

RenovaCare, Inc.
Form 10-K
March 28, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended **December 31, 2016**

- o **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
(State or other jurisdiction of
incorporation)

98-0170247
(I.R.S. Employer Identification No.)

430 Park Avenue
Suite 702

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New York, NY 10022

(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

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. Yes No

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

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| | | | |
|-------------------------|-----------------------|---------------------------|----------------------------------|
| Large accelerated filer | <input type="radio"/> | Accelerated filer | <input type="radio"/> |
| Non-accelerated filer | <input type="radio"/> | Smaller reporting company | <input checked="" type="radio"/> |

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 29, 2016, as reported on the OTCQB was \$33,305,880. 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 March 27, 2017, there were 74,650,675 shares of the registrant's common stock outstanding.

Documents incorporated by reference: None.

RENOVACARE, INC.

FORM 10-K

For The Fiscal Year Ended December 31, 2016

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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.

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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.

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) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

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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 74,650,675 shares are outstanding as of March 10, 2017, 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 430 Park Avenue, Suite 702, New York, NY 10022. 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, 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, we, through our wholly owned subsidiary, RenovaCare Sciences Corp., completed the acquisition of our flagship technologies (collectively, the “**CellMist™ System**”) along with the associated United States patent applications and two foreign patents, the first of which expires on August 22, 2027 and the second of which expires on April 26, 2031. One of the two US patent applications was granted to us on November 29, 2016 (Patent No.: US 9,505,000) and expires on or about March 3, 2035. 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. Based on these technologies we have recently filed two additional patent applications, one with the United States Patent and

Trademark Office titled “Modular Device for Cell Spraying,” and one with the European Patent Office titled “Disposable Apparatus and Device with Unsterile Reusable Apparatus for Sterile Application of a Liquid.” We effected the acquisition of the CellMist™ System through an asset purchase agreement with Dr. Jorg Gerlach, MD, PhD (the “APA”). Pursuant to the terms of the APA, as amended on September 9, 2014, we paid Dr. Gerlach an initial sum of \$100,000 and are obligated to pay him an additional \$300,000 in four installments: (a) \$100,000 on December 31, 2014; (b) \$50,000 on December 31, 2015; (c) \$50,000 on December 31, 2016; and (d) \$100,000 on December 31, 2017. Additionally, we issued to Dr. Gerlach a Series A Warrant allowing him to purchase up to 1,200,000 shares of our common stock at a purchase price of \$0.35 per share through July 12, 2019; the warrant vests in five equal annual installments.

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, we believe 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, since the ratio between the size of the wound area and the size of the donor site is quite low, i.e. the size of the skin removed must be substantially equal in size to the size of the damaged skin, the mesh-grafting approach is in many cases limited. Donor and injury sites can take weeks to heal, requiring expensive hospital stays, ongoing wound dressing management, and ever-changing anti-infection strategies. We are currently evaluating the efficacy and potential of our SkinGun™, in combination with our CellMist™ Solution, in the treatment of tissue that has been subject to severe trauma such as second and third degree burns. In small scale clinical trials, the CellMist™ System has shown the ability to regenerate a more natural and thicker skin. The CellMist™ System utilizes the patient’s own skin stem cells and is able to address much larger treatment areas and at the same time reduce the size of the donor site. Furthermore, we believe the CellMist™ System enables the effective treatment of other skin disorders with minimal scarring compared to skin grafting.

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In a clinical study of 19 patients with deep dermal wound burns to the face and neck conducted in Berlin, Germany prior to our purchase of the CellMist™ System, researchers stated that, “careful surgical debridement and consecutive application of CEA [cultured epithelial auto graft] suspensions using a spray technique results in excellent cosmetic outcomes compared with any other method.” The same researchers concluded that, “We refuse to perform a prospective randomized study with groups in which traditional skin grafting and/or wound healing are still applied for the therapy for deep dermal burns due to the excellent results in our study. ***The method of CEA spray application has become our standard of care for these indications. The faster wound closure, the promotion of spontaneous wound healing by keratinocyte application, as well as the preservation of donor sites are further advantages of the method.***” (Hartmann MD, Bernd, et al, “Sprayed Cultured Epithelial Autografts for Deep Dermal Burns of the Face and Neck” *Annals of Plastic Surgery*, 58.1(2007): 70-73. Print. ***emphasis added***). The CEA spray application used by the researchers in the publication refers to earlier iterations of what is now CellMist™ System. Dr. Gerlach, from whom we purchased the CellMist™ System, assisted in the study.

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.

Strategy

Our ultimate goal is to leverage the potential of our CellMist™ System 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 efficacy for treating wounds and burns;
- formalizing collaborations with universities and scientific partners;
- creating a network of clinical and research partners; and
- achieving Food and Drug Administration (the "FDA") and other regulatory approval.

Additionally, we will likely be required 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 raise such capital on acceptable terms, if at all.

Governmental Regulations

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 likely 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, and 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. We may be required to file for premarket approval (“**PMA**”) for the SkinGun™ 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.

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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 United States, 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.

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International Regulation

The regulation of any potential product candidates we may produce outside of the United States varies by country. Certain countries regulate human tissue products as a pharmaceutical 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 pharmaceutical 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.; Acelity L.P. Inc.; Fibrocell Science, Inc.; Shire Plc and Organogenesis, Inc.

Many of our competitors are large, well-established pharmaceutical, chemical, cosmetic or health care 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.

Strategy

Our ultimate goal is to leverage the potential of our CellMist™ System 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 efficacy for treating wounds and burns;

Additionally, we will likely be required 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 raise 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 three part-time contractors: Mr. Thomas Bold, President and Chief Executive Officer and Interim Chief Financial Officer; Ms. Patsy Trisler, Vice-President Clinical & Regulatory Affairs; and Dr. Roger Esteban-Vives, Director of Cell Sciences.

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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 430 Park Avenue, Suite 702, New York, NY 10022 and they are provided to us free of charge by one of our directors. We also have a lease agreement for an office in Pittsburgh, PA where our full time employee is based.

ITEM 3. LEGAL PROCEEDINGS

We are currently not a party to any material pending legal proceedings or government actions, including any bankruptcy, receivership, or similar proceedings. In addition, management is not aware of any known litigation or liabilities involving the operators of our properties that could affect our operations. Should any liabilities incur in the future, they will be accrued based on management's best estimate of the potential loss. As such, there is no adverse effect on our financial position, results of operations or cash flow at this time. Furthermore, we do not believe that there are any proceedings to which any of our directors, officers, or affiliates, any owner of record of the beneficially or more than five percent of our common stock, or any associate of any such director, officer, affiliate, or security

holder is a party adverse or has a material interest adverse to us.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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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.

| | | 1st | | 2nd | | 3rd | | 4th |
|-------------|----------------|-----------------------|----------------|-----------------------|----------------|-----------------------|----------------|-----------------------|
| | Quarter | | Quarter | | Quarter | | Quarter | |
| 2016 – High | \$ | 2.35 | \$ | 2.58 | \$ | 2.48 | \$ | 2.81 |
| 2016 – Low | \$ | 0.96 | \$ | 1.96 | \$ | 1.25 | \$ | 0.88 |
| 2015 – High | \$ | 1.50 | \$ | 1.45 | \$ | 2.26 | \$ | 2.18 |
| 2015 – Low | \$ | 0.81 | \$ | 1.25 | \$ | 1.26 | \$ | 1.50 |

The closing price of our common stock on March 20, 2017, was \$3.67. As of March 20, 2017, there were approximately 357 stockholders of record (this number does not include stockholders who hold their stock through brokers, banks and other nominees).

