

RenovaCare, Inc.  
Form S-1  
January 23, 2017

As filed with the U.S. Securities and Exchange Commission on January 23, 2017

Registration No. 333- \_\_\_\_\_

**U.S. SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**RenovaCare, Inc.**

*(Exact name of registrant as specified in its charter)*

<b>Nevada</b>	<b>3841</b>	<b>98-0384030</b>
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code number)	(I.R.S. Employer Identification No.)

**RenovaCare, Inc.**  
**430 Park Avenue, Suite 702**  
**New York, New York 10022**  
**(888) 398-0202**  
(Address and telephone number  
of principal executive offices)

**Thomas Bold**  
**RenovaCare, Inc.**  
**430 Park Avenue, Suite 702**  
**New York, New York 10022**  
**(888) 398-0202**  
(Name, address and telephone  
number of agent for service)

**Copies to:**

**Joseph Sierchio, Esq.**

**Elishama Rudolph, Esq.**

**Satterlee Stephens LLP**

**230 Park Avenue**

**Suite 1130**

**New York, New York 10169**

**Telephone: (212) 818-9200**

**Facsimile: (212) 818-9606**

**Approximate date of commencement of proposed sale to the public:** From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the 1933 Act, please check the following box and list the 1933 Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the 1933 Act, check the following box and list the 1933 Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the 1933 Act, check the following box and list the 1933 Act registration statement number of the earlier effective registration statement for the same offering.

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**CALCULATION OF REGISTRATION FEE**

<b>Title of each class of securities to be registered</b>	<b>Amount to be registered<sup>(1)</sup></b>	<b>Proposed maximum offering price per share</b>	<b>Proposed maximum aggregate offering price</b>	<b>Amount of registration fee</b>
Common stock, par value \$0.00001 <sup>(2)</sup>	946,000	\$ 2.20 <sup>(3)</sup>	\$ 2,081,200	\$ 241.21
Common stock, par value \$0.00001 <sup>(4)</sup>	1,010,000	\$ 1.10 <sup>(5)</sup>	\$ 1,111,000	\$ 128.76
<b>Total</b>	<b>1,956,000</b>		<b>\$ 3,192,200</b>	<b>\$ 369.98<sup>(6)</sup></b>

---

<sup>(1)</sup> In the event of a stock split, stock dividend or similar transaction involving our common stock, in order to prevent dilution, the number of shares registered shall be automatically increased to cover the additional shares in accordance with Rule 416(a) under the Securities Act of 1933, as amended.

**PROSPECTUS**

**SUBJECT TO COMPLETION, DATED JANUARY 23, 2017**

**The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sales is not permitted.**

**1,956,000 SHARES**

**RENOVACARE, INC. COMMON STOCK**

This prospectus relates to the resale by certain of our stockholders and holders of warrants to purchase our stock named in the section of this prospectus titled "Selling Stockholders" (collectively, the "**Selling Stockholders**") of up to 1,956,000 shares (collectively, the "**Shares**") of our common stock, par value \$0.00001. The Shares being offered under this prospectus are comprised of: (a) 946,000 shares of common stock that were purchased by the Selling Stockholder in a private transaction with us pursuant to exemptions from the registration requirements of the Securities Act of 1933, as amended (the "**Securities Act**") we completed on June 5, 2015 and (b) 1,010,000 shares of common stock issuable upon exercise of outstanding Series D Warrants that were purchased by the Selling Stockholder in a private transaction with us pursuant to exemptions from the registration requirements of the Securities Act we completed on June 5, 2015, allowing the holders to purchase shares of common stock at an exercise price of \$1.10 per share through June 5, 2020. The Series D Warrant may be exercised on a "cashless basis" using the formula set forth therein.

Although we will pay substantially all the expenses incident to the registration of the Shares, we will not receive any proceeds from the sales by the Selling Stockholders. The Selling Stockholders and any underwriter, broker-dealer or agent that participates in the sale of the Shares or interests therein may be deemed "underwriters" within the meaning of Section 2(a)(11) of the Securities Act. Any discounts, commissions, concessions, profit or other compensation any of them earns on any sale or resale of the shares, directly or indirectly, may be underwriting discounts and commissions under the Securities Act. The Selling Stockholders who are "underwriters" within the meaning of Section 2(a)(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

Our common stock is presently quoted for trading under the symbol "**RCAR**" on the OTC Markets Group Inc. QB<sup>TM</sup> tier (the "**OTCQB**"). On January 20, 2017, the closing price of our common stock, as reported on the OTCQB was \$2.44 per share. The Selling Stockholders have advised us that they will sell the shares of common stock registered hereunder from time to time in the open market, on the OTCQB, in privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or otherwise as described under the section of this prospectus titled "**Plan of Distribution.**"

The purchase of the Shares offered through this prospectus involves a high degree of risk. **Please refer to "Risk Factors" beginning on page 9.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is January 23, 2017

TABLE OF CONTENTS

	<b>Page #</b>
<b><u>PROSPECTUS SUMMARY</u></b>	5
<b><u>THE OFFERING</u></b>	7
<b><u>RISK FACTORS</u></b>	9
<b><u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u></b>	21
<b><u>USE OF PROCEEDS</u></b>	21
<b><u>DETERMINATION OF OFFERING PRICE</u></b>	21
<b><u>MARKET PRICE OF AND DIVIDENDS ON OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS</u></b>	22
<b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	22
<b><u>DESCRIPTION OF OUR BUSINESS AND PROPERTY</u></b>	26
<b><u>DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS</u></b>	30
<b><u>EXECUTIVE COMPENSATION</u></b>	34
<b><u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT</u></b>	36
<b><u>TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS</u></b>	37
<b><u>DESCRIPTION OF OUR SECURITIES</u></b>	39
<b><u>THE SELLING STOCKHOLDERS</u></b>	41
<b><u>PLAN OF DISTRIBUTION</u></b>	42
<b><u>LEGAL MATTERS</u></b>	44
<b><u>EXPERTS</u></b>	44
<b><u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u></b>	44
<b><u>INDEX TO CONSOLIDATED FINANCIAL STATEMENTS</u></b>	45
<b><u>CONSOLIDATED FINANCIAL STATEMENTS</u></b>	45

**You should rely only on the information contained in this prospectus or any related prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this prospectus or incorporated by reference herein is accurate only on the date of this prospectus. Our business, financial condition, results of operations and prospects may have changed since such date. Other than as required under the federal securities laws, we undertake no obligation to publicly update or revise such information, whether as a result of new information, future events or any other reason.**

**This prospectus is not an offer to sell, nor is it an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted.**

## **PROSPECTUS SUMMARY**

*This summary highlights certain information that we present more fully in the rest of this prospectus. This summary does not contain all of the information you should consider before investing in the securities offered pursuant to this prospectus. You should read the entire prospectus carefully, including the "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before making an investment decision.*

*Except where the context otherwise requires and for purposes of this prospectus only, "we," "us," "our," "Company," "our Company," and "RenovaCare" refer to RenovaCare, Inc., a Nevada corporation, and its consolidated subsidiaries.*

### **Overview**

We were incorporated under the laws of the State of Utah on July 14, 1983, under the name "Far West Gold, Inc." On May 9, 1996, our stockholders authorized a name change to "Far West Resources, Inc." On June 30, 1997, the stockholders authorized a name change to "American Alliance Corporation" and authorized a change in the state of domicile from Utah to Nevada. On May 20, 1999, we changed our name to "WhatsOnline.Com, Inc.," effective as of August 3, 2000, we changed our name to Entheos Technologies, Inc. and effective as of January 5, 2011, we changed our name to Janus Resources, Inc. 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. We have an authorized capital of 500,000,000 shares of common stock, par value \$0.00001 of which 70,274,264 shares are outstanding as of the date of this prospectus, and 10,000,000 shares of \$0.0001 par value preferred stock, of which none are outstanding.



## 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 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 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.

## Table of Contents

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

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

We are currently evaluating the potential of our CellMist™ System in the treatment of tissue that has been subject to severe trauma such as second degree burns. In recent years physicians have treated burn patients using our technology under innovative practice and experimental studies and the CellMist™ System has shown the ability to regenerate human skin. The CellMist™ System utilizes the patient's own skin stem cells, reduces the size of the donor site, and has shown to significantly decrease scarring. Furthermore, we believe the CellMist™ System could enable treatment of other skin disorders with minimal scarring.

## **Corporate Information**

Our corporate headquarters is located at 430 Park Avenue, Suite 702, New York, New York 10022. Our telephone number is (888) 398-0202. Our website is [www.renovacareinc.com](http://www.renovacareinc.com). Information contained on our web site (or any other website) does not constitute part of this prospectus.

## **Risk Factors**

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 you should consider, you are urged to carefully review and consider the section titled "**Risk Factors**" beginning on page 9 of this prospectus.



Table of Contents

**THE OFFERING**

**Securities Being Registered:** 1,956,000 shares of common stock, consisting of:

(a) 946,000 shares of common stock that were purchased by the Selling Stockholders in a transaction with us pursuant to exemptions from the registration requirements of the Securities Act; and

(b) 1,010,000 shares of common stock issuable upon exercise of Series D Warrants that that were purchased by the Selling Stockholders in a transaction with us pursuant to exemptions from the registration requirements of the Securities Act allowing the holder to purchase shares of common stock at an exercise price of \$1.10 per share through June 5, 2020 (as of the date of this prospectus one Selling Stockholder has exercised her Series D Warrant resulting in the issuance of 100,000 shares of common stock for which we received proceeds of \$110,000).

**Offering Price:** The Selling Stockholders will determine at what price they may sell the offered shares, and such sales may be made at prevailing market prices, or at privately negotiated prices.

**Selling Stockholders:** The Selling Stockholders are existing stockholders who purchased shares of our common stock and warrants to purchase shares of our common stock, from us in a private transaction pursuant to exemptions from the registration requirements of the Securities Act. Please refer to the section titled "**Selling Stockholders**" of this prospectus.

**Shares Outstanding Prior to Completion of the Offering:** 70,274,264

**Authorized Capital Stock:** Our authorized capital stock consists of stock of 500,000,000 shares of common stock, par value of \$0.00001, and 10,000,000 shares of preferred stock, par value of \$0.0001. No preferred shares are issued and outstanding.

**Shares Outstanding upon Closing of the Offering:** Upon completion of the offering, we will have 71,184,264 shares outstanding, assuming the full exercise of all outstanding Series D Warrants, without giving effect to the exercise of any other outstanding warrants or options.

**OTCQB Symbol:** RCAR

**Transfer Agent:** Worldwide Stock Transfer, LLC, One University Plaza, Suite 505, Hackensack, NJ 07601.

**Risk Factors:** 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 you should consider, you are urged to carefully review and consider the section titled "**Risk Factors**" beginning on page 9 of this prospectus.

***Use of Proceeds:***

Although we will pay substantially all the expenses incident to the registration of the Shares, we will not receive any proceeds from the sales by the Selling Stockholders. We may, however, receive proceeds from the exercise of the Series D Warrants; if such proceeds are received by us, they will be used to fund the research and development of the CellMist™ System and for working capital and general corporate purposes. See "**Use of Proceeds.**"

***Duration of Offering:***

We intend to keep the registration statement, of which this prospectus is a part of, effective until the earlier of: (a) the date all of the Selling Stockholders' securities registered hereunder have been sold in accordance with this prospectus or with Rule 144, as promulgated under the Securities Act ("**Rule 144**"); (b) such securities become eligible for resale without volume or manner-of-sale restrictions and without current public information pursuant to Rule 144 as set forth in a written opinion letter to such effect, addressed, delivered and acceptable to our transfer agent as reasonably determined by us, upon the advice of our counsel; or (c) such securities have otherwise been disposed of by the Selling Stockholders pursuant to an exemption from the registration requirements of the Securities Act; however, we are under no obligation to maintain this registration effective and may withdraw it at any time.

Table of Contents**Selected Financial Data**

The following tables set forth a summary of certain selected consolidated financial data for the nine months ended September 30, 2016 and 2015 and for the fiscal years ended December 31, 2015 and 2014. Historical results are not necessarily indicative of the results that may be expected for any future period. The consolidated financial data below should be read in conjunction with "**Management's Discussion and Analysis of Financial Condition and Results of Operations**" and the consolidated financial statements and notes included elsewhere in this prospectus.

	<b>For the Nine Months Ended</b>	<b>For the Nine Months Ended</b>
	<b>September 30,</b>	<b>September 30,</b>
<b>Statements of Operations Data</b>	<b>2016 Unaudited</b>	<b>2015 Unaudited</b>
Revenue	\$ 0	\$ 0
Loss from operations	\$ (1,578,076)	\$ (778,158)
Basic and diluted net loss per share	\$ (0.02)	\$ (0.01)
Weighted average shares outstanding used in basic and diluted net loss per share calculation	69,695,772	67,048,351

	<b>For the Year Ended</b>	<b>For the Year Ended</b>
	<b>December 31, 2015</b>	<b>December 31, 2014</b>
<b>Statements of Operations Data</b>		
Revenue	\$ 0	\$ 0
Loss from operations	\$ (1,318,507)	\$ (2,131,396)
Basic and diluted net loss per share	\$ (0.02)	\$ (0.03)
Weighted average shares outstanding used in basic and diluted net loss per share calculation	67,233,254	66,575,122

	<b>For the Nine Months Ended</b>	<b>As of</b>	<b>As of</b>
	<b>September 30,</b>	<b>December 31,</b>	<b>December 31,</b>
<b>Balance Sheet Data</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>

Edgar Filing: RenovaCare, Inc. - Form S-1

**Unaudited**

Cash and cash equivalents	\$	687,747	\$	397,589	\$	683,098
Working capital	\$	582,029	\$	172,099	\$	489,609
Total asset	\$	852,631	\$	560,736	\$	853,400
Total liability	\$	251,320	\$	335,783	\$	379,062
Total stockholders' equity	\$	601,311	\$	224,953	\$	474,338

Table of Contents

**RISK FACTORS**

*An investment in our securities involves a high degree of risk. You should carefully consider the risks described below before purchasing any of the Shares. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading price of our common stock could decline, and you may lose all or part of your investment. You should acquire the shares to which this prospectus relates only if you can afford to lose your entire investment. You should also refer to the other information contained in this prospectus, including our financial statements and the notes to those statements, and the information set forth under the caption "Cautionary Note Regarding Forward-Looking Statements." The risks described below and contained in our other periodic reports are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations.*

**Risks Related To Our Business**

*We have experienced significant losses, have not generated any revenues and expect losses to continue for the foreseeable future.*

We are a development-stage company. We do not have any commercialized products and have not generated any revenue since inception and do not expect to generate any revenue for the foreseeable future. We had a net loss from continuing operations of \$1,318,507 and \$2,131,396 for our fiscal years ended December 31, 2015 and 2014, respectively, and we have incurred a cumulative deficit of \$9.0 million through December 31, 2015. We anticipate incurring losses through at least December 31, 2017.

