to purchase up to 10,335,000 shares of common stock at an exercise price of \$2.00 per share through

November 26, 2025 Each of KCC's warrants may be exercised on a cashless basis other than the Series I Warrant. For tax purposes, a portion of the debt and equity securities of owned by KCC have been assigned to Kalen Capital Holdings, LLC, its wholly owned subsidiary.

<sup>(8)</sup> Includes (a) 2,529,425 shares of common stock held by Boston Financial Group, Ltd., and (b) 2,500,000 shares of common stock held by 1420527 Alberta Ltd., Mr. Bhogal is the sole principal of each entity and in such capacity, Mr. Bhogal may be deemed to have beneficial ownership of these shares. Does not include 30,800 shares of stock owned by Mr. Bhogal's wife, of which he disclaims beneficial ownership. Mr. Bhogal is the President and sole shareholder of Vector Asset Management, Inc., which provides us with consulting services.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

Our proposed business raises potential conflicts of interests between certain of our officers and directors and us. Certain of our directors may become directors of other biotechnology companies and, to the extent that such other companies may participate in ventures in which we may participate, our directors may have a conflict of interest in negotiating and concluding terms regarding the extent of such participation. In the event that such a conflict of interest arises at a meeting of our directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In appropriate cases, we will establish a special committee of independent directors to review a matter in which several directors, or management, may have a conflict.

In determining whether we will acquire a new technology or participate in a research and development program, the directors will primarily consider the potential benefits to us, the degree of risk to which we may be exposed and its financial position at that time. Other than as indicated, we have no other procedures or mechanisms to deal with conflicts of interest. We are not aware of the existence of any conflict of interest as described herein.

## **Transactions with Related Persons**

We do not have a formal written policy for the review and approval of transactions with related parties. However, our Code of Ethics and Corporate Governance Principles require actual or potential conflict of interest to be reported to the Board. Our employees are expected to disclose personal interests that may conflict with ours and they may not engage in personal activities that conflict with their responsibilities and obligations to us. Periodically, we inquire as to whether or not any of our directors have entered into any transactions, arrangements or relationships that constitute related party transactions. If any actual or potential conflict of interest is reported, our entire Board and outside legal counsel review the transaction and relationship disclosed and the Board makes a formal determination regarding each director's independence. If the transaction is deemed to present a conflict of interest, the Board will determine the appropriate action to be taken.

## **Review, Approval or Ratification of Transactions with Related Persons**

Our unwritten policy with regard to transactions with related persons is that all material transactions are to be reviewed by the entire Board for any possible conflicts of interest. In the event of a potential conflict of interest, the Board will generally evaluate the transaction in terms of the following standards: (i) the benefits to us; (ii) the impact on a director's independence in the event the related person is a director, an immediate family member of a director or an entity in which a director is a partner, shareholder or executive officer; (iii) the availability of other sources for comparable products or services; (iv) the terms and conditions of the transaction; and (v) the terms available to unrelated parties or the employees generally. The Board will then document its findings and conclusion in written minutes.

## **Transactions with Related Persons**

The Board is responsible for review, approval, or ratification of "related-person transactions" involving the Company and related persons. Under SEC rules (Section 404 (a) of Regulation S-K), a related person is a director, officer, nominee for director, or 10% stockholder of the company since the beginning of the previous fiscal year, and their immediate family members. We are required to report any transaction or series of transactions in which we or a subsidiary is a participant, the amount involved exceeds \$120,000, and a related person has a direct or indirect material interest.

The Board has determined that, barring additional facts or circumstances, a related person does not have a direct or indirect material interest in the following categories of transactions:

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any transaction with another company for which a related person's only relationship is as an employee (other than an executive officer), director, or beneficial owner of less than 10% of that company's shares, if the amount involved does not exceed the greater of \$1 million or 2% of that company's total annual revenue;

- compensation to executive officers determined by the Board;
- compensation to directors determined by the Board;
- transactions in which all security holders receive proportional benefits; and
- banking-related services involving a bank depository of funds, transfer agent, registrar, trustee under a trust indenture, or similar service.

The Board reviews transactions involving related persons who are not included in one of the above categories and makes a determination whether the related person has a material interest in a transaction and may approve, ratify, rescind, or take other action with respect to the transaction in its discretion. The Board reviews all material facts related to the transaction and takes into account, among other factors it deems appropriate, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances; the extent of the related person's interest in the transaction; and, if applicable, the availability of other sources of comparable products or services.