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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. Our stock is currently a “penny stock.” 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 to 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 74,650,675 shares of our common stock issued and outstanding at March 10, 2017, of which 50,434,437 shares are deemed “restricted 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.

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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

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 Year Ended December 31, 2016 versus December 31, 2015

| | Year Ended December 31, | | Increase / | Percentage |
|----------------------------|-------------------------|--------------|------------|------------|
| | 2015 | 2016 | (Decrease) | Change |
| Operating expense: | | | | |
| Research and development | \$ 309,503 | \$ 281,218 | \$ 28,285 | 10 |
| General and administrative | 1,306,457 | 978,167 | 328,290 | 34 |
| Stock compensation | 282,262 | 59,122 | 223,140 | 377 |
| Total operating expense | \$ 1,898,222 | \$ 1,318,507 | \$ 579,715 | 44 |

Research and Development

Research and development (“**R&D**”) costs represent costs incurred to develop our CellIM™ System and are incurred pursuant to agreements with third party providers. R&D costs are expensed when incurred. R&D costs increased during the year ended December 31, 2016 compared to 2015, as a result of increased expenditures made in anticipation of our FDA and other regulatory filings.

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General and Administrative

General and administrative costs include all expenditures incurred other than R&D related costs, including costs related to personnel, professional fees, travel and entertainment, public company costs, insurance and other office related costs. Costs increased during the year ended December 31, 2016 compared to 2015 due primarily to an investor outreach and name branding program, increase in legal fees related to the negotiating and drafting of agreements and higher personnel costs offset by decreases in certain consulting fees, travel costs and charitable donations of \$83,000 which were paid to the University of Pittsburgh in 2015.

Other Income (Expense)

Other income relates to interest earned on bank account deposits. Other expense relates to a convertible promissory note dated September 9, 2016 with a face amount of \$700,000. Interest expense relates to the stated interest of the convertible promissory note. Accretion of debt discount represents the accretion of the discount applied to the note as a result of the issuance of detachable warrants and the beneficial conversion feature contained in the note.

Liquidity and Capital Resources

We currently finance our activities through the sale of our equity securities and issuance of debt. There is no assurance that funding will be accessible to us at the times and in the amounts required to fund our ongoing operations. There are many conditions beyond our control, which have a direct bearing on the level of investor interest in the purchase of our securities. We do not have any agreements or understandings with any person as to additional financing.

At December 31, 2016, we had cash of \$418,031 and working capital of \$85,575. Total liabilities as of December 31, 2016 were \$363,991.

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America and applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. As discussed in Note 1 to the consolidated financial statements, we have incurred recurring operating losses since inception of \$11,051,584. We require additional funds to meet our obligations and maintain our operations. Subsequent to December 31, 2017, the Company received \$445,000 upon the sale of three convertible promissory notes. As a result, we have sufficient cash on hand to pay our administrative and general operating expenses through June 30, 2017. We do not currently have

cash flow from operations as we have no commercialized products; without cash flow from operations, we will need to obtain additional funds (presumably through equity offerings, debt borrowing or through the exercise of outstanding warrants, which, if exercised in total for cash would result in proceeds of \$6,562,000; all of our outstanding warrants currently include a “cashless exercise” feature) in order to implement our current research and development programs for the CellMist™ System. If we are unable to obtain adequate funds, or if such funds are not available to us on acceptable terms, our ability to continue our business as planned will be significantly impaired and it may cause us to curtail operations.

Net cash used in operating activities was \$1,788,608 during the year ended December 31, 2016, compared to net cash used in operating activities of \$1,295,509 during the year ended December 31, 2015.

Net cash used in investing activities was \$951 during the year ended December 31, 2016, compared to no cash used in investing activities during the year ended December 31, 2015.

Net cash provided by financing activities was \$1,810,001 during the year ended December 31, 2016, compared to \$1,010,000 during the year ended December 31, 2015.

On September 9, 2016, we entered into a loan agreement with KCC whereby KCC agreed to loan us up to \$900,000 with an initial loan in the amount of \$700,000.

On February 2, 2016, KCC exercised a portion of its Series B Warrant for 2,173,913 shares of our common stock at an exercise price of \$0.46 per share resulting in proceeds of \$1,000,000.

On June 5, 2015, we entered into subscription agreements with five investors for the purchase and sale of an aggregate of 1,010,000 units of our equity securities at a price of \$1.00 per unit for total gross proceeds of \$1,010,000. Each unit consisted of one share of common stock and one Series D Warrant allowing the holder to purchase one share of our common stock at a price of \$1.10 per share for a period of five years; we used the proceeds from the sale of the units for research and development and general corporate purposes.

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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 note 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. Our cash position, relative to our cash requirements with respect to our research and development, raises substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should we be unable to continue as a going concern. Our actual results could differ materially from those anticipated in these forward-looking statements.

Share Capital

At December 31, 2016, we had:

- Authorized share capital of 10,000,000 preferred shares with par value of \$0.0001.

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, 2016 and 2015, 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, 2016, 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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

Our audited consolidated financial statements are stated in United States dollars (US\$) and are prepared in accordance with United States Generally Accepted Accounting Principles.

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

| | |
|-------------------------------------------------------------------------------------------------------|----|
| <u>Report of Independent Registered Public Accounting Firm</u> | 15 |
| <u>Consolidated Balance Sheets as of December 31, 2016 and 2015</u> | 16 |
| <u>Consolidated Statements of Operations for the years ended December 31, 2016 and 2015</u> | 17 |
| <u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016 and 2015</u> | 18 |
| <u>Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015</u> | 19 |
| <u>Notes to the Consolidated Financial Statements</u> | 20 |

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors

RenovaCare, Inc.

New York, New York

We have audited the accompanying consolidated balance sheets of RenovaCare, Inc. and Subsidiaries (“the Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders’ equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of RenovaCare, Inc. and Subsidiaries as of December 31, 2016 and 2015 and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred net operating losses and operating cash flow deficits that raise substantial doubt about its ability to continue as a going concern. Management’s plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PETERSON SULLIVAN LLP