*We may require additional financing to expand, accelerate or sustain our current level of operations beyond our current fiscal year, and failure to obtain such financing would have a material adverse effect on our business, operating results, financial condition and prospects.*

As of September 30, 2016, we had cash and cash equivalents of \$687,747. We anticipate that we will remain engaged in research and product development activities through at least December 31, 2017. Based upon our current level of operations and expenditures, we believe that absent any modification or expansion of our existing research, development and testing activities, cash on hand should be sufficient to enable us to continue operations through March 31, 2017. There is no assurance that we will be able to generate revenue and achieve profitability or secure additional financing once our current cash balance is depleted. Any significant expansion in scope or acceleration in timing of our current research and development activities, or commencement of any marketing and sales activities, will require additional funds.



If adequate funds, including proceeds, if any, from this offering are not available on reasonable terms or at all, it would result in a material adverse effect on our business, operating results, financial condition and prospects. In particular, we may be required to delay, reduce the scope of or terminate one or more of our research programs, sell rights to our CellMist™ System or other technologies or products based upon such technologies, or license the rights to such technologies or products on terms that are less favorable to us than might otherwise be available. If we raise additional funds by issuing equity or debt securities, further dilution to stockholders may result and new investors could have rights superior to existing stockholders.

*Even if financing is available to us, because we cannot currently estimate the amount of funds or time required to commercialize our technologies, we may secure less funding than is actually required to effectuate our business plan.*

We cannot accurately predict the amount of funding or the time required to successfully commercialize our CellMist™ System, or any products derived therefrom. The actual cost and time required to commercialize this technology may vary significantly depending on, among other things, the results of our research and development efforts, the cost of developing, acquiring, or licensing various enabling technologies, changes in the focus and direction of our research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing claims with respect to patents, the regulatory approval process and manufacturing, marketing and other costs associated with commercialization of these technologies. Because of this uncertainty, even if financing is available to us, we may secure insufficient funding to effectuate our business plan.

Table of Contents

***The success of our research and development activities is uncertain. If such efforts are not successful, we will be unable to generate revenues from our operations and we may have to cease doing business.***

Commercialization of our CellMist™ System will require significant further research, development and testing as we must ascertain whether the CellMist™ System can form the basis for a commercially viable technology or product. If our research and development fails to prove commercial viability of the CellMist™ System, we may need to abandon our business model and/or cease doing business, in which case our shares may have no value and you may lose your investment. We anticipate we will remain engaged in research and development, through at least December 2017.

***We currently rely on a single third party to conduct our development activities for our CellMist™ System.***

We currently rely on the services of StemCell Systems GmbH ("**StemCell Systems**") to conduct our development activities for our CellMist™ System. In the event they are unable to provide us with these services, we may need to expend a considerable amount of resources, time and money to locate another research lab which could have a material and adverse effect of our research and development activities, as well as our operating results and financial condition.

***We may not be eligible to receive certain grants because of our foreign ownership.***

In order to fund the ongoing research and development of our CellMist™ System we may apply for grants. In order to be eligible to receive certain of these grants, particularly those administered by the U.S. federal government, at least 50% of the outstanding shares of a company must be owned by residents of the U.S. Because our majority shareholder is not a U.S. resident, we may not be eligible to receive such grants.

***The development of our CellMist™ System is subject to the risks of failure inherent in the development of any novel technology.***

Ultimately, the development and commercialization of our CellMist™ System is subject to a number of risks that are particular to the development and commercialization of any novel technology. These risks include, but are not limited to, the following:

we may fail to develop, acquire, or license various enabling technologies that may be integral to the commercialization of the CellMist™ System (or any derivatives);

*If we fail to manage our growth effectively, our business could be disrupted.*

Our future financial performance and ability to successfully commercialize our products, of which there is no guarantee, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We expect to make significant investments to enable our future growth through, among other things, new product development, clinical trials for new indications and expansion of our marketing and sales infrastructure. Any failure to manage future growth effectively could have a material adverse effect on our business and results of operations.

Table of Contents

***We could be subject to product liability lawsuits, which could result in costly and time-consuming litigation and significant liabilities.***

The development of medical device products, such as our CellMist™ System, involves an inherent risk of product liability claims and associated adverse publicity. Any products we may develop may be found to be harmful or to contain harmful substances. This exposes us to substantial risk of litigation and liability or may force us to discontinue production of certain products. There can be no assurance that we will be able to obtain or maintain insurance on reasonable terms or to otherwise protect ourselves against potential product liability claims that could impede or prevent commercialization of any products we may develop and commercialize. Furthermore, a product liability claim could damage our reputation, whether or not such claims are covered by insurance or are with or without merit. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect on our business or financial condition. Furthermore, product liability lawsuits, regardless of their success, would likely be time consuming and expensive to resolve and would divert management's time and attention, which could seriously harm our business.

***In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how.***

We rely on proprietary information (such as trade secrets, know-how and confidential information) to protect intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. We generally seek to protect this proprietary information by entering into confidentiality agreements, or consulting, services or employment agreements that contain non-disclosure and non-use provisions with our employees, consultants, contractors, scientific advisors and third parties. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information.

We have limited control over the protection of trade secrets used by our suppliers and service providers and could lose future trade secret protection if any unauthorized disclosure of such information occurs. In addition, our proprietary information may otherwise become known or be independently developed by our competitors or other third parties. To the extent that our employees, consultants, contractors, scientific advisors and other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our and relevant third parties' proprietary rights, failure to obtain or maintain protection for our proprietary information could adversely affect our competitive business position and if third parties are able to establish that we are using their proprietary information without their permission, we may be required to obtain a license to that information, or if such a license is not available, re-design our products to avoid any such unauthorized use or temporarily delay or permanently stop manufacturing or sales of the affected products. Furthermore, laws regarding trade secret rights in certain markets where we may operate may afford little or no protection to our trade secrets.

*In seeking to acquire or develop technologies, we are operating in highly competitive markets and our competitors enjoy numerous competitive advantages over us.*

Our commercial success will depend on our ability to compete effectively in product development areas such as, but not limited to, safety, efficacy, ease of use, customer compliance, price, marketing and distribution. Our competitors may succeed in developing products that are more effective than any products derived from our research and development efforts or that would render such products obsolete and non-competitive. The skin care and wound care industry is characterized by intense competition, rapid product development and technological change. Most of the competition that we encounter is expected to come from companies, research institutions and universities who are researching and developing technologies and products similar to or competitive with any we may develop.

Table of Contents

These companies enjoy numerous competitive advantages, including:

- significantly greater name recognition;
- established relations with customers;
- established distribution networks;
- more advanced technologies and product development;
- additional lines of products, and the ability to offer rebates, higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, obtaining regulatory approval for products, and marketing approved products;
- greater financial and human resources for product development, sales and marketing, and
- the ability to endure potentially prolonged patent litigation.

As a result, we may not be able to compete effectively against these companies or their products.

***To the extent we are able to develop and commercialize products based upon or derived from our CellMist™ System and underlying technology, if such products do not gain market acceptance, we may not achieve sales and market share.***

Even if we are able to develop and commercialize one or more products based upon or derived from the CellMist™ System and underlying technology, of which there is no guarantee, the development of a successful market for our products may be adversely affected by a number of factors, some of which are beyond our control, including:

- customer acceptance of our products;
- obtaining third-party coverage or reimbursement for our products;
- performance and reliability of our products as compared with other alternative products;
- the ability to offer our products for sale at an attractive value and the willingness of physicians to administer our products and their acceptance as part of the medical department routine;

- the prevalence and severity of any side effects;
- the efficacy, potential advantages and timing of introduction to the market of alternative treatments; and
- our failure to develop and maintain successful relationships with health care professionals, manufacturers, distributors, and other resellers, as well as strategic partners.

Failure to achieve market acceptance for any of our products, if and when they are approved for commercial sale, will have a material adverse effect on our business, financial condition and results of operations.

***We may be unsuccessful in commercializing our products due to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives.***

We cannot predict the pricing and reimbursement of any products we may develop and commercialize. The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. In some foreign jurisdictions, including the European Union, the pricing of medical devices and treatments is subject to governmental control. In these jurisdictions, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate.

As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in any products we may develop and commercialize, even after obtaining regulatory approval.

Table of Contents

Additionally, we cannot be sure that reimbursement will be available for any products we may develop and commercialize, or if reimbursement is available, what the level of reimbursement will be. Reimbursement may affect the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for any products we may develop and commercialize may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any products that we successfully develop. Eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services.

*Clinical medical device development is a lengthy and expensive process, with an uncertain outcome.*

We intend to develop and commercialize pipeline products based on our CellMist™ System and underlying technology. However, before obtaining regulatory approval for the sale of for any products we may develop and commercialize, we must conduct, at our own expense, clinical studies to demonstrate that the products are safe and effective.

Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process. Even if preclinical or clinical trials are successful, we still may be unable to commercialize the product, as success in preclinical trials, early clinical trials, or previous clinical trials, does not ensure commercial acceptance.

Similar or other events could delay or prevent our ability to complete necessary clinical trials for our pipeline products, including:

- regulators may not authorize us to conduct a clinical trial within a country or at a prospective trial site or may change the design of a study;
- delays may occur in reaching agreement on acceptable clinical trial terms with regulatory authorities or prospective sites, or obtaining institutional review board approval;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional trials or to abandon strategic projects;
-



the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we expect, or patients may not participate in necessary follow-up visits to obtain required data, any of which would result in significant delays in our clinical testing process;

- our third-party contractors, such as a research institution, may fail to comply with regulatory requirements or meet their contractual obligations to us;
- we may be forced to suspend or terminate our clinical trials if the participants are being exposed, or are thought to be exposed, to unacceptable health risks or if any participant experiences an unexpected serious adverse event;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;
- the cost of our clinical trials may be significantly greater than we anticipate;
- an audit of preclinical or clinical studies by regulatory authorities may reveal noncompliance with applicable protocols or regulations, which could lead to disqualification of the results and the need to perform additional studies; and
- delays may occur in obtaining our clinical materials.

Moreover, we do not know whether preclinical tests or clinical trials will begin or be completed as planned or will need to be restructured. Significant delays could also shorten the patent protection period during which we may have the exclusive right to commercialize our products or could allow our competitors to bring products to the market before we do, impairing our ability to commercialize our products.

Table of Contents

***Development and commercialization of any products requires successful completion of the regulatory approval process, and may suffer delays or fail.***

In the U.S., as well as other jurisdictions, we will be required to apply for and receive marketing authorization before we can market our products. This process can be time consuming and complicated and may result in unanticipated delays. To secure marketing authorization, an applicant generally is required to submit an application that includes the data supporting preclinical and clinical safety and efficacy as well as detailed information on the manufacturing and control of the product, proposed labeling and other additional information. Before marketing authorization is granted, regulatory authorities generally require the inspection of the manufacturing facility or facilities and quality systems (including those of third parties) at which the product candidate is manufactured and tested, as well as potential audits of the non-clinical and clinical trial sites that generated the data cited in the marketing authorization application.

We cannot predict how long the applicable regulatory authority or agency will take to grant marketing authorization or whether any such authorizations will ultimately be granted. Regulatory agencies, including the Food and Drug Administration (the “FDA”), have substantial discretion in the approval process, and the approval process and the requirements governing clinical trials vary from country to country. The policies of the FDA or other regulatory authorities may change or may not be explicit, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any products we may develop and commercialize. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S., Europe or elsewhere. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Additionally, any regulatory approval that we receive may also contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate. Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post-marketing information and reports, registration and continued compliance with good manufacturing practices for any clinical trials that we conduct post-approval.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or result in significant negative consequences following marketing approval, if any.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable

foreign regulatory authorities could order us to cease further development of or deny approval for our product candidates for any or all targeted indications. Any related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;

Table of Contents

***We may be subject to product liability claims and we do not currently maintain product liability insurance.***

The manufacture and sale of medical devices and other therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. If we manage to commercialize the CellMist™ System or its underlying technology we may become subject to product liability claims or liabilities in the future, including if patients die, or suffer some other serious adverse effect whether or not such patients were predisposed to adverse outcomes.

Any product liability claims could have a material negative effect on the market acceptance and sales of our products. We currently do not maintain any product liability insurance. We do not know if we will be able to obtain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may not be available on acceptable terms or at all. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to continue to develop or commercialize our products or any product candidates that may receive regulatory approval in the future. A successful product liability claim brought against us in excess of our insurance coverage, if any, may require us to make substantial payments. This could adversely affect our cash position and results of operations and could increase the volatility of our stock price.

***Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product candidate in other jurisdictions.***

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a drug candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

***We may fail to obtain regulatory approval for our product candidates.***

Our potential product candidates could fail to receive regulatory approval for many reasons, including one or more of the following:

- της ΦΔΑ ορ χομπαρβλε φορειγν ρεγυλατορψ αυτηοριτιεσ μαψ δισαγρεε ωιτη τηε δεσιγν ορ ιμπλεμεντατιον οφ ουρ χλινιχαλ τριαλσ ορ τηε παλιδατιον οφ ουρ χαρεγιωερ ανδ πατιεντ ρεπορτεδ ουτχομε ινστρυμεντσ;

Table of Contents

***Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.***

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Health Care Reform Law, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. healthcare industry. The Health Care Reform Law, among other things, (i) subjects biologic products to potential competition by lower-cost biosimilars, (ii) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, (iii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and (v) promotes a new Medicare Part D coverage gap discount program.

In addition, other legislative changes have been proposed and adopted in the U.S. since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

***We are subject to extensive environmental, health and safety, and other laws and regulations.***

Although our business involves the controlled use of biological materials, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any such chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures. Additional or more stringent laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits required pursuant to such laws and regulations, including costs to install new or updated pollution control equipment, modify our operations or perform other corrective actions at our respective facilities. In addition, fines and penalties may be imposed for

noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents.