The following are related party transactions for the fiscal years ended December 31, 2018 and 2017:

The law firm of Satterlee Stephens LLP (“Satterlee”), of which Joseph Sierchio, one of the Company’s former directors, is a partner, provides counsel to the Company. Mr. Sierchio is the Company’s primary attorney. During the years ended December 31, 2018 and 2017, the Company recognized \$577,718 and \$277,933 of fees for legal services billed by firms associated with Mr. Sierchio. At December 31, 2018 and 2017, the Company owed Satterlee \$171,828 and \$30,000 which is included in accounts payable. Mr. Sierchio continues to serve as a director of the Company. Effective June 30, 2018 Mr. Sierchio resigned as a director of the Company.

In connection with the Company’s anticipated FDA and other regulatory filings, the Company engaged StemCell Systems to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$80,229 and \$219,806 during the years ended December 31, 2018 and 2017, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

On July 21, 2017, the Company entered into the July 2017 Private Placement with KCC for the sale of 410,000 units at a price of \$2.44 per unit for \$1,000,400 in aggregate proceeds. Each unit consisted of one share of common stock and one Series G Warrant to purchase one (1) share of common stock at an exercise price of \$2.68 per share through July 21, 2022. The warrants may be exercised on a cashless basis. See “Note 6. Common Stock and Warrants” in the notes to the consolidated financial statements included in this Form 10-K for further discussion.

On February 23, 2017, the Company entered into two of the February 2017 Loan Agreements with Sierchio and KCC pursuant to which Sierchio loaned the Company \$25,000 and KCC loaned \$395,000 at an interest rate of 7%. On October 19, 2017, the Company repaid the Sierchio in full, including \$25,000 of note principal and \$1,149 of accrued interest. The remaining note with KCC was amended on January 29, 2018 to extend the maturity date to December 31, 2019. The February 2017 Note could be converted into shares of the Company’s common stock at conversion rate equal to the lesser of: (i) \$3.45; or (ii) a 20% discount to the average closing price of the Company’s common stock for the five days prior to the date on which the Holder(s) elect to convert the February 2017 Note(s), subject to a floor price of \$2.76. Per the February 2017 Loan Agreement, the Company issued Sierchio, and KCC a Series F Warrant to purchase up to 7,246 shares and 114,493 shares, respectively, of the Company’s common stock. See “Note 5. Debt” in the notes to the consolidated financial statements included in this Form 10-K for further discussion. On November 26, 2018 the February 2017 Note was further amended and settled pursuant to a private placement agreement. See “Note 6. Common Stock and Warrants” in the notes to the consolidated financial statements included in this Form 10-K for further discussion.

On September 9, 2016, the Company entered into the Loan Agreement with KCC whereby KCC loaned the Company \$700,000 at an interest rate of 7%. The Note was amended on January 29, 2018 to extend the maturity date to December 31, 2019. As of September 9, 2017, the Note, can be converted into shares of the Company’s common stock at conversion rate equal to the lesser of: (i) \$1.54; or (ii) a 20% discount to the average closing price of the Company’s common stock for the five days prior to the date on which KCC elects to convert the Note, subject to a floor price of

\$1.23. Per the Loan Agreement, the Company issued KCC a Series E Warrant to purchase up to 584,416 shares of the Company's common stock. See "Note 5. Debt" in the notes to the consolidated financial statements included in this Form 10-K for further discussion. On November 26, 2018 the Note was further amended and settled pursuant to a private placement agreement. See "Note 6. Common Stock and Warrants" in the notes to the consolidated financial statements included in this Form 10-K for further discussion.

For related party transactions that do not exceed \$120,000 please see "Note 9. Related Party Transactions" in the notes to the consolidated financial statements included in this Form 10-K for further discussion.

## Item 14. Principal Accounting Fees and Services

### INDEPENDENT PUBLIC ACCOUNTANTS

The Board has appointed Marcum LLP (“Marcum”) as the company’s independent registered public accounting firm for the fiscal year ending December 31, 2018. Marcum has served as the company’s registered public accountant since October 2018.