Seattle, Washington

March 28, 2017

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Table of Contents**RENOVACARE, INC****CONSOLIDATED BALANCE SHEETS**

| | December 31, | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------|
| | 2016 | 2015 |
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 418,031 | \$ 397,589 |
| Prepaid expenses | 31,535 | 10,293 |
| Total current assets | 449,566 | 407,882 |
| Equipment, net of accumulated depreciation of \$53 for 2016 | 898 | - |
| Intangible assets | 152,854 | 152,854 |
| Total assets | \$ 603,318 | \$ 560,736 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ - | \$ 71,563 |
| Accounts payable - related parties | 33,290 | 30,095 |
| Contract and contribution payable | 150,000 | 134,125 |
| Interest payable to related party | 15,220 | - |
| Convertible promissory notes payable to related party, net of discount of \$534,519 for 2016 | 165,481 | - |
| Total current liabilities | 363,991 | 235,783 |
| Contract and contribution payable, less current portion | - | 100,000 |
| Total liabilities | 363,991 | 335,783 |
| 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, 70,069,693 and 67,781,934 shares issued and outstanding at December 31, 2016 and 2015, respectively | 702 | 678 |
| Additional paid-in capital | 11,290,209 | 9,197,970 |
| Retained deficit | (11,051,584) | (8,973,695) |
| Total stockholders' equity | 239,327 | 224,953 |
| Total liabilities and stockholders' equity | \$ 603,318 | \$ 560,736 |

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

Table of Contents**RENOVACARE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Years Ended December 31, | |
|---------------------------------------------------------------------------------|-------------------------------------|----------------|
| | 2016 | 2015 |
| Revenue | \$ - | \$ - |
| Operating expense | | |
| Research and development | 309,503 | 281,218 |
| General and administrative | 1,588,719 | 1,037,289 |
| Total operating expense | 1,898,222 | 1,318,507 |
| Loss from operations | (1,898,222) | (1,318,507) |
| Other income (expense) | | |
| Interest income | 1,034 | - |
| Interest expense | (15,220) | - |
| Accretion of debt discount | (165,481) | - |
| Total other income (expense) | (179,667) | - |
| Net loss | \$ (2,077,889) | \$ (1,318,507) |
| Basic and Diluted Loss per Common Share | \$ (0.03) | \$ (0.02) |
| Weighted average number of common shares outstanding - basic and diluted | 69,772,485 | 67,233,254 |

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

Table of Contents**RENOVACARE, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY****FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015**

| | Common Stock | | Additional | Retained | Total |
|-------------------------------------------------------------------------|--------------|--------|--------------------|----------------|-------------------------|
| | Shares | Amount | Paid-in Capital | Deficit | Stockholders' Equity |
| Balance, December 31, 2014 | 66,575,122 | \$ 666 | \$ 8,128,860 | \$ (7,655,188) | \$ 474,338 |
| Issuance of common stock plus warrants | 1,010,000 | 10 | 1,009,990 | - | 1,010,000 |
| Issuance of common stock from the exercise of warrants | 196,812 | 2 | (2) | - | - |
| Stock based compensation due to common stock purchase options | - | - | 59,122 | - | 59,122 |
| Net loss for the year ended December 31, 2015 | - | - | - | (1,318,507) | (1,318,507) |
| Balance, December 31, 2015 | 67,781,934 | 678 | 9,197,970 | (8,973,695) | 224,953 |
| Issuance of common stock from the exercise of warrants | 2,273,913 | 24 | 1,109,977 | - | 1,110,001 |
| Issuance of common stock from the exercise of stock options | 13,846 | - | - | - | - |
| Stock based compensation due to common stock purchase options | - | - | 296,123 | - | 296,123 |
| Reversal of stock based compensation due to forfeiture of stock options | - | - | (13,861) | - | (13,861) |
| Discount on convertible promissory note due to detachable | - | - | 340,735 | - | 340,735 |

| | | | | | |
|------------------------------------------------------------------------------|------------|----|---------|-------------|--------------|
| warrants | | | | | |
| Discount on convertible promissory note due to beneficial conversion feature | - | - | 359,265 | - | 359,265 |
| Net loss for the year ended December 31, 2016 | - | - | - | (2,077,889) | (2,077,889) |
| Balance, December 31, 2016 | 70,069,693 | \$ | 702 | \$ | 11,290,209 |
| | | | | \$ | (11,051,584) |
| | | | | | \$ 239,327 |

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

Table of Contents**RENOVACARE, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | Years Ended December 31, | |
|----------------------------------------------------------------------------|-------------------------------------|-------------------|
| | 2016 | 2015 |
| Cash flows from operating activities | | |
| Net loss | \$ (2,077,889) | \$ (1,318,507) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation | 53 | - |
| Impairment loss | - | 10,000 |
| Stock based compensation expense | 282,262 | 59,122 |
| Accretion of debt discount | 165,481 | - |
| Changes in operating assets and liabilities: | | |
| Decrease (increase) in prepaid expenses | (21,242) | (2,845) |
| Increase (decrease) in accounts payable | (71,563) | 65,381 |
| Increase (decrease) in related party payable | 3,195 | 22,840 |
| Increase (decrease) in interest payable to related party | 15,220 | - |
| Increase (decrease) in contract and contributions payable | (84,125) | (131,500) |
| Net cash flows from operating activities | (1,788,608) | (1,295,509) |
| Cash flows from investing activity | | |
| Purchase of equipment | (951) | - |
| Net cash flows from investing activity | (951) | - |
| Cash flows from financing activities | | |
| Proceeds from exercise of warrants and issuance of common stock | 1,110,001 | 1,010,000 |
| Proceeds from the issuance of convertible promissory note | 700,000 | - |
| Net cash flows from financing activities | 1,810,001 | 1,010,000 |
| Increase (decrease) in cash and cash equivalents | 20,442 | (285,509) |
| Cash and cash equivalents at beginning of year | 397,589 | 683,098 |
| Cash and cash equivalents at end of year | \$ 418,031 | \$ 397,589 |
| Supplemental disclosure of cash flow information: | | |
| Interest paid in cash | \$ - | \$ - |
| Income taxes paid in cash | \$ - | \$ - |
| Supplemental disclosure of non-cash transactions: | | |
| Debt discount recorded for value of warrants issued | \$ 340,735 | \$ - |
| Debt discount recorded for beneficial conversion feature | \$ 359,265 | \$ - |

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

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RENOVACARE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization, Nature and Continuance of Operations

RenovaCare, Inc., together with its wholly owned subsidiary (the "Company"), 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. ("RenovaCare Sciences"), completed the acquisition of its flagship technologies (collectively, the "CellMist™ System") along with the associated United States patent applications and two foreign patents, the first of which expires on August 22, 2027 and the second of which expires on April 26, 2031. One of the two US patent applications was granted to the Company on November 29, 2016 (Patent No.: US 9,505,000) and expires on or about March 3, 2035. 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. Based on these technologies the Company has recently filed two additional patent applications, one with the United States Patent and Trademark Office titled "Modular Device for Cell Spraying," and one with the European Patent Office titled "Disposable Apparatus and Device with Unsterile Reusable Apparatus for Sterile Application of a Liquid."

The Company has recently incurred net operating losses and operating cash flow deficits. As of December 31, 2016, the Company's accumulated deficit is \$11,051,584. The Company does not currently generate revenues and will continue to incur losses from operations and operating cash flow deficits in the future. Subsequent to December 31, 2016, the Company received \$445,000 upon the sale of three convertible promissory notes. Management believes that the Company's cash and cash equivalent balances and other external sources of capital will be sufficient to meet the Company's cash requirements through June 2017. The Company's activities are subject to significant risks and uncertainties due to the stage of the development of the Company's cellular therapies. The future of the Company after June 2017 will depend on its ability to successfully raise capital from external sources to fund operations. If the Company is unable to obtain adequate funds, or if such funds are not available to it on acceptable terms, the Company's ability to continue its business to develop its cellular therapies will be significantly impaired and it may cause the Company to curtail operations.