Table of Contents

***We face competition from the existing standard of care and potential changes in medical practice and technology and the possibility that our competitors may develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours.***

The medical, biotechnology and pharmaceutical industries are intensely competitive and subject to significant technological and practice changes. We may face competition from many different sources with respect to any products we may develop and commercialize. Possible competitors may be medical practitioners, pharmaceutical, biotechnology, medical device, and wound care companies, academic and medical institutions, governmental agencies and public and private research institutions, among others. Should any competitor's product candidates receive regulatory or marketing approval prior to ours, they may establish a strong market position and be difficult to displace, or will diminish the need for our products.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products, treatments or procedures that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product that we may develop. Many of our current or future competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we may have. Mergers and acquisitions in the pharmaceutical, medical device, and biotechnology industries or wound care markets may result in even more resources being concentrated among a smaller number of our competitors. Other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***We may compete for the time and efforts of our officers and directors.***

Certain of our officers and directors are also officers, directors, and employees of other companies and we may have to compete with the other companies for their time, attention and efforts. Our officers provide us their services on a part-time basis and none of our directors anticipate devoting more than approximately five (5%) percent of their working time to our matters.

***We maintain at-will consulting agreements with our officers that may be terminated by us or the respective officer at any time and for any reason.***

We maintain at-will consulting agreements with our officers that may be terminated by us or the respective officer at any time and for any reason. If any of our officers terminate their consulting agreement it may have a material adverse



effect on our business, financial condition or ability to operate.

***Our growth and success depends on our ability to attract and retain additional highly qualified and skilled sales and marketing, research and development, operational, managerial and finance personnel.***

Our growth and success depends on our ability to attract and retain additional highly qualified and skilled sales and marketing, research and development, operational, managerial and finance personnel. Competition for skilled personnel is intense and the unexpected loss of an employee with a particular skill could materially adversely affect our operations until a replacement can be found and trained. If we cannot attract and retain skilled scientific and operational personnel, as required, for our research and development and manufacturing operations on acceptable terms, we may not be able to develop and commercialize any products we may develop and commercialize. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

Table of Contents

**Risks Related To Ownership of Our Common Stock and This Offering**

*The trading price of our common stock historically has been volatile and may not reflect its actual value.*

The trading price of our common stock has, from time to time, fluctuated widely and in the future may be subject to similar fluctuations. The trading price may be affected by a number of factors including the risk factors set forth herein, as well as our operating results, financial condition, general economic our control. In recent years, broad stock market indices in general, and smaller capitalization companies in particular, have experienced substantial price fluctuations. In a volatile market, we may experience wide fluctuations in the market price of our common stock. These fluctuations may have a negative effect on the market price of our common stock. In addition, the sale of our common stock into the public market upon the effectiveness of this registration statement could put downward pressure on the trading price of our common stock.

*The sale by our stockholders of restricted shares, either pursuant to a resale prospectus or Rule 144, may adversely affect our ability to raise the funds we will require to effectuate our business plan.*

As of the date of this prospectus we had 70,274,264 shares issued and outstanding, of which 46,015,713 are deemed “restricted securities” within the meaning of Rule 144. The possibility that substantial amounts of our common stock may be sold into the public market, either under Rule 144, or pursuant to a resale registration statement, 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 because of the perception that future resales could decrease our stock price and because of the availability of resale shares to those interested in investing in our common stock.

*Our common stock is a penny stock and is not traded on a national securities exchange; therefore you may find it difficult to sell shares of our common stock you may acquire in this offering.*

Our common stock is traded on the OTCQB. The OTCQB is viewed by most investors as a less desirable, and less liquid, marketplace. As a result, an investor may find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of our common stock.

Additionally, our common stock is subject to regulations of the SEC applicable to “penny stock.” Penny stock includes any non-NASDAQ equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. Rules 15g-1 through 15g-9 under the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), imposes certain sales practice requirements on broker-dealers who sell our common stock to persons other than established

customers and “accredited investors” (as defined in Rule 501(a) of the Securities Act). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser’s written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell our common stock and purchasers of our common stock to sell their shares of our common stock.

In addition, the penny stock regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule proscribed by the SEC relating to the penny stock market must be delivered by a broker-dealer to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-dealer and the registered representative and current price quotations for our common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements adversely affect the market liquidity of our common stock.

***Although our common stock is currently quoted on the OTCQB, if we do not meet or comply with the recent rule changes to the OTCQB our shares may be delisted from the OTCQB and would likely be traded on the OTC Pink (aka the Pink Sheets).***

Although our common stock is currently quoted on the OTCQB, effective as of May 1, 2014, the OTC Markets Group Inc. changed its rules for OTCQB eligibility. To be eligible for OTCQB, companies will be required to:

- meet a minimum bid price test of \$0.01. Securities that do not meet the minimum bid price test will be downgraded to OTC Pink;

In the event we do not submit an annual certification and pay the annual fee our common stock will likely be downgraded to the OTC Pink, which could adversely affect the market liquidity of our common stock.

Table of Contents

***Kalen Capital Corporation (“KCC”), a private corporation solely owned by Mr. Harmel Rayat, beneficially owns approximately 67% of our issued and outstanding stock. This ownership interest may permit KCC to influence significant corporate decisions.***

As of the date of this prospectus, KCC, a private corporation solely owned by Harmel S. Rayat, a former officer and director of ours, beneficially owned approximately 51,227,337 shares (including shares issuable upon exercise of outstanding warrants and convertible note), or approximately 67%, of our outstanding common stock. As a result, Mr. Rayat may be able to exercise significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant control over our management and policies. Mr. Rayat’s interests may be different from yours. For example, he may support proposals and actions with which you may disagree or which are not in your interest. This concentration of ownership could delay or prevent a change in control of our company or otherwise discourage a potential acquirer from attempting to obtain control of our company, which in turn could reduce the price of our common stock. In addition, Mr. Rayat could use his voting influence to maintain our existing management and directors in office, or support or reject other management and board proposals that are subject to stockholder approval, such as the adoption of employee stock plans and significant unregistered financing transactions.

***There is a loan in the principal amount of \$700,000 outstanding that we do not currently have the funds to repay.***

On September 9, 2016, we entered into a loan agreement (the “**Loan Agreement**”) with KCC pursuant to which KCC agreed to loan us up to \$900,000, of which we received \$700,000, at an annual interest rate of 7% per year, compounded quarterly and a maturity date of December 31, 2017; we do not currently have sufficient funds to repay this loan.

***There are options to purchase shares of our common stock currently outstanding.***

As of the date of this prospectus we have granted options to purchase shares of our common stock to various persons and entities, under which we could be obligated to issue up to 425,000 shares of our common stock. The exercise prices of these options range from \$0.65 to \$2.28 per share. If issued, the shares underlying these options would increase the number of shares of our common stock currently outstanding and dilute the holdings and voting rights of our then-existing stockholders.

***There are warrants to purchase shares of our common stock currently outstanding.***

As of the date of this prospectus we have issued warrants to purchase shares of our common stock to various persons and entities, under which we could be obligated to issue up to 7,040,503 shares of common stock. The exercise prices of these warrants are: (1) \$0.35 per share for the 720,000 Series A Warrant (240,000 shares of which have vested and are unexercised as of the date hereof); (2) \$0.46 per share for the 1,326,087 shares issuable upon exercise of the Series B Warrant; (3) \$0.49 for the 3,500,000 shares issuable upon exercise of the Series C Warrant; (4) \$1.10 for the 910,000 shares issuable upon exercise of the Series D Warrants; and (5) the lesser of (i) \$1.54 or (ii) a twenty percent (20%) discount to the average closing price of our common stock as quoted on the OTCQB for the five (5) days prior to the date on which the holder elects to exercise the warrant for the 584,416 shares issuable upon exercise of the Series E Stock Purchase Warrant (the “**Series E Warrant**”). If issued, the shares underlying the warrants would increase the number of shares of our common stock currently outstanding and dilute the holdings and voting rights of our then-existing stockholders.

*We may issue preferred stock which may have greater rights than our common stock.*

Our Articles of Incorporation allow our Board of Directors (the “**Board**”) to issue up to 10,000,000 shares of preferred stock. Currently, no shares of preferred stock are issued and outstanding. However, we can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from the holders of our common stock. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation premiums and may have greater voting rights than our common stock. In addition, such preferred stock may contain provisions allowing it to be converted into shares of common stock, which could dilute the value of our common stock to then current stockholders and could adversely affect the market price, if any, of our common stock.

Table of Contents

***We have entered into a registration rights agreement with KCC requiring us to register all the shares owned by KCC as of November 29, 2013 (the “11/29 Financing”), including all shares issuable upon conversion of any warrants then owned by KCC. If we fail to timely file the registration statements we will be obligated to issue additional shares of our common stock to KCC.***

As part of the 11/29 Financing, we entered into the Registration Rights agreement with KCC pursuant to which we agreed to file such number of registration statements as required to register for resale with the SEC all the shares owned by KCC as of November 29, 2013, including all shares issuable upon conversion of any warrants then owned by KCC. The first registration statement that we are obligated to file covers the shares and warrants issued to KCC as part of the 11/29 Financing. If we fail to timely file the registration statements we will be obligated to issue additional shares of our common stock to KCC. In the event the we fail to file a registration statement in the time period required, we will issue to KCC additional shares of our common stock equal to 5% of the shares of our common stock that were to be registered for every thirty day period for which we fail to file such registration statement, subject to proration for any portion of such thirty day period and up to a maximum number of shares of our common stock equal to 25% of the number of shares of our common stock that were to be registered. Additionally, in the event we fail to cause a registration statement to be declared effective within ninety days from the date of filing, we will issue to KCC additional shares of our common stock equal to 2.5% of the shares of our common stock that were to be registered for every thirty day period for which we fail to cause the SEC to declare such registration statement effective, subject to proration for any portion of such thirty day period and up to a maximum number of shares of our common stock equal to 10% of the number of shares of common stock included in such registration statement. We timely filed the initial registration statement that we were required to file on behalf of KCC.

***Our compliance with changing laws and rules regarding corporate governance and public disclosure may result in additional expenses to us which, in turn, may adversely affect our ability to continue our operations.***

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and, in the event we are ever approved for listing on a registered national exchange, such exchange’s rules, will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our failure to adequately comply with any of these laws, regulations, standards or rules may result in substantial fines or other penalties and could have an adverse impact on our ongoing operations.

***Because we do not intend to pay dividends for the foreseeable future you should not purchase our shares if you are seeking dividend income.***

We currently intend to retain future earnings, if any, to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize their investment. Investors seeking cash dividends should not purchase the shares offered by us pursuant to this prospectus.

Table of Contents

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains certain "forward-looking statements," as well as information relating to the Company 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 prospectus 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;

The reader is cautioned that no statements contained in this prospectus 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 have little likelihood of long-term success unless we are able to continue to raise capital from the sale of our securities or financing from other sources until, if ever, we generate positive cash flow from operations.**

**USE OF PROCEEDS**



This prospectus relates to the resale of certain shares of our common stock that may be offered and sold from time to time by the Selling Stockholders. This prospectus also relates to shares of our common stock to be issued to the Selling Stockholders upon exercise of outstanding Series D Warrants. We will not receive any proceeds from the sale of shares of our common stock in this offering. We may, however, receive proceeds from the exercise of the Series D Warrants, unless they are exercised on a "cashless basis." We will use the proceeds, if any, from the exercise of the Series D Warrants to fund the research, development and commercialization of the CellMist™ System and for general working capital.

#### **DETERMINATION OF OFFERING PRICE**

The Selling Stockholders will determine at what price they may sell the offered shares, and such sales may be made at prevailing market prices, or at privately negotiated prices. The Series D Warrants are exercisable at a per share price of \$1.10 per share through June 5, 2020. The exercise price of the Series D Warrants has been arbitrarily determined by us, and bears no significant relationship to our assets, earnings, book value or any other objective standard of value. **Please refer to "Plan of Distribution."**

Table of Contents

**MARKET PRICE OF AND DIVIDENDS ON OUR COMMON STOCK  
AND RELATED STOCKHOLDER MATTERS**

Our common stock is quoted on the OTCQB under the symbol "RCAR." Our warrants are not currently traded on any market. The closing price of our common stock as quoted on the OTCQB on January 20, 2017, was \$2.44.

As of the date of this prospectus there were 70,274,264 shares of our common stock outstanding and held by approximately 320 stockholders of record. A portion of our common stock is held in "street name" or by beneficial holders, whose shares are held of record by banks, brokers, and other financial institutions.

The following table sets forth the range of high and low bid prices for our common stock for each quarter during the past two fiscal years as reported on the OTCQB:

<b>Fiscal Year Ended December 31, 2015</b>		<b>High</b>		<b>Low</b>
First Quarter (January 1 - March 31, 2015)	\$	1.50	\$	0.81
Second Quarter (April 1 – June 30, 2015)	\$	1.45	\$	1.25
Third Quarter (July 1 – September 30, 2015)	\$	2.26	\$	1.26
Fourth Quarter (October 1 – December 31, 2015)	\$	2.18	\$	1.50

<b>Fiscal Year Ended December 31, 2014</b>		<b>High</b>		<b>Low</b>
First Quarter (January 1 - March 31, 2014)	\$	1.90	\$	0.85
Second Quarter (April 1 – June 30, 2014)	\$	1.10	\$	0.90
Third Quarter (July 1 – September 30, 2014)	\$	1.40	\$	0.80
Fourth Quarter (October 1 – December 31, 2014)	\$	1.10	\$	0.60

**Dividend Policy**

We have not paid any dividends on our common stock and our Board presently intends to continue a policy of retaining earnings, if any, for use in our operations. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by the Board in light of conditions then existing, including earnings, financial condition, capital requirements and other factors.