At a meeting held on October 22, 2018, the Board approved the dismissal of Peterson Sullivan, LLP (“Peterson”) as our independent registered public accounting firm, effective October 22, 2018, and the appointment of Marcum as our independent registered public accounting firm, effective October 22, 2018, to perform independent audit services for the fiscal year ending December 31, 2018. The reports of Peterson on our consolidated financial statements for the fiscal years ended December 31, 2017 and 2016 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles. During the fiscal years ended December 31, 2017 and 2016, and the subsequent interim period through October 22, 2018, there were no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) with Peterson on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreement if not resolved to the satisfaction of Peterson would have caused Peterson to make reference thereto in its reports.

During the fiscal years ended December 31, 2017 and 2016, and the subsequent interim period through September 30, 2018, neither we nor anyone on our behalf consulted with Marcum regarding (i) either: the application of accounting principles to a specific transaction, either completed or proposed; or the type of audit opinion that might be rendered on our financial statements, and either a written report or oral advice was provided to us that Marcum concluded was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue, or (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K or any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

Our Board, in its discretion, may direct the appointment of different public accountants at any time during the year, if the Board believes that a change would be in the best interests of the stockholders. The Board has considered the audit fees, audit-related fees, tax fees and other fees paid to our independent registered public accounting firm, as disclosed below, and has determined that the payment of such fees is compatible with maintaining the independence of the accountants.

We do not currently have an audit committee.





**PRINCIPAL ACCOUNTING FEES AND SERVICES**

The following table presents aggregate fees for professional services rendered by our auditors during the years ended December 31, 2018 and 2017:

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
Audit fees	\$58,500	\$37,382
Audit-related fees	23,600	18,292
Tax fees	3,200	4,200
Total fees	\$85,300	\$59,874

**Audit Fees**

Audit fees for the years ended December 31, 2018 and 2017, totaled \$45,000 and \$37,382, respectively, and consist of the aggregate fees billed by Marcum LLP (2017: Peterson Sullivan) for the audit of the financial statements included in our Annual Report on Form 10-K and review of interim financial statements included in the quarterly reports on Form 10-Q during the years ended December 31, 2018 and 2017.

**Audit-Related Fees**

Audit-related fees for the years ended December 31, 2018 and 2017, totaled \$23,600 and \$18,292, respectively, and consist of the aggregate fees billed by Peterson Sullivan for discussions and research related to financial reporting inquiries and the review and providing of consents for our registration statement on Form S-1, Form S-3 and Form S-8 and amendments thereto that were filed with the SEC.

**Tax Fees**

Tax fees for the years ended December 31, 2018 and 2017, totaled \$3,200 and \$4,200, respectively, and consist of the aggregate fees billed by Peterson Sullivan for professional services rendered for tax compliance, tax advice and tax planning.

**All Other Fees**

There were no fees billed to us for products and services provided by Marcum LLP (2017: Peterson Sullivan LLP), other than reported under Audit Fees, Audit-Related Fees and Tax Fees for the years ended December 31, 2018 and 2017.

The Board feels that the services rendered by Marcum LLP and Peterson Sullivan were compatible with maintaining the principal accountant's independence.

## **PART IV**

### **Item 15. Exhibits, Financial Statement Schedules**

The following documents are filed as a part of this Form 10-K.

#### **1. Financial Statements**

The following financial statements, notes related thereto and reports of independent auditors are included in Part II, Item 8 of this Form 10-K:

- Report of Independent Registered Public Accounting Firm
- Balance Sheets as of December 31, 2018 and 2017
- Statements of Operations for the years ended December 31, 2018 and 2017
- Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017
- Statements of Cash Flows for the years ended December 31, 2018 and 2017
- Notes to Financial Statements

#### **2. Financial Statement Schedules**

Financial statement schedules are omitted because they are not required or are not applicable, or the required information is provided in the consolidated financial statements or notes described in Item 15(a)(1) above.

#### **3. Exhibits**

The Exhibits listed in the Exhibit Index, which appears immediately following the signature page, are incorporated herein by reference, and are filed as part of this Form 10-K.