The matters described above raise substantial doubt about the Company's ability to continue as a going concern within one year after the date these consolidated financial statements were issued. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going

concern.

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.

Applicable Accounting Guidance

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.

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In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-09, “Compensation-Stock Compensation: Improvements to Employee Share-Based Payment Accounting (Topic 718)”, which is intended to simplify several aspects of the accounting for share-based payment award transactions. The guidance will be effective for the fiscal year beginning after December 15, 2016, including interim periods within that year. The Company does not expect adoption of ASU 2016-09 to have a material impact on its 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. ASU 2015-17 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. The Company has determined that the adoption of ASU 2015-17 will currently have no 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 accounting principles generally accepted in the United States of America 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.

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.

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Fair Value of Financial Instruments

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 note 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:

| | Estimated Useful Lives |
|-----------------------|-----------------------------------|
| 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. The Company did, however, determine that an intangible asset related to wound care technology, acquired during 2013, was impaired during the period ended March 31, 2015 and recorded an impairment loss (a component of research and development expenses) amounting to \$10,000 which was equal to the amount capitalized.

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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. The Company's policy is to issue new shares upon exercise of options.

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, 2016 and 2015:

**Years Ended
December 31,**

| | 2016 | 2015 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------|
| Basic and Diluted EPS Computation | | |
| Numerator: | | |
| Loss available to common stockholders' | \$ (2,077,889) | \$ (1,318,507) |
| Denominator: | | |
| Weighted average number of common shares outstanding | 69,772,485 | 67,233,254 |
| Basic and diluted EPS | \$ (0.03) | \$ (0.02) |
| 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 | 385,000 | 257,500 |
| Warrants | 7,280,503 | 8,970,000 |
| Convertible debt | 464,428 | - |
| Total shares not included in the computation of diluted losses per share | 8,129,931 | 9,227,500 |

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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, 2016 and 2015.

Note 4. Contract and Contribution Payable

On May 1, 2015, the Company entered into an option agreement (the "Option Agreement") with Dr. Gerlach, pursuant to which the Company obtained a one-year exclusive option to evaluate a wound cap technology (the "Technology"). Pursuant to the terms of the Option Agreement, the Company paid Dr. Gerlach a non-refundable fee of \$24,000 in four quarterly installments of \$6,000, with the first installment paid in May 2015 and the final payment made during the three months ended March 31, 2016.

On September 25, 2014, the Company entered into a Charitable Grant Agreement with the University of Pittsburgh (the "University"), pursuant to which the Company committed to provide a charitable donation to the University in the aggregate amount of \$75,000 (the "Grant"). The Company paid the Grant in eight quarterly installments of \$9,375, with the first payment made in October 2014 and the final payment made in July 2016. Dr. Gerlach, from whom the Company purchased the CellMist™ System, is a professor at the University.

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

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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, 2016; and (d) \$100,000 on December 31, 2017. At December 31, 2016, \$150,000 of the amount payable to Dr. Gerlach was recorded as current liabilities in the accompanying consolidated balance sheet.

Below is a summary of contract and contribution payable at December 31, 2016 and 2015:

| | 2016 | 2015 |
|--------------------------------------------------------------------------------------------------------------------------------------------------|------------------|-------------------|
| Contribution payable to the University of Pittsburgh, in quarterly installments of \$9,375, through July 2016 | \$ - | \$ 28,125 |
| Contract payable to Dr. Jorg Gerlach in connection with the APA. \$50,000 was due on December 31, 2016 and \$100,000 is due on December 31, 2017 | 150,000 | 200,000 |
| Contract for option agreement purchase | - | 6,000 |
| Total | 150,000 | 234,125 |
| Less: current portion | (150,000) | (134,125) |
| Long-term portion | \$ - | \$ 100,000 |

See also "Note 9. Related Party Transactions."

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Note 5. Debt

On September 9, 2016, the Company entered into a loan agreement (the “Loan Agreement”) with Kalen Capital Corporation (“KCC”); KCC is wholly owned by Mr. Harmel S. Rayat, the Company's majority shareholder. 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 may be loaned prior to December 31, 2017, upon the mutual agreement of the Company and KCC. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matures on December 31, 2017, and, beginning on the first anniversary of the Note, can be converted, at KCC's sole discretion, into shares of the Company's common stock at conversion rate equal to the lesser of: (i) \$1.54, or the closing price of the Company's common stock on the day prior to the issuance of the Note 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.

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 Loan Agreement provides KCC with registration rights for all of the shares issuable upon conversion of the Note, including conversion of the note issued for the remaining \$200,000, if applicable, and exercise of the Series E Warrant, beginning on the first anniversary of the Loan Agreement.

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 the 1.25 year term of the Note.

During the year ended December 31, 2016, the Company recognized \$15,220 of interest expense and \$165,481 of accretion related to the debt discount. The remaining debt discount of \$534,519 will be amortized over the next four quarters through December 31, 2017.

Note 6. Common Stock and Warrants

Common Stock

At December 31, 2016, the Company had 500,000,000 authorized shares of common stock with a par value of \$0.00001 per share, 70,069,693 shares of common stock outstanding and 19,595,000 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").

During the year ended December 31, 2016, the Company had the following common stock related transactions:

- 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 \$110,001 of proceeds to the Company.

Table of Contents*Warrants*

The following table summarizes information about warrants outstanding at December 31, 2016 and 2015:

| Description | Shares of Common Stock Issuable from Warrants Outstanding as of December 31, | | Weighted Average Exercise Price | Expiration |
|-------------|------------------------------------------------------------------------------------------|-----------|------------------------------------------|-------------------|
| | 2016 | 2015 | | |
| Series A | 960,000 | 960,000 | \$ 0.35 | July 12, 2019 |
| Series B | 1,326,087 | 3,500,000 | \$ 0.46 | November 29, 2018 |
| Series C | 3,500,000 | 3,500,000 | \$ 0.49 | November 29, 2018 |
| Series D | 910,000 | 1,010,000 | \$ 1.10 | June 5, 2020 |
| Series E | 584,416 | - | \$ 1.13 | September 8, 2021 |
| Total | 7,280,503 | 8,970,000 | | |

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.

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 11/29 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.

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.

A Series D Warrant, with an exercise price of \$1.10, to purchase 1,010,000 shares of common stock was 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.

A Series E Warrant to purchase 584,416 shares of common stock was issued on September 9, 2016 in connection with the Loan Agreement. The Series E Warrant has an exercise price of the lesser of: (i) \$1.54, the closing price of the Company's common stock as quoted on the OTCQB on the day prior to issuance of the Warrant; or (ii) a twenty percent (20%) discount to the average closing price of the Company's common stock as quoted on the OTCQB for the five days prior to the date on which KCC elects to exercise the Warrant. The Warrant is exercisable for a period of five years from the date of issuance and may be exercised on a cashless basis using the formula contained therein.

Table of Contents**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, 2016, there were 19,595,000 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.