The Nevada Revised Statutes prohibit us from declaring dividends where, if after giving effect to the distribution of the dividend:

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

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

### **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our results and the timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this prospectus.*

Table of Contents**Results of Operations*****Three and Nine Months Ended September 30, 2016 Compared with the Three and Nine Months Ended September 30, 2015*****Operating Expenses**

A summary of our operating expense for the three and nine months ended September 30, 2016 and 2015 follows:

**Three Months Ended**

	<b>September 30,</b>		<b>Increase /</b>	<b>Percentage</b>
	<b>2016</b>	<b>2015</b>	<b>(Decrease)</b>	<b>Change</b>
Operating expense				
Research and development	\$ 45,381	\$ 80,667	\$ (35,286)	-44%
General and administrative	210,881	197,484	13,397	7%
Stock compensation	12,951	18,879	(5,928)	-31%
Total operating expense	\$ 269,213	\$ 297,030	\$ (27,817)	-9%

**Nine Months Ended**

	<b>September 30,</b>		<b>Increase /</b>	<b>Percentage</b>
	<b>2016</b>	<b>2015</b>	<b>(Decrease)</b>	<b>Change</b>
Operating expense				
Research and development	\$ 231,013	\$ 192,292	\$ 38,721	20%
General and administrative	1,059,825	546,324	513,501	94%
Stock compensation	287,238	39,542	247,696	626%
Total operating expense	\$ 1,578,076	\$ 778,158	\$ 799,918	103%

***Research and Development***

Research and development (“**R&D**”) costs represent costs incurred to develop our CellIM<sup>TM</sup> System and are incurred pursuant to agreements with third party providers. R&D costs are expensed when incurred. R&D costs decreased during the three months ended September 30, 2016 compared to 2015, as a result of the timing of certain of our R&D expenses, which we expect will increase in the fourth quarter. R&D costs increased during the nine months ended

September 30, 2016 compared to 2015 as a result of increased expenditures made in anticipation of our FDA and other regulatory filings.

*General and Administrative*

General and administrative costs include all expenditures incurred other than research and development related costs, including costs related to personnel, professional fees, travel and entertainment, public company costs, insurance and other office related costs. Costs increased during the three and nine months ended September 30, 2016 compared to 2015 due primarily to an investor outreach and branding program, increase in legal fees related to the drafting of a master clinical trial agreement and higher personnel costs.

**Other Income (Expense)**

Other income and expense primarily 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.

Table of Contents*Year Ended Year Ended December 31, 2015 (Fiscal 2015) versus December 31, 2014 (Fiscal 2014)*

	<b>For the Years Ended December 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>\$ change</b>	<b>% change</b>
Operating expenses				
Research and development	\$ 281,218	\$ 975,667	(694,449)	(71.2)
General and administrative	1,037,289	1,155,729	(118,440)	(10.2)
Net loss	\$ (1,318,507)	\$ (2,131,396)	\$ (812,889)	(38.1)

*Continuing Operations*

Our expenses consist primarily of research and development expenses, professional fees and administrative costs. For the years ended December 31, 2015 and 2014, general and administrative expenses were \$1,037,289 and \$1,155,729, respectively. The decrease in general and administrative fees in 2015 of \$118,440 was due primarily to a decrease of \$355,333 in legal and consulting fees related to the acquisition of the wound care technology, offset in part by a \$170,988 increase in public and investor relations costs and a \$90,748 increase in compensation and related expenses. Research and development expenses related to our CellMist™ System were \$281,218 in 2015 and \$975,667 in 2014. The decrease of \$694,449 related primarily to the \$837,219 decrease in expenses related to the amendment of the APA, offset in part by a \$143,709 increase in costs associated with the development of the CellMist™ System.

As a result of the foregoing, net loss from continuing operations for the years ended December 31, 2015 and 2014 was \$(1,318,507) and \$(2,131,396), respectively.

**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 September 30, 2016, we had cash of \$687,747 (December 2015: \$397,589) and working capital of \$582,029 (December 2015: \$172,099). Total liabilities as of September 30, 2016 were \$251,320 (December 2015: \$335,783).

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 \$10.6 million. We require additional funds to meet our obligations and maintain our operations. We have sufficient working capital to (i) pay our administrative and general operating expenses through March 31, 2017, and (ii) to conduct our preliminary research and development programs through that date. 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 and/or debt borrowing) 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 \$1,409,842 during the nine months ended September 30, 2016, compared to net cash used in operating activities of \$787,206 during the nine months ended September 30, 2015.

Net cash provided by financing activities was \$1,700,000 during the nine months ended September 30, 2016, compared to \$1,010,000 during the nine months ended September 30, 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.

## Table of Contents

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.

## **Dividends**

We have neither declared nor paid any dividends on its 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**

Fair value estimates of financial instruments are made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of significant judgment, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair value.

The carrying value of cash and cash equivalents, contract and contribution payable, accounts payable, note payable and accrued expenses approximate their fair value because of the short-term nature of these instruments.

Management is of the opinion that we are not exposed to significant interest or credit risks arising from these financial instruments.

## **Market Risk Disclosures**

We have not entered into derivative contracts either to hedge existing risks or for speculative purposes during or subsequent to the periods presented.



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

We do not have any off-balance sheet arrangements or contractual obligations at September 30, 2016, and the subsequent period to through the date of this prospectus, 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 attached hereto.

Table of Contents

**DESCRIPTION OF OUR BUSINESS AND PROPERTY**

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, 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 Cell Mist™ System is comprised of (a) the CellMist™ Solution, a treatment methodology for cell isolation for the regeneration of human skin cells and (b) the SkinGun™, a solution sprayer device 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 development of our CellMist™ System is in the early stage and we anticipate that we will be required to expend significant time and resources to further develop our technology and determine whether a commercially viable product can be developed. Research and development of new technologies involves a high degree of risk and there is no assurance that our development activities will result in a commercially viable product. The long-term profitability of our operations will be, in part, directly related to the cost and success of our development programs, which may be affected by a number of factors.

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

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

We are currently evaluating the potential of our CellMist™ System in the treatment of tissue that has been subject to severe trauma such as second degree burns. In recent years physicians have treated burn patients using our technology

under innovative practice and experimental studies and the CellMist™ System has shown the ability to regenerate human skin. The CellMist™ System utilizes the patient's own skin stem cells, reduces the size of the donor site, and has shown to significantly decrease scarring. Furthermore, we believe the CellMist™ System could enable treatment of other skin disorders with minimal scarring.

## **Our Market Opportunity**

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

### ***Burn Wounds***

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

## Table of Contents

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

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

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

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

## ***Our Technology***

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

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

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

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

#### *Domestic Regulation*

Governmental authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products or devices such as those we are attempting to develop. Our device candidates, to the extent they are developed, will 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.

Table of Contents

**Premarket Approval**

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.

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

**Investigational Device Exemption ("IDE")**

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

*HIPAA Requirements*

Other federal legislation may affect our ability to obtain certain health information in conjunction with any research activities we conduct. The Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable

health information. In relevant part, the U.S. Department of Health and Human Services ("**HHS**"), has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research.

*Other U.S. Regulatory Requirements*

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

## Table of Contents

### *International Regulation*

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

### **Competition**

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

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

### **Strategy**

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

- initiating a series of clinical trials to determine the CellMist™ System's efficacy for treating wounds and burns;



- formalizing collaborations with universities and scientific partners;
- creating a network of clinical and research partners;
- achieving FDA and other regulatory approval; and
- expanding the range of possible applications.

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.

Table of Contents

**Employees**

We currently have one full time employee, Mr. Andrew Danielson, Director of Operations, and four part-time contractors: Mr. Thomas Bold, President and Chief Executive Officer and Interim Chief Financial Officer; Ms. Patsy Trisler, Vice-President Clinical & Regulatory Affairs; Ms. Michaela Purcell and Dr. Roger Esteban-Vives, Director of Cell Sciences.

**Our Office Facilities**

Our corporate office is located at 430 Park Avenue, Suite 702, New York, New York 10022. This office space is provided to us on a complimentary basis by one of our directors. We also have a lease agreement for an office in Pittsburgh, PA where our full time employee is based.

**Legal Proceedings**

We are not party to nor are we aware of any material pending lawsuit, litigation or proceeding.

**DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS**

The following table sets forth the names and ages of all of our directors and executive officers. We have a Board comprised of two members. Each director holds office until a successor is duly elected or appointed. Executive officers serve at the discretion of the Board and are appointed by the Board.

<b>Name</b>	<b>Age</b>	<b>Current Position With Us</b>	<b>Director or Officer Since</b>
Thomas Bold	55	President and Chief Executive Officer	December 2013

**Biographical Information**

Set forth below are the names of all of our directors and executive officers, all positions and offices held by each person, the period during which each has served as such, and 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:

### **Current Directors and Officers**

**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.

Table of Contents

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

**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.

**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.

**Family Relationships and Other Matters**

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

### **Legal Proceedings**

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

### **SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

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.

Table of Contents

**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. A copy of our Code of Ethics may be obtained at no charge by sending a written request to our President and Chief Executive Officer, Thomas Bold, 430 Park Avenue, Suite 702, New York, New York 10022.

**CORPORATE GOVERNANCE**

We have adopted Corporate Governance Guidelines applicable to our Board. Our Corporate Governance Guidelines will be available on our website upon its completion. A copy of our Corporate Governance Guidelines may be obtained at no charge by sending a written request to our President and Chief Executive Officer, Thomas Bold, 430 Park Avenue, Suite 702, New York, New York 10022.

**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.

**Board Leadership Structure**

We currently have three executive officers and two directors. Our Board has reviewed our current Board leadership structure in light of the composition of the Board, our size, the nature of our business, the regulatory framework under

which we operate, our stockholder base, our peer group and other relevant factors, and has determined that this structure is currently the most appropriate Board leadership structure for our company. Nevertheless, the Board intends to carefully evaluate from time to time to determine what the Board believes is best for us and our stockholders.

### **Board Role in Risk Oversight**

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

Table of Contents

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

During the fiscal year ended December 31, 2015, the Board held a total of eight (8) meetings, including actions by written consent. All members of the Board attended 100% of all meetings of the Board. We do not maintain a policy regarding director attendance at annual meetings and we did not have an annual meeting during the fiscal year ended December 31, 2015.

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

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

While the Board is solely responsible for the selection and nomination of directors, the Board may consider nominees recommended by stockholders as it deems appropriate. The Board evaluates each potential nominee in the same manner regardless of the source of the potential nominee's recommendation. Although we do not have a policy regarding diversity, the Board does take into consideration the value of diversity among Board members in background, experience, education and perspective in considering potential nominees for recommendation to the Board for selection. Stockholders who wish to recommend a nominee should send nominations to our Chief Executive Officer, Thomas Bold, 430 Park Avenue, Suite 702, New York, NY 10022, that include all information relating to such person that is required to be disclosed in solicitations of proxies for the election of directors. The recommendation must be accompanied by a written consent of the individual to stand for election if nominated by the Board and to serve if elected.

**Compensation Consultants**

We have not historically relied upon the advice of compensation consultants in determining Named Executive Officer compensation. Instead, the full Board reviews compensation levels and makes adjustments based on their personal knowledge of competition in the market place, publicly available information and informal surveys of human resource professionals.



## **Stockholder Communications**

Stockholders who wish to communicate with the Board may do so by addressing their correspondence to: RenovaCare, Inc., Attention: Board of Directors, 430 Park Avenue, Suite 702, New York, New York 10022. The Board will review and respond to all correspondence received, as appropriate.

## **COMPENSATION OF DIRECTORS**

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

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

Effective as of August 1, 2013, we agreed to pay non-employee directors an annual fee of \$6,000 for their services, paid quarterly. Directors are entitled to participate in, and have been issued options under, our 2013 Long-Term Stock Incentive Plan.

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

Table of Contents

Name		Fees earned or paid in cash <sup>(1)</sup>	Stock awards	Option awards	Non-equity incentive plan compensation	Nonqualified Deferred compensation earnings	All other compensation <sup>(2)</sup>	Total
			Aggregate Grant Date Fair Value	Aggregate Grant Date Fair Value				
J o s e p h Sierchio <sup>(3)</sup>	2015	\$ 6,000	\$ Nil	\$ 3,716	\$ Nil	\$ Nil	\$ Nil	\$ 9,716
	2014	\$ 6,000	\$ Nil	\$ 11,890	\$ Nil	\$ Nil	\$ Nil	\$ 17,890
K e n n e t h Kirkland	2015	\$ 6,000	\$ Nil	\$ 3,716	\$ Nil	\$ Nil	\$ Nil	\$ 9,716
	2014	\$ 6,000	\$ Nil	\$ 11,890	\$ Nil	\$ Nil	\$ Nil	\$ 17,890

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

(2) The amounts in this column represent stock-based compensation expense granted to Messrs. Kirkland and Sierchio.

(3) The amounts set forth in this table do not include fees paid to Satterlee Stephens LLP or Sierchio & Partners, LLP, the firm's current and former legal counsel, respectively, of which Mr. Sierchio is, and was, a partner.

### EXECUTIVE COMPENSATION

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

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

- attract and retain executives experienced in developing and delivering products such as our own;
- motivate and reward executives whose experience and skills are critical to our success;
- reward performance; and

- align the interests of our executive officers and stockholders by motivating executive officers to increase stockholder value.

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

Name and principal position (a)	Year December (b)	Salary/ consulting fee (c)	Bonus awards (d)	Stock awards (e)	Option awards (f)	Non-equity Non-qualified		All other compensation (i)	Total (\$) (j)
						incentive plan compensation (g)	deferred earnings (h)		
Thomas Bold <sup>(1)</sup> President & CEO and Interim CFO	2015	100,000	Nil	Nil	5,267	Nil	Nil	Nil	105,267
	2014	70,833	Nil	Nil	Nil	Nil	Nil	Nil	70,833
Rhonda B. Rosen <sup>(2)</sup>  Former President & CEO, CFO and Director	2015	46,800	Nil	Nil	1,858	Nil	Nil	Nil	48,658
	2014	31,125	Nil	Nil	5,945	Nil	Nil	Nil	37,070
Patsy Trisler <sup>(3)</sup>  VP – Clinical & Regulatory Affairs	2015	60,000	Nil	Nil	12,762	Nil	Nil	Nil	72,762
	2014	45,000	Nil	Nil	41,615	Nil	Nil	Nil	86,615

(1) On December 1, 2013, we appointed Mr. Bold as our President & CEO and 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 have all vested as of the date hereof.



Table of Contents

- (2) On October 1, 2013, we appointed Ms. Rosen to serve as our CFO on a part-time basis, for which she is paid a monthly fee of \$3,900. On August 14, 2014, we granted to Ms. Rosen an option to purchase 10,000 shares of common stock at an exercise price of \$0.80 per share, the closing price of our common stock as quoted on the OTCQB on August 13, 2014, and a stock option to purchase up to 20,000 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 have all vested as of the date hereof. Ms. Rosen's at-will services agreement was terminated as of September 9, 2016.
- (3) On April 1, 2014, we appointed Ms. Patsy Trisler as our Vice President – Clinical & Regulatory Affairs and entered into an at-will consulting agreement with Ms. Trisler. Pursuant to which we Ms. Trisler issued an option to purchase up to 50,000 shares of the Company's common stock at a price of \$1.05 per share, the closing price of the Company's common stock as quoted on the OTCQB on April 1, 2014. The options may be exercised on a cashless basis using the formula contained therein and, subject to Ms. Trisler's continued service, the options vest(ed) as follows, 10,000 on: (a) April 1, 2015; (b) April 1, 2016; (c) April 1, 2017; (d) April 1, 2018; and (e) April 1, 2019.