**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.

**RENOVACARE, INC.**

Date: April 12, 2019 By: /s/ Harmel S. Rayat  
Name: Harmel S. Rayat  
Title: Chief Executive Officer, (Principal Executive Officer,)

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Patsy Trisler</u> Patsy Trisler	Vice-President - Clinical & Regulatory Affairs	April 12, 2019
<u>/s/ Kenneth Kirkland</u> Kenneth Kirkland	Director	April 12, 2019
<u>/s/ Stephen Yan-Klassen</u> Stephen Yan-Klassen	Chief Financial Officer	April 12, 2019

**Exhibit Index**

<b>Exhibit #</b>	<b>Description of Exhibit</b>
3.1	Articles of Incorporation, as amended, of the Company, incorporated by reference and included in the Company's Registration Statement on Form 10-SB 12g filed on May 11, 1999, SEC file number 000-30156-99616992.
3.2	<u>Articles of Incorporation, as amended, of the Company incorporated by reference and included in the Company's Form 8-K filed on January 10, 2011, SEC file number 000-30156-11520181.</u>
3.3	<u>Articles of Incorporation, as amended, of the Company incorporated by reference and included in the Company's Form 8-K filed on January 10, 2014, SEC file number 000-30156-14521612.</u>
3.4	By-laws of the Company incorporated by reference and included in the Company's Registration Statement on Form 10-SB 12g filed on May 11, 1999, SEC file number 000-30156-99616992.
4.1†	<u>Form of Series A Common Stock Purchase Warrant dated July 12, 2013, incorporated by reference and included in the Company's Form 8-K filed on July 18, 2013, as amended on November 21, 2013 and December 27, 2013, SEC file number 000-30156-131300357.</u>
4.2	<u>Form of Stock Purchase Warrant, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657.</u>
4.3	<u>Registration Rights Agreement dated November 29, 2013, between Kalen Capital Corporation and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657.</u>
4.4	<u>Form of Series D Common Stock Purchase Warrant, incorporated by reference and included in the Company's Form 8-K filed on June 10, 2015, SEC file number 000-30156-15981571.</u>
4.5	<u>Convertible Promissory Note dated September 9, 2016, between Kalen Capital Corporation and the Company; incorporated by reference and included in the Company's Form 8-K filed on September 16, 2016, SEC file number 000-30156-161888353</u>
4.6	<u>Series E Stock Purchase Warrant dated September 9, 2016; incorporated by reference and included in the Company's Form 8-K filed on September 16, 2016, SEC file number 000-30156-161888353</u>
4.7	<u>Form of Convertible Promissory Note dated February 23, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 1, 2017, SEC file number 000-30156-17654590</u>
4.8	<u>Form of Series F Stock Purchase Warrant dated February 23, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 1, 2017, SEC file number 000-30156-17654590</u>
4.9	<u>Convertible Promissory Note dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968</u>
4.10	<u>Form of Series G Stock Purchase Warrant dated July 21, 2017; incorporated by reference and included in the Company's Form 8-K filed on July 24, 2017, SEC file number 000-30156-17978114</u>
4.11	<u>Form of Series H Stock Purchase Warrant dated October 16, 2017; incorporated by reference and included in the Company's Form 8-K filed on October 18, 2017, SEC file number 000-30156-171141509</u>
4.11	Form of Subscription Agreement dated July 21, 2017; incorporated by reference and included in the Company's Form 8-K filed on July 24, 2017, SEC file number 000-30156-17978114
4.12	<u>Form of Securities Purchase Agreement dated October 16, 2017; incorporated by reference and included in the Company's Form 8-K filed on October 18, 2017, SEC file number 000-30156-171141509</u>
10.1	<u>Employment Agreement dated June 20, 2013, between Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156-131259657</u>
10.2	<u>Asset Purchase Agreement dated as of June 21, 2013, between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on July 18, 2013, as amended on November 21, 2013 and December 27, 2013, SEC file number 000-30156-131300357</u>
10.3§	

Form of Stock Option Agreement, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156-131259657.