Stock Option Activity

The following table summarizes stock option activity for the period ended December 31, 2016:

| Number of Options | Weighted Average Exercise Price (\$) | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value (\$) |
|------------------------------|---------------------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------|
|------------------------------|---------------------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------|

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| | | | | |
|------------------------------------------|------------|------|------------|---------|
| Outstanding at December 31, 2014 | 185,000 | 0.83 | | |
| Grants | 80,000 | 1.54 | | |
| Forfeitures | (7,500) | 1.43 | | |
| Outstanding at December 31, 2015 | 257,500 | 1.07 | | |
| Grants | 187,500 | 1.92 | | |
| Forfeitures | (40,000) | 1.65 | | |
| Exercises | (20,000) | 0.80 | | |
| Outstanding at December 31, 2016 | 385,000 | 1.42 | 8.30 years | 277,625 |
| Exercisable at December 31, 2016 | 347,500 | 1.44 | 8.36 years | 244,925 |
| Available for grant at December 31, 2016 | 19,595,000 | | | |

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. There were 187,500 stock options granted during the year ended December 31, 2016 with a weighted-average grant date fair value of \$1.41. There were 80,000 stock options granted during the year ended December 31, 2015 with a weighted-average grant date fair value of \$1.18. There were 20,000 options exercised on a cashless basis during the year ended December 31, 2016, with an aggregate intrinsic value of \$36,000. There were no stock options exercised during the year ended December 31, 2015. 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:

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| | 2016 | 2015 |
|-----------------------------------|-------------|-------------|
| Risk-free interest rate | 1.23%-1.41% | 1.49%-1.70% |
| Expected life in years | 5.5 | 5.0 |
| Weighted Avg. Expected Volatility | 92% | 88.4-105.3% |
| Expected dividend yield | 0 | 0 |

The fair value of the Company's stock options is expensed ratably over their respective vesting periods. During the years ended December 31, 2016 and 2015, the Company recognized \$282,262 and \$59,122, respectively, in share-based compensation cost resulting from stock option grants, including those previously granted and vesting over time. Stock-based compensation expense is recognized as general and administrative expenses. As of December 31, 2016, the Company had \$8,404 of unrecognized compensation cost related to unvested stock options which is expected to be recognized over a period of 2.25 years.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2016:

| Range of Exercise Prices | Stock Options Outstanding | | | Stock Options Exercisable | | |
|-----------------------------------|--------------------------------------|--------------------------------|------------------------------|--------------------------------------|--------------------------------|------------------------------|
| | Number | Weighted | | Number | Weighted | |
| | of Shares | Average | Weighted | of Shares | Average | Weighted |
| | Subject to Outstanding Options | Contractual Life (years) | Average Exercise Price | Subject To Options Exercise | Contractual Life (Years) | Average Exercise Price |
| \$ 0.65 | 40,000 | 7.01 | \$ 0.65 | 40,000 | 7.01 | \$ 0.65 |
| 0.75 | 40,000 | 6.92 | 0.75 | 40,000 | 6.92 | 0.75 |
| 0.80 | 30,000 | 7.62 | 0.80 | 30,000 | 7.62 | 0.80 |
| 1.05 | 55,000 | 7.25 | 1.05 | 25,000 | 7.25 | 1.05 |
| 1.25 | 7,500 | 8.46 | 1.25 | 7,500 | 8.46 | 1.25 |
| 1.34 | 7,500 | 8.50 | 1.34 | 7,500 | 8.50 | 1.34 |
| 1.65 | 10,000 | 8.84 | 1.65 | 10,000 | 8.84 | 1.65 |
| 1.70 | 7,500 | 8.79 | 1.70 | 7,500 | 8.79 | 1.70 |
| 1.91 | 180,000 | 9.21 | 1.91 | 180,000 | 9.21 | 1.91 |
| 2.28 | 7,500 | 9.56 | 2.28 | - | 9.56 | 2.28 |
| Total | 385,000 | 8.30 | \$ 1.42 | 347,500 | 8.36 | \$ 1.44 |

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 Company has the option to terminate the Lease on the twelve month anniversary of the commencement date, upon one hundred and twenty days’ prior written notice. The Lease was renewed effective March 1, 2016 at a monthly rate of \$800. Rent expense for the years ended December 31, 2016 and 2015 was \$9,500 and \$9,000, respectively.

On August 1, 2013, the Company and Vector Asset Management, Inc. (“Vector”) entered into a Consulting Agreement whereby Vector will assist the Company with identifying subject matter experts in the medical device and biotechnology industries and to assist the Company with its ongoing research, development and eventual commercialization of its Regeneration Technology (collectively, the “Services”). On May 1, 2016, Vector and the Company entered into an amendment to the consulting agreement. Pursuant to the amendment, the term of the agreement terminates only upon written notice, and the monthly consulting fee, in consideration of the Services, was increased to \$6,800 from \$5,000. No other changes were made to the agreement.

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. Pursuant to this engagement the Company incurred expenses of \$184,517 and \$194,336 in during the years ended December 31, 2016 and 2015, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

See also “Note 9. Related Party Transactions.”

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Note 9. Related Party Transactions

As compensation for their service on the Board, Dr. Kirkland and Mr. Sierchio will receive an annual retainer of \$6,000, payable in equal yearly installments in arrears and prorated for any partial years of service. 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, the closing price of the Company's common stock on the day prior to the grant. The options became fully vested upon grant and may be exercised on a "cashless basis" using the formula contained therein.

The law firm of Sierchio & Partners, LLP, of which Joseph Sierchio, one of the Company's directors, was a principal, has provided counsel to the Company since August 26, 2010. Beginning in September 2016, Mr. Sierchio became a partner at Satterlee Stephens LLP ("Satterlee"). Concurrently with Mr. Sierchio's move to Satterlee, the Company engaged with Satterlee to provide legal counsel with Mr. Sierchio maintaining his role as the Company's primary attorney. During the years ended December 31, 2016 and 2015, the Company recognized \$168,775 and \$101,700 of fees for legal services billed by firms associated with Mr. Sierchio. Included in accounts payable, at December 31, 2016, is \$11,750 owed to Satterlee and at December 31, 2015, is \$8,322 owed Sierchio & Partners, LLP. Mr. Sierchio continues his role with the Company as a director.

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 \$184,517 and \$194,336 during the years ended December 31, 2016 and 2015, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

On September 25, 2014, the Company entered into a Charitable Grant Agreement with the University, pursuant to which the Company committed to provide a charitable donation to the University in the aggregate amount of \$75,000. The Company paid the Grant in eight quarterly installments of \$9,375, with the final payment made on July 22, 2016. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a professor at the University. Effective November 1, 2015, the Company entered into a Charitable Gift Agreement with the University, pursuant to which the Company committed to provide a charitable donation to the University in the aggregate amount of \$83,000. The Gift was paid in full in December 2015.

Dr. Gerlach is entitled to payments for consulting services. During the years ended December 31, 2016 and 2015, the Company recognized expenses related to Dr. Gerlach services of \$42,480 and \$36,720, respectively.