**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, 2015.

<b>Name</b>	<b>Number of Securities Underlying Unexercised Options (#) Exercisable</b>	<b>Number of Securities Underlying Unexercised Options (#) Unexercisable</b>	<b>Option Exercise Price (\$)</b>	<b>Option Expiration Date</b>
Thomas Bold	40,000	0	\$ 0.75	12/01/2023
Rhonda Rosen	10,000	0	\$ 0.80	08/14/2024
Patsy Trisler	10,000	40,000	\$ 1.05	04/01/2024

**PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL**

There are no understandings or agreements known by management at this time which would result in a change in control.

**Options/SAR Grants Table**

During the years ended December 31, 2015 and 2014, stock-based compensation expense of \$59,122 and \$59,860, respectively, was recognized as general and administrative expenses. As of December 31, 2015 we had \$69,032 in unrecognized compensation cost related to unvested stock options.

We do not repurchase shares to fulfill the requirements of options that are exercised. Further, we issue new shares when options are exercised.

Table of Contents**Aggregated Option/SAR Exercises and Fiscal Year-End Option/SAR Value Table**

At December 31, 2015 we had 257,500 (2014 – 185,000) stock options outstanding. At no time during the last completed fiscal year did we, while a reporting company pursuant to Section 13(a) of 15(d) of the Exchange Act, adjust or amend the exercise price of the stock options or SARs previously awarded to any of the Named Executive Officers, whether through amendment, cancellation or replacement grants, or any other means.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information as of the date of this prospectus by (i) all persons who are known by us to beneficially own more than 5% of our outstanding shares of common stock, (ii) each director, director nominee, and Named Executive Officer; and (iii) all executive officers and directors as a group:

Name and Address of Beneficial Owner <sup>(1)</sup>	Number of shares Beneficially Owned <sup>(2)</sup>	% of Class Owned <sup>(2)</sup>
<b><u>Directors and Officers</u></b>		
Thomas Bold <sup>(3)</sup>	110,000	*
Patsy Trisler <sup>(4)</sup>	20,000	*
Kenneth Kirkland <sup>(5)</sup>	90,000	*
Joseph Sierchio <sup>(6)</sup>	633,846	*
All Directors and Officers as a Group (4 people)	853,846	1.21

**5% Shareholders**

Kalen Capital Corporation <sup>(7)</sup>		
The Kalen Capital Building		
688 West Hastings St.		
Suite 700		
Vancouver, BC V6B 1P1	51,227,337	66.57

\* 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.

- (2) Calculated pursuant to Rule 13d-3(d) of the Exchange Act. Beneficial ownership is calculated based on 70,274,264 shares of common stock issued and outstanding as of the date of this prospectus. Under Rule 13d-3(d) of the Exchange Act, shares not outstanding which are subject to options, warrants, rights or conversion privileges exercisable within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person, but are not deemed outstanding for the purpose of calculating the percentage owned by each other person listed.
- (3) Consists of 5,000 shares of common stock and a Series D Warrant to purchase 5,000 shares of common stock purchased by Mr. Bold in a private placement we conducted in 2015. Includes vested options to purchase up to 100,000 shares of common stock.
- (4) Ms. Trisler was appointed as our Vice President – Clinical & Regulatory Affairs on April 1, 2014; as part of her appointment she was granted a stock option to purchase up to 50,000 shares of common stock. The option vests in five equal installments of 10,000 on April 1, 2015-2019, subject to her continued service with the Company.
- (5) Consists of vested options to purchase 90,000 shares of common stock.
- (6) Includes 550,000 shares of common stock owned by Mr. Sierchio, 13,846 shares issued to Mr. Sierchio upon the cashless exercise of an option to purchase 20,000 shares and vested options to purchase 70,000 shares of common stock.
- (7) KCC is a private Alberta corporation wholly owned by Mr. Harmel Rayat. In such capacity, Mr. Rayat may be deemed to have beneficial ownership of these shares. Consists of: (a) 44,550,713 shares of our common stock owned by KCC and its wholly owned subsidiary; (b) a Series B Warrant to purchase up to 1,326,087 shares of our common stock at an exercise price of \$0.46 per share through November 29, 2018; (c) a Series C Warrant to purchase up to 3,500,000 shares of our common stock at an exercise price of \$0.49 per share through November 29, 2018; (d) a Series D Warrant to purchase up to 800,000 shares of our common stock at an exercise price of \$1.10 per share through June 5, 2020; (e) a Series E Warrant to purchase up to 584,416 shares of our common stock at an exercise price of the lesser of (i) \$1.54 or (ii) a 20% discount to the average closing price of our common stock as quoted on the OTCQB for the 5 days prior to the date on which KCC elects to exercise the warrant through September 9, 2021; and (f) 466,121 shares issuable upon exercise of a convertible note in the principal amount of \$700,000 and accrued interest, based upon a conversion price of \$1.54, as of January 19, 2017 (as of the date of this prospectus, we have not received a notice of conversion from KCC). For tax purposes, all of the debt and equity securities of the Company owned by KCC have been assigned to Kalen Capital Holdings, LLC, its wholly owned subsidiary.



Table of Contents

**TRANSACTIONS WITH RELATED PERSONS, PROMOTERS  
AND CERTAIN CONTROL PERSONS**

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

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

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

**Transactions with Related Persons**

The Board is responsible for review, approval, or ratification of "related-person transactions" involving the Company and related persons. Under SEC rules (Section 404 (a) of Regulation S-K), a related person is a director, officer, nominee for director, or 5% stockholder of the company since the beginning of the previous fiscal year, and their immediate family members. We are required to report any transaction or series of transactions in which we or a subsidiary is a participant, the amount involved exceeds \$120,000, and a related person has a direct or indirect material interest.

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

- any transaction with another company for which a related person's only relationship is as an employee (other than an executive officer), director, or beneficial owner of less than 10% of that company's shares, if the amount involved does not exceed the greater of \$1 million or 2% of that company's total annual revenue;
- compensation to executive officers determined by the Board;
- compensation to directors determined by the Board;
- transactions in which all security holders receive proportional benefits; and
- banking-related services involving a bank depository of funds, transfer agent, registrar, trustee under a trust indenture, or similar service.

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

Table of Contents

The following are related party transactions for the fiscal years ended December 31, 2015 and 2014 and in the period between December 31, 2015 and the date of this prospectus:

On December 31, 2013, we completed the sale of 100% of the issued and outstanding shares of Fostung Resources to Duke for a promissory note in the amount of \$80,000, which amount approximated the fair value of the leases and mining claims controlled by Fostung Resources, as concluded by an independent third-party geological consultant. Mr. Herdev S. Rayat, the majority shareholder of Duke is the brother of Mr. Harmel S. Rayat, our majority shareholder. During 2014 management determined that collection of any portion of the principal outstanding under the promissory note from Duke was no longer probable. As a result, we wrote off the balance of principal due under the note amounting to \$83,200, including interest receivable of \$3,200, during the year ended December 31, 2014.

During the year ended December 31, 2015, directors' fees of \$12,000 (2014 - \$12,000) were paid or due to our non-officer directors.

During the year ended December 31, 2015, legal fees of \$106,743 (2014 - \$156,175) were paid or are due to our attorney, Mr. Sierchio, who was appointed to our Board effective August 26, 2010.

We engaged StemCell Systems to provide us with prototypes and related documents related to our anticipated regulatory submissions. Pursuant to this engagement we incurred expenses of \$194,336 in the year ended December 31, 2015. Dr. Gerlach, from whom we purchased the CellMist™ System technology, is a principal of StemCell Systems.

On September 25, 2014, we entered into a Charitable Grant Agreement with the University, pursuant to which we committed to provide a charitable donation to the University in the aggregate amount of \$75,000. We will pay the Grant in eight quarterly installments of \$9,375, with the first payment made on or before October 2014 and the final payment to be made on or before July 31, 2016. Dr. Gerlach, from whom we purchased the CellMist™ System technology, is a professor at the University. Effective November 1, 2015, we entered into a Charitable Gift Agreement with the University, pursuant to which we 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.

On May 1, 2015, we 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 we would like to purchase or license the Technology. Pursuant to the terms of the Option Agreement, we will pay 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 \$24,000 option payment was recognized as research and development expense during the period ended December 31, 2015. At December 31, 2015, \$6,000 of the amount payable was recorded as current liabilities in the

accompanying consolidated balance sheet.

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 and rendered \$1,000,000 as payment. KCC is wholly owned by Mr. Harmel S. Rayat, our majority shareholder.

On September 9, 2016, we entered into the Loan Agreement with KCC pursuant to which KCC agreed to loan us up to \$900,000, of which we received \$700,000, at an annual interest rate of 7% per year, compounded quarterly with a maturity date of December 31, 2017. Per the Loan Agreement, we 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 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. 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.

Table of Contents

**DESCRIPTION OF OUR SECURITIES**

Our authorized capital stock consists of 500,000,000 shares of common stock, par value \$0.00001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share. As of the date of this prospectus, there were 70,274,264 shares of our common stock issued and outstanding and no shares of preferred stock issued and outstanding.

**Common Stock**

Subject to any special voting rights of any series of preferred stock that we may issue in the future, each holder is entitled to one vote for each share held on all matters to be voted upon by the stockholders, including the election of directors. The shares of common stock do not have cumulative voting rights. This means that the holders of more than 50% of the shares of common stock can elect all of our directors, subject to the rights of any outstanding series of preferred stock.

The holders of common stock are entitled to receive a pro-rata share of dividends, if any, as may be declared from time to time by the board out of funds legally available for the payment of dividends, subject to any preferential dividend rights of any outstanding series of preferred stock.

In the event of our liquidation, dissolution, or winding up, the holders of common stock are entitled to share pro-rata in all assets remaining after payment of our liabilities and subject to the prior rights of any outstanding series of preferred stock. Shares of common stock have no preemptive, conversion, or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

**Preferred Stock**

Our Board is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 10,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The rights of holders of our common stock may be subject to, and adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control and may adversely affect the voting and other rights of holders of our common stock.

## **Warrants**

As of the date of this prospectus, we have issued the following warrants that remain outstanding: (a) Series A Warrant to purchase 720,000 shares of common stock exercisable at \$0.35 per share through July 12, 2019. The Series A Warrant vests in equal installments of 240,000 on July 12, 2015-2018 and expires on July 12, 2019; (b) Series B Warrant to purchase 1,326,097 shares of common stock exercisable at \$0.46 per share through November 29, 2018; (c) Series C Warrant to purchase 3,500,000 shares of common stock exercisable at \$0.49 per share through November 29, 2018; (d) Series D Warrants to purchase 910,000 shares of common stock exercisable at \$1.10 through June 5, 2020; and (e) a Series E Warrant to purchase 584,416 shares of common stock exercisable at the lesser of (i) \$1.54 or (ii) a twenty percent (20%) discount to the average closing price of our common stock as quoted on the OTCQB for the five (5) days prior to the date on which the holder elects to exercise the through September 9, 2021. Each of the warrants may be exercised on a "cashless basis" using the formula set forth therein.

## **Options**

As of the date of this prospectus, there are options outstanding to purchase an aggregate of 425,000 shares of our common stock issued to various persons and entities at prices ranging between \$0.65 and \$2.28; of which 355,000 have vested. If issued, the shares underlying these options would increase the number of shares of our common stock currently outstanding and will dilute the holdings and voting rights of our then-existing shareholders.

## Table of Contents

### **Debt**

On September 9, 2016, we entered into the Loan Agreement with KCC pursuant to which KCC agreed to loan us up to \$900,000 at an annual interest rate of 7% per year, compounded quarterly. KCC provided 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 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.

### **Shares Eligible for Resale**

There is currently no liquid trading market for our common stock and one may not develop in the future. Future sales of substantial amounts of common stock, including shares of common stock issued upon exercise of outstanding options and exercise of the warrants offered in this prospectus in the public market, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities.

### **Rule 144**

As of the date of this prospectus there were 70,274,264 shares of our common stock issued and outstanding, of which 46,015,713 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 nine 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. Please refer to "**Risk Factors.**"

### **Registration Rights Agreements**

As part of the 11/29 Financing, we entered into the Registration Rights agreement with KCC pursuant to which we agreed to file such number of registration statements as required to register for resale with the SEC all the shares owned by KCC as of November 29, 2013, including all shares issuable upon conversion of any warrants then owned by KCC. The first registration statement that we are obligated to file covers the shares and warrants issued to KCC as part of the 11/29 Financing. If we fail to timely file the registration statements we will be obligated to issue additional shares of our common stock to KCC. In the event the we fail to file a registration statement in the time period required, we will issue to KCC additional shares of our common stock equal to 5% of the shares of our common stock that were to be registered for every thirty day period for which we fail to file such registration statement, subject to proration for any portion of such thirty day period and up to a maximum number of shares of our common stock equal to 25% of the number of shares of our common stock that were to be registered. Additionally, in the event we fail to cause a registration statement to be declared effective within ninety days from the date of filing, we will issue to KCC additional shares of our common stock equal to 2.5% of the shares of our common stock that were to be registered for every thirty day period for which we fail to cause the SEC to declare such registration statement effective, subject to proration for any portion of such thirty day period and up to a maximum number of shares of our common stock equal to 10% of the number of shares of common stock included in such registration statement. We timely filed the initial registration statement that we were required to file on behalf of KCC.



Table of Contents

Per the Loan Agreement we entered into on September 9, 2016 with KCC, we have given KCC 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 SELLING STOCKHOLDERS**

The following table presents information regarding the Selling Stockholders. The Selling Stockholders may sell up to 1,956,000 shares of common stock (including shares issuable upon exercise of the Series D Warrants). The percentage of outstanding shares beneficially owned is based on 70,274,264 shares of common stock issued and outstanding as of the date of this prospectus. Information with respect to beneficial ownership is based upon information provided to us by the Selling Stockholders. Except as may be otherwise described below, to the best of our knowledge, the named Selling Stockholders beneficially own and have sole voting and investment authority as to all of the shares set forth opposite his name, none of the Selling Stockholders is known to us to be a registered broker-dealer or an affiliate of a registered broker-dealer. Each of the Selling Stockholders has acquired his, hers or its shares solely for investment and not with a view to or for resale or distribution of such securities.