10.4 Finder's Agreement dated August 13, 2013, between Vector Asset Management, Inc. and the Company, incorporated by reference and included in the Company's Form 10-Q filed on August 14, 2013, SEC file number 000-30156-13109753

10.5 At-Will Executive Services Agreement dated October 1, 2013, between Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 10-Q filed on November 14, 2013, SEC file number 000- 30156-13129717

- 10.6 Subscription Agreement for 3,500,000 units dated November 29, 2013, between Kalen Capital Corporation and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657
- 10.7 At-Will Consulting Agreement effective as of December 1, 2013, between Thomas Bold and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156- 131259657
- 10.8 Stock Purchase Agreement dated December 31, 2013, between Duke Mountain Resources, Inc., Fostung Resources Ltd. and the Company, incorporated by reference and included in the Company's Form 8-K filed on January 7, 2014, SEC file number 000-30156-14513586
- 10.9 At-Will Consulting Agreement effective as of April 1, 2014, between Patsy Trisler and the Company, incorporated by reference and included in the Company's Form 8-K filed on April 7, 2014, SEC file number 000-30156- 14838542
- 10.10 Stock Option Agreement dated April 1, 2014, between Patsy Trisler and the Company, incorporated by reference and included in the Company's Form 8-K filed on April 7, 2014, SEC file number 000-30156-14838542
- 10.11 Stock Option Agreements dated August 14, 2014, between Kenneth Kirkland, Joseph Sierchio, Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 8-K filed on August 20, 2014, SEC file number 000-30156-141054256
- 10.12 Post-Closing Amendment to Asset Purchase Agreement between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on September 15, 2014, SEC file number 000- 30156-141102510
- 10.13 Option Agreement dated May 1, 2015 between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on May 5, 2015; SEC file number 000-30156-158333270.
- 10.14 Form of Subscription Agreement, incorporated by reference and included in the Company's Form 8-K filed on June 10, 2015, SEC file number 000-30156-15923671.
- 10.15 Loan Agreement between Kalen Capital Corporation and the Company; incorporated by reference and included in the Company's Form 8-K filed on September 16, 2016, SEC file number 000-30156-161888353
- 10.16 Form of Loan Agreement dated February 23, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 1, 2017, SEC file number 000-30156-17654590
- 10.17 Loan Agreement dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968
- 10.18 Amendment to Loan Agreement between Joseph Sierchio and the Company dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968
- 10.19 Amendment to Loan Agreement between Kalen Capital Corporation and the Company dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968
- 10.20 Form of Subscription Agreement dated July 21, 2017; incorporated by reference and included in the Company's Form 8-K filed on July 24, 2017, SEC file number 000-30156-17978114
- 10.21 Form of Securities Purchase Agreement dated October 16, 2017; incorporated by reference and included in the Company's Form 8-K filed on October 18, 2017, SEC file number 000-30156-171141509
- 10.22\* January 29, 2018 Amendment to Convertible Promissory Note dated February 23, 2017
- 10.23\* January 29, 2018 Amendment to Convertible Promissory Note dated September 9, 2016
- 10.24\* Corporate Research Agreement dated August 1, 2017
- 10.25\* Amendment to Consulting Agreement dated May 1, 2016 between Vector Asset Management, Inc. and the Company
- 10.26 January 29, 2018 First Amendment to Loan Agreement dated February 23, 2017
- 10.27 January 29, 2018 First Amendment to Loan Agreement dated September 9, 2016



- 10.28 Executive Consulting Agreement dated June 22, 2018, incorporated by reference and included in the Company's Form 8-K filed on June 25, 2018, SEC file number 000-30156-18916934

- 14.1 Code of Ethics, incorporated by reference and included in the Company's Form 10-K file on April 15, 2009, SEC file number 000-30156-09750383.
  - 23.1 Consent of Peterson Sullivan\*
  - 23.2 Consent of Marcum LLP
  - 31.1 Certification of the Chief Executive Officer pursuant to Rule 13a-14(a).\*
  - 31.2 Certification of the Chief Financial Officer pursuant to Rule 13a-14(a).\*\*
  - 32.1 Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002\*
  - 32.2 Certification by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*
  - 99.1 2013 Long-Term Incentive Plan, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156-13933444.
- 101.INS XBRL Instance Document\*\*  
101.SCH XBRL Taxonomy Extension - Schema Document\*\*  
101.CAL XBRL Taxonomy Extension - Calculation Linkbase Document\*\*  
101.DEF XBRL Taxonomy Extension - Definition Linkbase Document\*\*  
101.LAB XBRL Taxonomy Extension - Label Linkbase Document\*\*  
101.PRE XBRL Taxonomy Extension - Presentation Linkbase Document\*\*

\*Filed herewith.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and the omitted material have been separately filed with the Securities and Exchange Commission.

§ Indicates a management contract or compensatory plan or arrangement.

\*\* Furnished herewith. XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.