On May 1, 2015, the Company entered into the Option Agreement with Dr. Gerlach, pursuant to which the Company obtained a one-year exclusive option to evaluate the Technology, for the purpose of determining whether the Company would like to purchase or license the Technology. Pursuant to the terms of the Option Agreement, the Company paid Dr. Gerlach a non-refundable fee of \$24,000, payable in four quarterly installments of \$6,000, with the first installment due on May 1, 2015. The entire \$24,000 option payment was recognized as research and development expense during the period ended December 31, 2015. The final \$6,000 payment was made on February 1, 2016.

On September 9, 2016, the Company entered into a 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 the Note; the remaining \$200,000 may be loaned prior to December 31, 2017, upon the mutual agreement of the Company and KCC. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matures on December 31, 2017, and, beginning on the first anniversary of the Note, can be converted, at KCC's sole discretion, into shares of the Company's common stock at conversion rate equal to the lesser of: (i) \$1.54, or the closing price of the Company's common stock on the day prior to the issuance of the Note 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.

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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 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.

On February 2, 2016, KCC exercised a portion of its Series B Warrant for 2,173,913 shares of the Company's common stock at an exercise price of \$0.46 per share resulting in proceeds of \$1,000,000.

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.

There is no current or deferred tax expense for 2016 and 2015, 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, utilizing a 34% income tax rate, of temporary differences comprising the deferred tax assets and deferred tax liabilities is a result of the following at December 31:

| | 2016 | 2015 |
|---------------------------------------------------|--------------|--------------|
| Deferred tax assets: | | |
| Net operating loss and contribution carryforwards | \$ 3,217,000 | \$ 2,646,000 |
| Intangible asset | 158,000 | 84,000 |
| Capital loss carryforward | 236,000 | - |
| Stock-based compensation | 139,000 | 46,000 |
| | 3,750,000 | 2,776,000 |
| Valuation allowance | (3,750,000) | (2,776,000) |
| Net deferred tax assets | \$ - | \$ - |

The 2016 increase in the valuation allowance was \$974,000 (2015: \$154,000).

The Company has available net operating loss and contribution carryforwards of approximately \$9,302,000 for tax purposes to offset future taxable income which expire commencing 2018 through to the year 2036. The capital loss carryforward expires 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 2014 through 2016 remain open to examination by federal agencies and other jurisdictions in which it operates.

A reconciliation between the statutory federal income tax rate (34%) and the effective rate of income tax expense for the years ended December 31 follows:

| | 2016 | 2015 |
|-----------------------------------|-------------|-------------|
| Statutory federal income tax rate | 34% | 34% |
| Permanent differences and other | 13% | (22)% |
| Valuation allowance | (47)% | (12)% |
| | 0% | 0% |

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Note 11. Subsequent Events

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 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 President, CEO and Interim Chief Financial Officer 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 separate loan agreements containing identical terms (the "February 2017 Loan Agreements") with Joseph Sierchio ("Sierchio") and KCC (collectively, the "Holders"). Pursuant to the terms of the February 2017 Loan Agreements, Sierchio agreed to loan the Company \$25,000 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 (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 mature 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 and KCC a Series F Stock Purchase Warrant (the "Series F Warrant") to purchase up to 7,246 shares and 114,193 shares, respectively, of the Company's common stock at an exercise 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 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 March 1, 2017, KCC exercised a Series B Warrant to purchase up to 1,326,087 shares, on a cashless basis, resulting in the issuance of 1,181,194 shares of common stock.

On March 1, 2017, KCC exercised a Series C Warrant to purchase up to 3,500,000 shares, on a cashless basis, resulting in the issuance of 3,092,637 shares of common stock.

On March 9, 2017, the Company entered into a loan agreement with an investor (the "Investor") on the same terms as the February 2017 Loan Agreements (the "March 2017 Loan Agreement"). Pursuant to the terms of the March 2017 Loan Agreement, the Investor agreed to loan the Company \$25,000 at an annual interest rate of 7% per year, compounded quarterly. The loan was evidenced by a convertible promissory note (the "March 2017 Note"). The March 2017 Note, including any interest due thereon, may not be prepaid without the consent of the Investor. The March 2017 Note mature on February 23, 2018, and, beginning on the one month anniversary, can be converted, at the Investor's sole discretion, 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 Investor elects to convert the March 2017 Note, subject to a floor price of \$2.76.

Per the March 2017 Loan Agreement, the Company issued the Investor a Series F Warrant to purchase up to 7,246 shares of the Company's common stock at an exercise per share 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 Investor 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.

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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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of the end of the period covered by this annual report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded as of December 31, 2016, that our disclosure controls and procedures were effective such that the information required to be disclosed in our United States Securities and Exchange Commission (the “SEC”) reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on the evaluation, management, after evaluating the effectiveness of our “disclosure controls and procedures” (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), have concluded that, as of December 31, 2016, our disclosure controls and procedures were effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Evaluation of and Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over our financial reporting. Management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our internal control over financial reporting as of December 31, 2016, based on the criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations.

Based on this evaluation, management concluded that, as of December 31, 2016, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

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, 2016, 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.

Table of Contents**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 March 10, 2017. 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.

| Name | Age | Position | Director / Officer Since |
|------------------|------------|---------------------------------------------------------------------------|---------------------------------|
| Thomas Bold | 56 | President, Chief Executive Officer and Interim Chief Financial Officer | December 2013 |
| Patsy Trisler | 69 | Vice-President, Regulatory & Clinical Affairs | April 1, 2014 |
| Joseph Sierchio | 67 | Director | August 2010 |
| Kenneth Kirkland | 74 | 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.

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 Food and Drug Administration (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. Rosen was appointed to serve as our Vice-President, Regulatory & Clinical Affairs due to her extensive regulatory guidance and clinical compliance experience.

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Joseph Sierchio. Mr. Sierchio earned his J.D. at Cornell University Law School in 1974, and a B.A., with Highest Distinction in Economics from Rutgers College at Rutgers University in 1971. Mr. Sierchio has been engaged in the practice of law as a member of Satterlee Stephens LLP, our counsel, since September 2016. Prior to that, Mr. Sierchio was engaged in the practice of law as a member of Sierchio & Partners, LLP from May 2007 through September 2016. Since 1975, Mr. Sierchio has continuously practiced corporate and securities law in New York City, representing domestic and foreign corporations, investors, brokerage firms, entrepreneurs, and public and private companies in the U.S., Canada, United Kingdom, Germany, Italy, Switzerland, Australia, and Hong Kong. Mr. Sierchio is admitted in all New York state courts and federal courts in the Eastern, Northern, and Southern Districts of the State of New York as well as the federal Court of Appeals for the Second Circuit. Mr. Sierchio is also a director of SolarWindow Technologies Inc., which is engaged in the research and development of renewable energy technology. Mr. Sierchio was invited to join the Board due to his experience representing corporations (public and private) and individuals in numerous and various organizational, compliance, administrative, governance, finance (equity and debt private and public offerings), regulatory and legal matters.

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.

Certain Relationships

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

Our proposed business raises potential conflicts of interests between certain of our officers and directors and us. Certain of our directors are directors of other mineral resource 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. From time to time, several companies may participate in the acquisition, exploration and development of natural resource properties thereby allowing for their participation in larger programs, involvement in a greater number of programs and reduction of the financial exposure with respect to any one program. It may also occur that a particular company will assign all or a portion of its interest in a particular program to another of these companies due to the financial position of the company making

the assignment.