<b>Selling Stockholders</b>	<b># of Shares Beneficially Owned Prior to the Offering</b>	<b>% of Issued and Outstanding Shares Owned Prior to the Offering <sup>(1)</sup></b>	<b># of Shares Registered and to be Sold in this Offering <sup>(2)</sup></b>	<b># of Shares Beneficially Owned After this Offering <sup>(2)</sup></b>
Kalen Capital Holdings, LLC	51,227,337(3)	66.57	1,600,000(4)	49,627,337
Cindy Bains	136,000(5)	*	136,000	0
Narinder Thouli	200,000(6)	*	200,000	0
Thomas Bold	110,000(7)	*	10,000(8)	100,000
Rhonda Rosen	40,000(9)	*	10,000(8)	30,000
<b>Total</b>	<b>51,713,337</b>		<b>1,956,000</b>	<b>49,757,337</b>

\* Less than 1%

(1) Calculated pursuant to Rule 13d-3(d) of the Exchange Act. Beneficial ownership is calculated based on 70,274,264 shares of common stock issued and outstanding as of the date of this prospectus. Under Rule 13d-3(d) of the Exchange Act, shares not outstanding which are subject to options, warrants, rights or conversion privileges exercisable within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person, but are not deemed outstanding for the purpose of calculating the percentage owned by each other person listed.

Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding as of the date of this prospectus.

Table of Contents

- (2) The Selling Stockholders may offer and sell, from time to time, any or all of our common stock issued to them and registered for resale. Because the Selling Stockholders may offer all or only some portion of the 1,956,000 shares of common stock registered, no exact number can be given as to the amount or percentage of these shares of common stock that will be held by the Selling Stockholders upon termination of the offering. We can only make estimates and assumptions. The number of shares listed in the category titled "% of Issued and Outstanding Shares Owned After This Offering," in the table above, represent an estimate of the number of shares of common stock that will be held by the Selling Stockholders after the offering. To arrive at this estimate, we have assumed that the Selling Stockholders will sell all of the shares to be registered pursuant to this offering and will not be acquiring any additional shares. Please refer to "Plan of Distribution."
- (3) For additional information regarding Kalen Capital Holdings, LLC's share ownership see footnote 8 to the beneficial ownership table.
- (4) Represents 800,000 shares of common stock and 800,000 shares of common stock issuable upon exercise of a Series D Warrant purchased by the Selling Stockholder in a private transaction with us completed on June 5, 2015.
- (5) Represents 136,000 shares of common stock beneficially owned by the Selling Stockholder as of the date of this prospectus, including 100,000 shares issued to the Selling Stockholder upon exercise of a Series D Warrant for which we received \$110,000.
- (6) Represents 100,000 shares of common stock and 100,000 shares issuable upon exercise of a series D Warrant purchased by the Selling Stockholder in a private transaction with us completed on June 5, 2015.
- (7) For additional information regarding Mr. Bold's share ownership see footnote 3 to the beneficial ownership table.
- (8) Represents 5,000 shares of common stock and 5,000 shares issuable upon exercise of a series D Warrant purchased by the Selling Stockholder in a private transaction with us completed on June 5, 2015.
- (9) Includes 5,000 shares of common stock and a Series D Warrant allowing Ms. Rosen to purchase up to an additional 5,000 shares of common stock, which Ms. Rosen purchased from us as part of a private placement completed on June 5, 2015 and 30,000 shares of common stock reserved for issuance upon the exercise of stock options granted to Ms. Rosen, our former Chief Financial Officer, which vested as of the date hereof. On September 9, 2016, we terminated Ms. Rosen's at-will executive services agreement.

Other than the relationships described in the table and footnotes, none of the Selling Stockholders had or have any material relationship with us or any of our affiliates within the past three years. None of the Selling Stockholders is a broker-dealer or an affiliate of a broker-dealer.

We may require the Selling Stockholders to suspend the sales of the securities offered by this prospectus upon the occurrence of any event that makes any statement in this prospectus or the related registration statement untrue in any material respect or that requires the changing of statements in these documents in order to make statements in those documents not misleading.

## PLAN OF DISTRIBUTION

Each Selling Stockholder of the common stock and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on the OTCQB or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- a broker-dealer agreement with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

Table of Contents

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA NASD Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASD IM-2440.

In connection with the sale of the common stock or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The Selling Stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the Shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We are required to pay certain fees and expenses incurred by Selling Stockholders incident to the registration of the shares. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker-dealer acting in connection with the proposed sale of the shares by the Selling Stockholders.

We are under no obligation to keep the registration statement of which this prospectus is a part of effective and we may choose to withdraw it at any time.

The Shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the Shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the Shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Shares by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

Table of Contents

**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Satterlee Stephens LLP, 230 Park Avenue, Suite 1130, New York, New York 10169. Joseph Sierchio, a partner of Satterlee Stephens LLP, is one of our directors and the beneficial owner of 633,846 shares of our common stock.

**EXPERTS**

Our consolidated financial statements for the fiscal years ended December 31, 2015 and 2014, appearing herein, have been audited by Peterson Sullivan LLP, an independent registered public accounting firm, as set forth in its report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We file periodic reports with the SEC, including quarterly reports and annual reports which include our audited financial statements. This registration statement, including exhibits hereto, and all of our periodic reports may be inspected without charge at the Public Reference Room maintained by the SEC at 100 F Street, NE, Washington, D.C. 20549. You may obtain copies of this registration statement, including the exhibits hereto, and all of our periodic reports after payment of the fees prescribed by the SEC. For additional information regarding the operation of the Public Reference Room, you may call the SEC at 1-800-SEC-0330. The SEC also maintains a website which provides on-line access to reports and other information regarding registrants that file electronically with the SEC at: [www.sec.gov](http://www.sec.gov). In addition, you may request a copy of any of our periodic reports filed with the Securities and Exchange Commission at no cost, by writing us at: RenovaCare, Inc., 430 Park Avenue, Suite 702, New York, NY 10022.

Table of Contents

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page #</b>
<u>Consolidated Balance Sheet as of September 30, 2016 (Unaudited)</u>	F-1
<u>Consolidated Statement of Operations (Unaudited) for the Nine Months Ended September 30, 2016</u>	F-2
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the Nine Months Ended September 30, 2016 (Unaudited)</u>	F-3
<u>Consolidated Statement of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2016</u>	F-4
<u>Notes to Consolidated Financial Statements</u>	F-5
<u>Report of Peterson Sullivan LLP</u>	F-14
<u>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>	F-15
<u>Consolidated Statements of Operations for the Years Ended December 31, 2015 and 2014</u>	F-16
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015 and 2014</u>	F-17
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2015 and 2014</u>	F-18
<u>Notes to Consolidated Financial Statements for the Years Ended December 31, 2015 and 2014</u>	F-19



**RENOVACARE, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**SEPTEMBER 30, 2016 AND DECEMBER 31, 2015**

	<b>September 30, 2016 (unaudited)</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 687,747	\$ 397,589
Prepaid expenses	12,030	10,293
<b>Total current assets</b>	<b>699,777</b>	<b>407,882</b>
Intangible assets	152,854	152,854
<b>Total assets</b>	<b>\$ 852,631</b>	<b>\$ 560,736</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 28,156	\$ 71,563
Accrued expenses - related parties	39,592	30,095
Contract and contribution payable	50,000	134,125
<b>Total current liabilities</b>	<b>117,748</b>	<b>235,783</b>
Convertible promissory note payable to related party, net of discount of \$669,247	30,753	-
Interest payable to related party	2,819	-
Contract and contribution payable, less current portion	100,000	100,000
<b>Total liabilities</b>	<b>251,320</b>	<b>335,783</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
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, 69,955,847 and 67,781,934 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	700	678
Additional paid-in capital	11,185,186	9,197,970
Retained deficit	(10,584,575)	(8,973,695)
<b>Total stockholders' equity</b>	<b>601,311</b>	<b>224,953</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 852,631</b>	<b>\$ 560,736</b>

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

F-1

Table of Contents**RENOVACARE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)****FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Revenue</b>	\$ -	\$ -	\$ -	\$ -
<b>Operating expense</b>				
Research and development	45,381	80,667	231,013	192,292
General and administrative	223,832	216,363	1,347,063	585,866
<b>Total operating expense</b>	<b>269,213</b>	<b>297,030</b>	<b>1,578,076</b>	<b>778,158</b>
<b>Loss from operations</b>	<b>(269,213)</b>	<b>(297,030)</b>	<b>(1,578,076)</b>	<b>(778,158)</b>
<b>Other income (expense)</b>				
Interest income	149	-	768	-
Interest expense	(2,819)	-	(2,819)	-
Accretion of debt discount	(30,753)	-	(30,753)	-
<b>Total other income (expense)</b>	<b>(33,423)</b>	<b>-</b>	<b>(32,804)</b>	<b>-</b>
<b>Net loss</b>	<b>\$ (302,636)</b>	<b>\$ (297,030)</b>	<b>\$ (1,610,880)</b>	<b>\$ (778,158)</b>
<b>Basic and Diluted Loss per Common Share</b>	<b>\$ (0.00)</b>	<b>\$ (0.00)</b>	<b>\$ (0.02)</b>	<b>\$ (0.01)</b>
<b>Weighted average number of common shares outstanding - basic and diluted</b>	<b>69,955,847</b>	<b>67,704,921</b>	<b>69,695,772</b>	<b>67,048,351</b>

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

Table of Contents**RENOVACARE, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY****FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 (UNAUDITED) AND YEAR ENDED  
DECEMBER 31, 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	2,173,913	22	999,978	-	1,000,000
Discount on convertible promissory note due to detachable warrants	-	-	340,735	-	340,735
Discount on convertible promissory note due to beneficial conversion feature	-	-	359,265	-	359,265
Stock based compensation due to common stock purchase options	-	-	287,238	-	287,238
	-	-	-	(1,610,880)	(1,610,880)

Net loss for the nine  
m o n t h s e n d e d  
September 30, 2016

Balance, September  
30, 2016 (Unaudited)

69,955,847	\$	700	\$	11,185,186	\$	(10,584,575)	\$	601,311
------------	----	-----	----	------------	----	--------------	----	---------

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

Table of Contents

**RENOVACARE, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015**

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (1,610,880)	\$ (778,158)
Adjustments to reconcile net loss to net cash used in operating activities		
Impairment loss	-	10,000
Stock based compensation expense	287,238	39,542
Accretion of debt discount	30,753	-
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	(1,737)	(26,869)
Increase (decrease) in accounts payable	(43,407)	77,859
Increase (decrease) in related party payable	9,497	6,545
Increase (decrease) in related party interest expense	2,819	-
Increase (decrease) in contract and contributions payable	(84,125)	(116,125)
Net cash used in operating activities	(1,409,842)	(787,206)
<b>Cash flows from financing activities</b>		
Proceeds from exercise of warrants and issuance of common stock	1,000,000	1,010,000
Proceeds from the issuance of convertible promissory note	700,000	-
Net cash provided by financing activities	1,700,000	1,010,000
<b>Increase in cash and cash equivalents</b>	<b>290,158</b>	<b>222,794</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>397,589</b>	<b>683,098</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 687,747</b>	<b>\$ 905,892</b>
<b>Supplemental disclosure of cash flow information:</b>		
Interest paid in cash	\$ -	\$ -
Income taxes paid in cash	\$ -	\$ -
<b>Supplemental disclosure of non-cash transactions:</b>		
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)

F-4

Table of Contents

**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. The Cell Mist™ System is comprised of (a) a treatment methodology for cell isolation for the regeneration of human skin cells (the "CellMist™ Solution") and (b) a solution sprayer device (the "SkinGun™") for delivering the cells to the treatment area. The solution sprayer device also is a medical-grade liquid spraying device for general use in wound care and irrigation. 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 September 30, 2016, the Company's accumulated deficit is \$10,584,575. The Company does not currently generate revenues and will continue to incur losses from operations and operating cash flow deficits in the future. 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 January 2017. The future of the Company after January 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 as planned will be significantly impaired and it may cause the Company to curtail operations.

**Note 2. Significant Accounting Policies**

*Basis of Presentation and Principles of Accounting*



The interim consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") pursuant to Part 210 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such SEC rules and regulations, although the Company believes that the disclosures included are adequate to make the information presented not misleading.

In management's opinion, the unaudited consolidated financial statements contained herein reflect all adjustments, consisting solely of normal recurring items, which are necessary for the fair presentation of the Company's financial position, results of operations, and cash flows on a basis consistent with that of the Company's prior audited consolidated financial statements. The Company has evaluated information about subsequent events that became available to us through the date the financial statements were issued. This information relates to events, transactions or changes in circumstances that would require us to adjust the amounts reported in the financial statements or to disclose information about those events, transactions or changes in circumstances. The results of operations for interim periods may not be indicative of results to be expected for the full fiscal year. Therefore, these financial statements should be read in conjunction with the Company's audited financial statements, including the notes thereto for the year ended December 31, 2015, which may be found under the Company's profile on EDGAR.

#### *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.

Table of Contents

*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.

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-19, Stock Compensation, 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 is in the process of evaluating the impacts of the adoption of this ASU.

In February 2016, the FASB issued ASU 2016-02, Leases, 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 May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers, 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.

Table of Contents

*Fair Value of Financial Instruments*

The carrying value of cash and cash equivalents, accounts payable, contract and contribution, note payable and interest 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 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.

*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.

*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.

F-7

Table of Contents*Income Taxes*

The Company recognizes income taxes on an accrual basis based on tax positions taken, or expected to be taken, in tax returns. A tax position is defined as a position in a previously filed tax return or a position expected to be taken in future tax filing that is reflected in measuring current or deferred income tax assets and liabilities. Tax positions are recognized only when it is more likely than not (i.e., likelihood of greater than 50%), based on technical merits, that the position would be sustained upon examination by taxing authorities. Tax positions that meet the more likely than not threshold are measured using a probability-weighted approach as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement. 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. Should they occur, the Company's policy is to classify interest and penalties related to tax positions as interest expense. Since the Company's inception, no such interest or penalties have been incurred. The Company did not record an income tax provision during the periods presented due to net taxable losses.

*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 three and nine months ended September 30, 2016 and 2015:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Basic and Diluted EPS Computation</b>				
Numerator:				
Loss available to common stockholders'	\$ (302,636)	\$ (297,030)	\$ (1,610,880)	\$ (778,158)
Denominator:				
Weighted average number of common shares outstanding	69,955,847	67,704,921	69,695,772	67,048,351
Basic and diluted EPS	\$ (0.00)	\$ (0.00)	\$ (0.02)	\$ (0.01)

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	445,000	207,500	445,000	207,500
Warrants	7,380,503	8,970,000	7,380,503	8,970,000
Convertible debt	623,067	-	623,067	-
Total shares not included in the computation of diluted losses per share	8,448,570	9,177,500	8,448,570	9,177,500

#### *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 7. Related Party Transactions," for further discussion.

Table of Contents

**Note 3. 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 three and nine months ended September 30, 2016, the Company recognized \$2,819 of interest expense and \$30,753 of accretion related to the debt discount. The remaining debt discount of \$669,247 will be amortized over the next five quarters through December 31, 2017.



**Note 4. Common Stock Options**

*2013 Long-Term Incentive Plan*

On June 20, 2013, the Board of Directors (the "Board") adopted, subject to receiving shareholder approval, the 2013 Long-Term Incentive Plan (the "Incentive Plan"). The Incentive Plan provides for the issuance of stock options of up to 20,000,000 shares (subject to adjustment) of the Company's common stock to officers, directors, key employees and consultants of the Company. Options granted to employees under the Incentive 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. On November 15, 2013, shareholders owning a majority of the Company's issued and outstanding shares approved the Incentive Plan.

Table of Contents

The Incentive Plan is administered by the Board or a committee designated by the Board. Subject to the provisions of the Incentive 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 Incentive 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 Incentive 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 Incentive 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 Incentive Plan after June 20, 2023.

As of September 30, 2016, there were 19,555,000 shares available for grant.

*Stock Option Activity*

The following table summarizes stock option activity for the period ended September 30, 2016:

	Number of Options	Weighted Average Exercise Price (\$)	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (\$)
Outstanding at December 31, 2015	257,500	1.07		
Grants	187,500	1.92		
Outstanding at September 30, 2016	445,000	1.43	8.62 years	81,125
Exercisable at September 30, 2016	357,500	1.41	8.63 years	73,625
Available for grant at September 30, 2016	19,555,000			

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 nine months ended September 30, 2016 with a weighted-average grant date fair value of \$1.41. There were 15,000 stock options granted during the nine months ended September 30,

Edgar Filing: RenovaCare, Inc. - Form S-1

2015 with a weighted-average grant date fair value of \$1.08. 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:

	<b>2016</b>	<b>2015</b>
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

F-10

Table of Contents

The fair value of our stock options is expensed ratably over their respective vesting periods. The following table sets forth the share-based compensation cost resulting from stock option grants, including those previously granted and vesting over time, that were recorded in the Company's Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock based compensation expense	\$ 12,951	\$ 18,879	\$ 287,238	\$ 39,542

Stock-based compensation expense is recognized as general and administrative expenses. As of September 30, 2016, the Company had \$58,916 of unrecognized compensation cost related to unvested stock options which is expected to be recognized over a period of 4.25 years.

The following table summarizes information about stock options outstanding and exercisable at September 30, 2016:

Range of Exercise Prices	Stock Options Outstanding			Stock Options Exercisable				
	Number of Shares Subject to Outstanding Options	Weighted Average Contractual Life (years)	Weighted Average Exercise Price	Number of Shares Subject To Options Exercise	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price		
\$ 0.75	40,000	7.17	\$ 0.75	40,000	7.17	\$ 0.75		
0.80	90,000	7.87	0.80	90,000	7.87	0.80		
1.05	55,000	7.50	1.05	25,000	7.50	1.05		
1.25	7,500	8.71	1.25	7,500	8.71	1.25		
1.34	7,500	8.75	1.34	7,500	8.75	1.34		
1.65	50,000	9.09	1.65	-	9.09	1.65		
1.70	7,500	9.04	1.70	7,500	9.04	1.70		
1.91	180,000	9.46	1.91	180,000	9.46	1.91		
2.28	7,500	9.81	2.28	-	9.81	2.28		
Total	445,000	8.62	\$ 1.43	357,500	8.63	\$ 1.41		

**Note 5. Common Stock**

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.

The following table summarizes information about warrants outstanding at September 30, 2016:

	<b>Shares of Common Stock</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
Series A	960,000	\$ 0.35	July 12, 2019
Series B	1,326,087	\$ 0.46	November 29, 2018
Series C	3,500,000	\$ 0.49	November 29, 2018
Series D	1,010,000	\$ 1.10	June 5, 2020
Series E	584,416	\$ 1.13	September 8, 2021
Outstanding as of September 30, 2016	7,380,503		

Table of Contents**Note 6. 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. 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 July 12, 2013, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an asset purchase agreement 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. As amended, the asset purchase agreement 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 September 30, 2016, \$50,000 of the amount payable to Dr. Gerlach was recorded as current liabilities and \$100,000 was recorded as long-term liabilities in the accompanying consolidated balance sheet.

Below is a summary of contract and contribution payable at September 30, 2016 and December 31, 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 is 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	(50,000)	(134,125)
Long-term portion	\$ 100,000	\$ 100,000

See also "Note 7. Related Party Transactions."

**Note 7. 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.

For the three and nine months ended September 30, 2016, directors' and consulting fees with respect to officers and directors of the Company were \$3,000 (2015: \$3,000) and \$9,000 (2015: \$9,000). Legal fees incurred with respect to one of the Company's directors in the three and nine months ended September 30, 2016 were \$30,080 (2015: \$20,583) and \$121,595 (\$83,138), respectively. Amounts included in accrued expenses – related parties were \$30,080 at September 30, 2016 and \$30,095 as of December 31, 2015.

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 \$24,000 and \$80,667 for the three months ended September 30, 2016 and 2015, respectively, and \$134,567 and \$140,627 for the nine months ended September 30, 2016 and 2015, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System, is a principal of StemCell Systems.

Table of Contents

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.

Per the Loan Agreement, the Company issued KCC a Series E Stock Purchase 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 our common stock at an exercise price of \$0.46 per share resulting in proceeds of \$1,000,000.

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 certain technology for a fee of \$24,000, payable in four quarterly installments of \$6,000, with the first installment due on May 1, 2015. The final payment under the Option agreement was paid 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, pursuant to which it 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 first payment made in October 2014 and the final payment made July 20, 2016. Dr. Gerlach, from whom the Company purchased the CellMist™ System, is a professor at the University of Pittsburgh.

**Note 8. Subsequent Events**

Management has reviewed material events subsequent of the quarterly period ended September 30, 2016 and prior to the filing of financial statements in accordance with FASB ASC 855 "Subsequent Events" and has determined there are



no events to report.

F-13

Table of Contents

**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, 2015 and 2014, 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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of 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 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, 2015 and 2014 and the results of their operations and their cash flows for the year 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, 2016

F-14

Table of Contents

**RENOVACARE, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31, 2015	December 31, 2014
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 397,589	\$ 683,098
Prepaid expenses	10,293	7,448
<b>Total current assets</b>	<b>407,882</b>	<b>690,546</b>
Intangible assets	152,854	162,854
<b>Total assets</b>	<b>\$ 560,736</b>	<b>\$ 853,400</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 71,563	\$ 6,182
Accrued expenses - related parties	30,095	7,255
Contract and contribution payable	134,125	187,500
<b>Total current liabilities</b>	<b>235,783</b>	<b>200,937</b>
Contract and contribution payable, less current portion	100,000	178,125
<b>Total liabilities</b>	<b>335,783</b>	<b>379,062</b>
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock: \$0.0001 par value: Authorized: 10,000,000 shares, Issued and outstanding: nil	-	-
Common stock: \$0.00001 par value: Authorized: 500,000,000 shares, issued and outstanding: 67,781,934 and 66,575,122 shares, respectively	678	666
Additional paid-in capital	9,197,970	8,128,860
Accumulated deficit	(8,973,695)	(7,655,188)
<b>Total stockholders' equity</b>	<b>224,953</b>	<b>474,338</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 560,736</b>	<b>\$ 853,400</b>

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

Table of Contents

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

**For the Year Ended**

**December 31,**

**2015                      2014**

<b>Revenue</b>	\$	-	\$	-
<b>Expenses</b>				
Research and development expenses		281,218		975,667
General and administrative expenses		1,037,289		1,155,729
Total operating expenses		1,318,507		2,131,396
<b>Net loss</b>		(1,318,507)		(2,131,396)
<b>Earnings per share</b>				
Loss per common share	\$	(0.02)	\$	(0.03)
Weighted average shares outstanding		67,233,254		66,575,122

(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, 2014 and 2015**

	Common Stock Shares	Common Stock Amount	Additional paid-in capital	Accumulated deficit	Total
Balance, December 31, 2013	66,575,122	\$ 666	\$ 7,220,612	\$ (5,523,792)	\$ 1,697,486
S t o c k b a s e d compensation - Series A Warrant			848,388		848,388
S t o c k b a s e d compensation – options			59,860		59,860
Net loss, December 31, 2014				(2,131,396)	(2,131,396)
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
S t o c k b a s e d compensation – options			59,122		59,122
Exercise of warrants	196,812	2	(2)		-
Net loss, 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

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

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

	<b>For the Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (1,318,507)	\$ (2,131,396)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Impairment loss	10,000	-
Stock based compensation expense	59,122	59,860
Stock based consulting expense	-	848,388
Bad debt expense	-	80,000
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses	(2,845)	(6,218)
(Decrease) increase in accounts payable and accrued expenses	65,381	(5,040)
(Decrease) increase in accounts payable – related parties	22,840	(36,964)
(Decrease) increase in contract and contribution payable	(131,500)	365,625
<b>Net cash flows from operating activities</b>	<b>(1,295,509)</b>	<b>(825,745)</b>
<b>Cash flows from financing activities:</b>		
Sale of common stock and warrants	1,010,000	-
<b>Net cash flows from financing activities</b>	<b>1,010,000</b>	<b>-</b>
<b>Change in cash and cash equivalents</b>	<b>(285,509)</b>	<b>(825,745)</b>
Cash and cash equivalents, beginning of period	683,098	1,508,843
<b>Cash and cash equivalents, end of period</b>	<b>\$ 397,589</b>	<b>\$ 683,098</b>

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

Table of Contents

**RENOVACARE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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. The Company was previously involved in the exploration and development of both mineral exploration properties and oil and gas properties. The Company sold its oil and gas properties on February 18 and 19, 2013 and sold its subsidiary which controlled various mineral leases and mining claims on December 31, 2013.

On July 12, 2013, the Company, together with its wholly owned subsidiary, RenovaCare Sciences Corp. ("RenovaCare Sciences"), a Nevada corporation formerly known as Janus Acquisition Corp., entered into an asset purchase agreement with Dr. Jörg Gerlach, MD, PhD, pursuant to which RenovaCare Sciences purchased all of Dr. Gerlach's rights, title and interest to a treatment methodology for cell isolation for the regeneration of human skin cells, along with a medical-grade liquid spraying device and associated equipment (the "SkinGun™"), along with the associated US and foreign patents and patent applications. The development of the SkinGun™ is in the early stages and the Company anticipates that significant time and financial resources will be required to further develop the technology and determine whether a commercially viable product can be developed.

On December 31, 2013, the Company entered into a stock purchase agreement with Duke Mountain Resources, Inc. ("Duke"), a Nevada corporation, pursuant to which the Company sold to Duke 100% of the issued and outstanding shares of Fostung Resources Ltd. ("Fostung Resources"), a corporation organized under the laws of Ontario, Canada and a wholly owned subsidiary of ours, for a promissory note in the amount of \$80,000, which amount approximated the fair value of the leases and mining claims controlled by Fostung Resources, as concluded by an independent third-party geological consultant. During 2014 management determined that collection of any portion of the principal outstanding under the promissory note from Duke was no longer probable. As a result, the Company wrote off the balance of principal due under the note amounting to \$83,200, including interest receivable of \$3,200, during the year ended December 31, 2014.

The Company has recently incurred net operating losses and operating cash flow deficits. The Company's total accumulated deficit is \$9.0 million as of December 31, 2015. The Company does not currently generate revenues and will continue to incur losses from operations and operating cash flow deficits in the future. Management believes that the Company's cash and cash equivalent balances, and other external sources of capital will be sufficient to meet our cash requirements through June 30, 2016. The future of the Company after June 2016 will depend in large part on its ability to successfully raise capital from external sources to fund operations.



The matters described above raise substantial doubt about the Company's 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 the Company be unable to continue as a going concern.

## **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.

Table of Contents

*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.

*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 of Financial Instruments*

The carrying amounts for cash and cash equivalents, contract and contribution payable and accounts payable and accrued expenses approximate fair value based on observable quoted prices for active markets – Level 1 inputs.

*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.

*Intangible Assets*

The intangible asset consists primarily of the SkinGun™ 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 SkinGun™ technology is not impaired. The Company did, however, determine that an intangible asset related to wound care technology, acquired during 2013, was impaired during the year ended December 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.

## Table of Contents

### *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.

### *Income Taxes*

The Company recognizes income taxes on an accrual basis based on tax positions taken, or expected to be taken, in tax returns. A tax position is defined as a position in a previously filed tax return or a position expected to be taken in future tax filing that is reflected in measuring current or deferred income tax assets and liabilities. Tax positions are recognized only when it is more likely than not (i.e., likelihood of greater than 50%), based on technical merits, that the position would be sustained upon examination by taxing authorities. Tax positions that meet the more likely than not threshold are measured using a probability-weighted approach as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement. 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 our 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. No provision for income taxes was recorded during the periods presented because the Company had a net taxable loss. Should they occur, our policy is to classify interest and penalties related to tax positions as interest expense. Since our inception, no such interest or penalties have been incurred.

### *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. Potentially dilutive shares of common stock consisted of warrants to purchase shares of common stock (9,013,188 shares for 2015 and 8,200,000 for 2014) and options to purchase shares of common stock (257,500 shares for 2015 and 185,000 shares for 2014). During the periods presented, potentially dilutive shares of common stock were not included in the computation of dilutive loss per share as to do so would be anti-dilutive.

### *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 6. Related Party Transactions," for further discussion.

#### *New Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") 605, Revenue Recognition. The new revenue recognition standard requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. ASU 2014-09 is effective for interim and annual reporting periods beginning after December 15, 2017 and is to be applied retrospectively. The Company does not currently have any revenue. As such, ASU 2014-09 will not have any effect on the Company's results of operations and financial position. If the Company begins generating revenue prior to the effective date of ASU 2014-09, it will evaluate the effect that ASU 2014-09 will have on its results of operations and financial position.