In determining whether we will participate in a particular program and the interest therein to be acquired by it, 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.

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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;

The Board and Board Meetings

Our Board consists of two members. Directors serve for a term of one year and stand for election at our annual meeting of stockholders. Pursuant to our Bylaws, any vacancy occurring in the Board, including a vacancy created by an increase in the number of directors, may be filled by the stockholders or by the affirmative vote of a majority of the remaining directors though less than a quorum of the Board. A director elected to fill a vacancy shall hold office only until the next election of directors by the stockholders. If there are no remaining directors, the vacancy shall be filled by the stockholders.

At a meeting of stockholders, any director or the entire Board may be removed, with or without cause, provided the notice of the meeting states that one of the purposes of the meeting is the removal of the director. A director may be removed only if the number of votes cast to remove him exceeds the number of votes cast against removal.

Our Board and management are committed to responsible corporate governance to ensure that we are managed for the long-term benefit of its shareholders. To that end, the Board and management periodically review and update, as appropriate, our corporate governance policies and practices. In doing so, the Board and management review published guidelines and recommendations of institutional shareholder organizations and current best practices of similarly situated public companies. The Board and management also regularly evaluate and, when appropriate, will revise our corporate governance policies and practices in accordance with the requirements of the Sarbanes-Oxley Act of 2002 and the rules and listing standards issued by the SEC.

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During the year ended December 31, 2016, the Board held a total of eleven (11) meetings and actions by written consent. All members of the Board attended all meetings of the Board and participated in actions by written consent.

Directors' and Officers' Liability Insurance

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

Board Committees and Corporate Governance

Audit Committee

The Board does not currently have a standing Audit Committee. The full Board performs the principal functions of the Audit Committee. The full Board monitors our financial reporting process and internal control system and appoints our independent registered public accounting firm.

Compensation Committee

The Board does not currently have a standing Compensation Committee. The full Board establishes overall compensation policies for us and reviews recommendations submitted by our management.

Nominating Committee

The Board does not currently have a standing Nominating Committee. All nominating functions are handled directly by the full Board, which the Board believes is the most effective and efficient approach, based on the size of the Board and our current and anticipated operations and needs. As outlined above in selecting a qualified nominee, the Board considers such factors as it deems appropriate which may include: the current composition of the Board; the range of talents of the nominee that would best complement those already represented on the Board; the extent to which the nominee would diversify the Board; the nominee's standards of integrity, commitment and independence of thought and judgment; and the need for specialized expertise.

Legal Proceedings

During the past five years none of our directors, executive officers, promoters or control persons has been:

- the subject of any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
 1. Any Federal or State securities or commodities law or regulation; or
- any federal or state judicial or administrative proceedings based on violations of federal or state securities, commodities, banking or insurance laws and regulations, or any settlement to such actions (excluding settlements between private parties); and

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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 of 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.

Corporate Governance

We have adopted Corporate Governance Guidelines applicable to our Board.

Board Leadership Structure

We currently have one executive officer and two directors. Our Board has reviewed our current Board and executive leadership structure — which consists of a President & Chief Executive Officer and a Chief Financial Officer, both of which are held by Mr. Thomas Bold, and no Chairman of the Board — in light of 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 leadership structure for our company. Nevertheless, the Board intends to carefully evaluate from time to time whether our Chief Executive Officer and Chairman positions should be combined based on 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, is 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.

Table of Contents**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. 430 Park Avenue, Suite 702, New York, NY 10022. The Board has approved a process pursuant to which the President reviews and forward correspondence to the appropriate director or group of directors for response.

ITEM 11. EXECUTIVE COMPENSATION

The responsibility for establishing, administering and interpreting our policies governing the compensation and benefits for our executive officers lies with our Board. In administering their responsibilities for determining executive compensation, the Board has not retained the services of 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;

The following table and descriptive materials set forth information concerning compensation earned for services rendered to us by: the President & Chief Executive Officer (“**CEO**”); the Chief Financial Officer (“**CFO**”); and the 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 December 31, | Salary/ consulting fee | Bonus | Stock awards | Option awards | All other compensation | Total |
|--------------------------------|----------------------|---------------------------|-------|--------------|---------------|------------------------|---------|
| | | (\$) | (\$) | (\$) | (\$) | (\$) | (\$) |
| Thomas Bold ⁽¹⁾ | 2016 | 100,000 | - | - | 83,796 | - | 183,796 |
| President, CEO and Interim CFO | 2015 | 100,000 | - | - | - | - | 100,000 |

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| | | | | | | | |
|--------------------------------|------|--------|---|---|--------|---|--------|
| Rhonda B. Rosen ⁽²⁾ | 2016 | 30,100 | - | - | 27,932 | - | 58,032 |
| Former CFO | 2015 | 46,800 | - | - | - | - | 46,800 |
| Patsy Trisler ⁽³⁾ | 2016 | 60,000 | - | - | - | - | 60,000 |
| V P – | | 60,000 | - | - | - | - | 60,000 |
| Clinical & Regulatory Affairs | 2015 | | | | | | |

- (1) On December 1, 2013, we 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, and 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. 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; and (c) 60,000 vested on March 16, 2016.

Table of Contents**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, 2016.

| Name | Option Awards | | Option Exercise Price (\$) | Option Expiration Date |
|-----------------|-----------------------------------------------------------------|-------------------------------------------------------------------|----------------------------|------------------------|
| | Number of securities underlying unexercised options exercisable | Number of securities underlying unexercised options unexercisable | | |
| Thomas Bold | 40,000 | - | 0.75 | November 30, 2023 |
| | 60,000 | - | 1.91 | March 15, 2026 |
| Rhonda B. Rosen | 10,000 | - | 0.80 | October 8, 2018 |
| | 20,000 | - | 1.91 | October 8, 2018 |
| Patsy Trisler | 20,000 | 30,000 | 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, 2016, there were 19,595,000 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.

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Employment Contracts

We maintain an “at-will” consulting agreement with Mr. Thomas Bold, our President, CEO and Interim CFO. Our entire Board sets the current year compensation levels of each Named Executive Officer.

There are no arrangements or plans in which we provide pension, retirement or similar benefits for directors or executive officers. 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.

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;

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. Directors are entitled to participate in, and have been issued options under, our 2013 Plan. We also reimburse directors for any actual expenses incurred to attend meetings of the Board.

On August 1, 2013, we appointed Dr. Kenneth Kirkland to serve as a member of our Board. Effective as of that date we agreed to pay non-employee directors an annual fee of \$6,000, payable quarterly.

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

| Name | | Fees earned or paid in cash ⁽¹⁾ (\$) | Option awards Aggregate Grant Date Fair Value (\$) | Total (\$) |
|--------------------------------|------|----------------------------------------------------------------|-----------------------------------------------------------------------|-------------------|
| Joseph Sierchio ⁽³⁾ | 2016 | 6,000 | 69,830 | 75,830 |
| | 2015 | 6,000 | - | 6,000 |
| Kenneth Kirkland | 2016 | 6,000 | 69,830 | 75,830 |
| | 2015 | 6,000 | - | 6,000 |

⁽¹⁾ The amounts in this column represent the quarterly compensation.

Table of Contents**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS**

| Name and Address of Beneficial Owner ⁽¹⁾ | Number of shares Beneficially Owned ⁽²⁾ | % of Class Owned ⁽²⁾ |
|-----------------------------------------------------|-------------------------------------------------------------|------------------------------------|
| <u>Directors and Officers</u> | | |
| Thomas Bold ⁽³⁾ | 104,296 | * |
| Patsy Trisler ⁽⁴⁾ | 30,000 | * |
| Kenneth Kirkland ⁽⁵⁾ | 79,642 | * |
| Joseph Sierchio ⁽⁶⁾ | 618,415 | * |
| All Directors and Officers as a Group (4 people) | 832,353 | 1.11 |
| <u>5% Shareholders</u> | | |
| Kalen Capital Corporation ⁽⁷⁾ | | |
| The Kalen Capital Building | | |
| 688 West Hastings St. | | |
| Suite 700 | | |
| Vancouver, BC V6B 1P1 | 50,008,783 | 66.06 |
| Jatinder Singh Bhogal ⁽⁸⁾ | | |
| 1962 Knox Road | | |
| Vancouver, BC V6T 1S6 | 5,631,925 | 7.54 |

* 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 430 Park Avenue, Suite 702, New York, New York 10022.

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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

The Board is responsible for review, approval, or ratification of “related-person transactions” entered into between us 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 our outstanding shares of common stock 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:

- 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;

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, 2016 and 2015:

The law firm of Sierchio & Partners, LLP, of which Joseph Sierchio, one of our directors, was a principal, has provided us counsel since August 26, 2010. Beginning in September 2016, Mr. Sierchio became a partner at Satterlee. Concurrently with Mr. Sierchio's move to Satterlee, we engaged Satterlee to provide us with legal counsel with Mr. Sierchio maintaining his role as our primary attorney. During the years ended December 31, 2016 and 2015, we recognized \$168,775 and \$101,700 of fees for legal services billed by firms associated with Mr. Sierchio. At December 31, 2016, we owed Satterlee \$11,750 which is included in accounts payable. There is no accounts payable to Sierchio & Partners, LLP as of December 31, 2016. Mr. Sierchio continues to serve as a member of the Board.

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In connection with our anticipated FDA and other regulatory filings, we engaged StemCell Systems to provide us with prototypes and related documents. Pursuant to this engagement we incurred expenses of \$184,517 and \$194,336 during the years ended December 31, 2016 and 2015, respectively. Dr. Gerlach, from whom we purchased the CellMist™ System technologies, is a principal of StemCell Systems.

On September 9, 2016, we entered into a loan agreement with KCC. Pursuant to the terms of the Loan Agreement, KCC agreed to loan us up to \$900,000 at an annual interest rate of 7% per year, compounded quarterly. KCC provided us with an initial loan in the amount of \$700,000, which was evidenced by the Note; the remaining \$200,000 may be loaned prior to December 31, 2017, upon the mutual agreement. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matures on December 31, 2017, and, beginning on the first anniversary of the Note, can be converted, at KCC's sole discretion, into shares of our common stock at conversion rate equal to the lesser of: (i) \$1.54, or 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 the Loan Agreement, we issued KCC a Series E Stock Purchase Warrant to purchase up to 584,416 shares of our common stock at a purchase price of the lesser of: (i) \$1.54, the closing price of our common stock on the day prior to issuance of the Series E Warrant; 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 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.

On February 2, 2016, Kalen Capital Corporation exercised a portion of its Series B Warrant for 2,173,913 shares of our common stock at an exercise price of \$0.46 per share and rendered \$1,000,000 as payment. Kalen Capital Corporation is wholly owned by Mr. Harmel S. Rayat, our majority shareholder.

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.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

INDEPENDENT PUBLIC ACCOUNTANTS

Peterson Sullivan LLP (“**Peterson Sullivan**”) currently serves as our independent registered public accounting firm to audit our financial statements for the fiscal year ended December 31, 2016. To the knowledge of management, neither such firm nor any of its members has any direct or material indirect financial interest in us or any connection with us in any capacity otherwise than as independent accountants.

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 Peterson Sullivan, 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.

Table of Contents**PRINCIPAL ACCOUNTING FEES AND SERVICES**

The following table presents aggregate fees for professional services rendered by Peterson Sullivan during the years ended December 31, 2016 and 2015:

| | Year Ended December 31, | |
|--------------------|------------------------------------|-------------|
| | 2016 | 2015 |
| Audit fees | \$ 40,420 | \$ 36,021 |
| Audit-related fees | 3,444 | 5,998 |
| Tax fees | 6,692 | 6,090 |
| Total fees | \$ 50,456 | \$ 48,109 |

Audit Fees

Audit fees for the years ended December 31, 2016 and 2015, totaled \$40,420 and \$36,021, respectively, and consist of the aggregate fees billed by 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, 2016 and 2015.

Audit-Related Fees

Audit-related fees for the years ended December 31, 2016 and 2015, totaled \$3,444 and \$5,998, respectively, and consist of the aggregate fees billed by Peterson Sullivan for the review and providing of consents for our registration statement on Form S-1 and amendments thereto that were filed with the SEC.

Tax Fees

Tax fees for the years ended December 31, 2016 and 2015, totaled \$6,692 and \$6,090, 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 Peterson Sullivan LLP, other than reported under Audit Fees, Audit-Related Fees and Tax Fees for the years ended December 31, 2016 and 2015.

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

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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 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, 2016 and 2015
- Statements of Operations for the years ended December 31, 2016 and 2015
- Statements of Stockholders' Equity for the years ended December 31, 2016 and 2015
- Statements of Cash Flows for the years ended December 31, 2016 and 2015
- 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.

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SIGNATURES

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

RENOVACARE, INC.

Date: March 28, 2017

By: */s/ Thomas Bold*
 Name: Thomas Bold
 Title: Chief Executive Officer, Interim Chief
 Financial Officer
 (Principal Executive Officer, Principal
 Financial Officer,
 Principal Accounting 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.

| Signature | Title | Date |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <i>/s/ Thomas Bold</i> Thomas Bold | President, Chief Executive Officer, Interim Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer) | March 28, 2017 |
| <i>/s/ Patsy Trisler</i> Patsy Trisler | Vice-President - Clinical & Regulatory Affairs | March 28, 2017 |
| <i>/s/ Kenneth Kirkland</i> Kenneth Kirkland | Director | March 28, 2017 |
| <i>/s/ Joseph Sierchio</i> Joseph Sierchio | Director | March 28, 2017 |

Table of Contents**Exhibit Index**

| Exhibit # | Description of Exhibit |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 | 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. |
| 3.3 | 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. |
| 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† | 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. |
| 4.2 | 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. |
| 4.3 | 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. |
| 4.4 | 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. |
| 4.5 | 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 |
| 4.6 | 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 |
| 10.1§ | 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. |
| 10.2 | 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. |
| 10.3 | 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. |
| 10.4 | Amendment to Consulting Agreement dated May 1, 2016 between Vector Asset Management, Inc. and the Company* |
| 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* |
| 31.1 | Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a).* |
| 32.1 | 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. |

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|---------|------------------------------------------------------------|
| 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.