## Table of Contents

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements – Going Concern (Topic 915): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which states that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The update becomes effective for the Company during the first quarter of 2016 and is not expected to have a material effect on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases, 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.

### **3. Assets – Intellectual Property**

On July 12, 2013, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an asset purchase agreement with Dr. Jörg Gerlach, MD, PhD, pursuant to which RenovaCare Sciences purchased all of Dr. Gerlach's rights, title and interest in the SkinGun™. The Company plans to further the development of the SkinGun™ and, if commercially viable, bring the product to market. 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. Additional costs capitalized during 2013, and which related to an option to evaluate a wound cap technology, amounted to \$10,000. The Company allowed this option to expire, and during the year ended December 31, 2015 recorded an impairment loss amounting to \$10,000, which was equal to the amount capitalized. Intangible assets amounted to \$152,854 and \$162,854 at December 31, 2015 and December 31, 2014, respectively.

The asset purchase agreement was amended on June 9, 2014 (the "Amended APA"). Pursuant to the terms of the Amended APA, an additional \$300,000 will be paid 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. The expense associated with the consideration was recorded during 2014. The Company paid the first installment of \$100,000 in January 2015. At December 31, 2015, \$100,000 of the amount payable to Dr. Gerlach was recorded as current liabilities and \$100,000 was recorded as long-term liabilities in the accompanying consolidated balance sheet.

As consideration for the SkinGun™ and services performed in connection therewith, the Company issued to Dr. Gerlach a Series A Stock Purchase Warrant (the "Series A Warrant") entitling him to purchase 1,200,000 shares (each a "Warrant Share") of the Company's common stock at an exercise price of \$0.35 per share. Originally, vesting of the

warrant was contingent on the achievement of certain milestones and on Dr. Gerlach's continuing to provide consulting services. As of September 9, 2014, the effective date of the Amended APA, vesting will no longer be contingent on the achievement of certain milestones and on Dr. Gerlach's continuing to provide consulting services to the Company, but instead on passage of time. 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.

Prior to September 9, 2014, the value of the Series A Warrant was recognized as consulting expenses over the vesting term. Effective September 9, 2014, the Company measured and expensed the value of the Series A Warrant in full and recorded this value as research and development costs. The fair value of each Warrant Share as of September 9, 2014, using the Black-Scholes option pricing model, was \$0.91. The warrants were valued using the Black-Scholes option pricing model based on the following assumptions: risk free interest rate of 1.72%, contractual life of 4.75 years, expected volatility of 93.8% and a dividend yield of 0%.

Consulting expense associated with the Series A Warrant amounted to \$0 during the year ended December 31, 2015 (2014: \$311,173). Research and development expense associated with the Series A Warrant amounted to \$0 during the year ended December 31, 2015 (2014: \$537,217).

## Table of Contents

On May 1, 2015, the Company entered into a new 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"), 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 will pay 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 \$24,000 option payment was recognized as research and development expense during the period ended December 31, 2015. At December 31, 2015, \$6,000 of the amount payable was recorded as current liabilities in the accompanying consolidated balance sheet.

### **4. Stockholders' Equity**

On August 5, 2015, Dr. Gerlach exercised 240,000 Series A Warrants, on a cashless basis, and the Company issued 196,812 shares of common stock.

On June 5, 2015, the Company entered into subscription agreements with five investors for the purchase and sale of an aggregate of 1,010,000 units of equity securities (the "**Units**") at a price of \$1.00 per Unit for total gross proceeds of \$1,010,000. Each Unit consists of one share of common stock and one Series D Warrant (the "Series D Warrant") allowing the holder to purchase one share of the Company's common stock at a price of \$1.10 per share for a period of five years; the Series D Warrants contain a provision allowing the holder to exercise the Series D Warrant on a cashless basis as further set forth therein.

The relative fair value of the common stock was estimated to be approximately \$590,000 and the relative fair value of the warrants was estimated to be \$420,000 as determined based on the relative fair value allocation of the proceeds received. The warrants were valued using the Black-Scholes option pricing model based on the following assumptions: risk free interest rate of 1.75%, contractual life of five years, expected volatility of 88.0% and a dividend yield of 0%.

### *Approval of the 2013 Long-Term Incentive Plan*

On June 20, 2013, the Board of Directors (the "**Board**") adopted, subject to receiving shareholder approval, the 2013 Long-Term Incentive Plan (the "**Incentive Plan**"). The Incentive Plan provides for the issuance of stock options of up to 20,000,000 shares (subject to adjustment) of the Company's common stock to officers, directors, key employees and consultants of the Company. Options granted to employees under the Incentive 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.



The Incentive Plan is administered by the Board or a committee designated by the Board. Subject to the provisions of the Incentive 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 Incentive 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 Incentive 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 Incentive 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 Incentive Plan after June 20, 2023.

As of December 31, 2015, there were 19,742,500 shares available for grant.

Table of Contents*Stock Option Activity*

The following table summarizes stock option activity for the year ended December 31, 2015.

	<b>Options Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Aggregate Intrinsic Value</b>
Balance January 1, 2015	185,000	\$ 0.83	9.12	-
Options granted	80,000	\$ 1.54	-	-
Options cancelled	(7,500)	1.43	-	-
Balance December 31, 2015	257,500	\$ 1.04	8.58	\$ 146,825
Exercisable at December 31, 2015	160,000	\$ 0.82	8.22	\$ 124,825

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. The estimated weighted average fair value of stock options granted during 2015 and 2014 was approximately \$0.72 to \$1.14 per share. 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 a 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 are presented in the table below:

	<b>2015</b>	<b>2014</b>
Risk-free interest rate	1.58 – 1.72%	1.58 – 1.62%
Expected life in years	5.50	5.50
Weighted Avg Expected Volatility	75.1% - 98.1%	94.4% - 105.3%
Expected dividend yield	0%	0%

During the years ended December 31, 2015 and 2014, stock-based compensation expense of \$59,122 and \$59,860, respectively, was recognized as general and administrative expenses. As of December 31, 2015, the Company had \$69,032 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized by November 1, 2020.

The following table summarizes information about stock options outstanding and exercisable under our stock incentive plan at December 31, 2015:

	<b>Number Outstanding</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Weighted Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Weighted Average Exercise Price</b>
\$0.50 to \$1.00	130,000	8.07	\$ 0.74	130,000	8.07	\$ 0.74
\$1.01 to \$1.50	127,500	9.10	\$ 1.35	30,000	8.85	\$ 1.17
	257,500	8.58	\$ 1.04	160,000	8.22	\$ 0.82

The Company issues new shares when options are exercised.

#### *Warrants*

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

	<b>Shares of Common Stock</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
Series A	1,003,188	\$ 0.35	July 12, 2019
Series B	3,500,000	\$ 0.46	November 29, 2018
Series C	3,500,000	\$ 0.49	November 29, 2018
Series D	1,010,000	\$ 1.10	June 5, 2020
Outstanding as of December 31, 2015	9,013,188		

Table of Contents**5. 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. Payments due under the lease in 2016 and 2017 are \$9,500 and \$1,600, respectively. Rent expense for the years ended December 31, 2015 and 2014 was \$9,000 and \$3,250, respectively.

On August 1, 2013, the Company engaged Vector to 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"). In consideration of the Services, the Company will pay Vector a monthly consulting fee of \$5,000.

In connection with the Company's anticipated Section 510(k) submission of its proprietary spray deposition device to the Food and Drug Administration, the Company has engaged StemCell Systems GmbH to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$194,336 in the twelve months ended December 31, 2015. Dr. Gerlach, from whom the Company purchased the SkinGun™ technology, is a principal of StemCell Systems.

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 will pay the Grant in eight quarterly installments of \$9,375, with the first payment made on or before October 2014 and the final payment to be made on or before July 31, 2016. Dr. Gerlach, from whom the Company purchased the SkinGun™ technology, is a professor at the University. At December 31, 2015, \$28,125 of the amount payable to the University was recorded as current liabilities and \$0 was recorded as long-term liabilities in the accompanying consolidated balance sheet.

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

	<b>2015</b>	<b>2014</b>
Contribution payable to the University of Pittsburgh, in quarterly installments of \$9,375, through July 2016	\$ 28,125	\$ 65,625
Contract payable to Dr. Jorg Gerlach in connection with the APA. \$50,000 is currently due. \$50,000 is due on December 31, 2016 and \$100,000 is due on December 31, 2017	\$ 200,000	\$ 300,000

Contract for option agreement purchase	\$	6,000	\$	-
Other	\$	234,125	\$	365,625
Less: current portion	\$	(134,125)	\$	(187,500)
Long-term portion	\$	100,000	\$	178,125

See also "Note 6. Related Party Transactions."

## 6. 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 August 14, 2014, the Company granted to each of Dr. Kirkland and Mr. Sierchio an incentive stock option to purchase up to 20,000 shares of the Company's common stock at an exercise price of \$0.80 per share, the closing price of the Company's common stock as quoted on the OTC Markets Group Inc. QB tier (the "OTCQB") on the day prior to the grant. Subject to their continued service as a member of the Board, 10,000 of the shares vested immediately and 10,000 of the shares vested on the first anniversary of date of grant and may be exercised on a "cashless basis" using the formula contained therein.

F-25

Table of Contents

For the year ended December 31, 2015 directors' fees incurred were \$12,000 (2014: \$12,000). Legal fees incurred with respect to one of the Company's directors in the year ended December 31, 2015 were \$106,743 (2014: \$156,175). Amounts included in accounts payable and accrued expenses, and due to related parties, at December 31, 2015 were \$30,095 (2014: \$7,255).

In connection with the Company's anticipated Section 510(k) submission of its proprietary SkinGun™ to the FDA it engaged StemCell Systems to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$194,336 in the year ended December 31, 2015. Dr. Gerlach, from whom the Company purchased the SkinGun™ technology, is a principal of StemCell Systems.

On September 25, 2014, the Company entered into a Charitable Grant Agreement with the University, pursuant to which it committed to provide a charitable donation to the University in the aggregate amount of \$75,000. The Company will pay the Grant in eight quarterly installments of \$9,375, with the first payment made on or before October 2014 and the final payment to be made on or before July 31, 2016. Effective November 1, 2015, the Company entered into a Charitable Gift Agreement with the University, pursuant to which it 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, from whom the Company purchased the SkinGun™ technology, is a professor at the University.

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 will pay 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 \$24,000 option payment was recognized as research and development expense during the period ended December 31, 2015. At December 31, 2015, \$6,000 of the amount payable was recorded as current liabilities in the accompanying consolidated balance sheet.

On December 31, 2013, the Company completed the sale of 100% of the issued and outstanding shares of Fostung Resources to Duke for a promissory note in the amount of \$80,000, which amount approximated the fair value of the leases and mining claims controlled by Fostung Resources, as concluded by an independent third-party geological consultant. Mr. Herdev S. Rayat, the majority shareholder of Duke is the brother of Mr. Harmel S. Rayat, the Company's majority shareholder. During 2014 management determined that collection of any portion of the principal outstanding under the promissory note from Duke was no longer probable. As a result, the Company wrote off the balance of principal due under the note amounting to \$83,200, including interest receivable of \$3,200, during the year ended December 31, 2014.

**7. Income Taxes**

Edgar Filing: RenovaCare, Inc. - Form S-1

There is no current or deferred tax expense for 2015 and 2014, 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:

	<b>2015</b>	<b>2014</b>
Deferred tax assets:		
Net operating loss and contribution carryforwards	\$ 2,646,000	\$ 2,285,000
Other	\$ 130,000	\$ 337,000
	\$ 2,776,000	\$ 2,622,000
Valuation allowance	\$ (2,776,000)	\$ (2,622,000)
Net deferred tax assets	\$ -	\$ -

The 2015 increase in the valuation allowance was \$154,000 (2014: \$509,000).

Table of Contents

The Company has available net operating loss and contribution carryforwards of approximately \$7,780,000 for tax purposes to offset future taxable income which expires commencing 2015 through to the year 2035. 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 2012 through 2015 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:

	<b>2015</b>	<b>2014</b>
Statutory federal income tax rate	34%	34%
Permanent differences and other	(22%)	-%
Valuation allowance	(12%)	(34%)
	0%	0%

**8. Subsequent Events**

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 and rendered \$1,000,000 as payment.

On March 16, 2016, the Company granted Mr. Thomas Bold, the Company's President & CEO, a stock option to purchase up to 60,000 shares of the Company's common stock, all of which vested on the date of the grant.

On March 16, 2016, the Company granted Ms. Rhonda Rosen, the Company's Chief Financial Officer, a stock option to purchase up to 20,000 shares of the Company's common stock, all of which vested on the date of the grant.

On March 16, 2016, the Company granted Dr. Kenneth Kirkland, a director of the Company, a stock option to purchase up to 50,000 shares of the Company's common stock, all of which vested on the date of the grant.

On March 16, 2016, the Company granted Mr. Joseph Sierchio, a director of the Company, a stock option to purchase up to 50,000 shares of the Company's common stock, all of which vested on the date of the grant.



The exercise price of each of the aforementioned options was \$1.91 per share, the closing price of the Company's common stock as listed on the OTCQB on March 15, 2016. The options may be exercised through March 15, 2026 on a cashless basis using the formula contained in the stock option agreement entered into between the above listed individual and the Company.

F-27

Table of Contents

**RENOVACARE, INC.**

**1,956,000 SHARES**

**COMMON STOCK**

**PROSPECTUS**

**JANUARY 23, 2017**

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

Our estimated expenses in connection with the issuance and distribution of the securities being registered are:

SEC filing fee	\$	1,000
Accounting fees and expenses	\$	5,000
Legal fees and expenses	\$	15,000
Miscellaneous	\$	1,000
Total	\$	22,000

**ITEM 14. INDEMNIFICATION OF OFFICERS AND DIRECTORS**

Section 78.7502(1) of the Nevada Revised Statutes ("**NRS**") authorizes a Nevada corporation to indemnify any director, officer, employee, or corporate agent "who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation" due to his or her corporate role. Section 78.7502(1) extends this protection "against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with the action, suit or proceeding if he acted in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful."

Section 78.7502(2) of the NRS also authorizes indemnification of the reasonable defense or settlement expenses of a corporate director, officer, employee or agent who is sued, or is threatened with a suit, by or in the right of the corporation. The party must have been acting in good faith and with the reasonable belief that his or her actions were in or not opposed to the corporation's best interests. Unless the court rules that the party is reasonably entitled to indemnification, the party seeking indemnification must not have been found liable to the corporation.

To the extent that a corporate director, officer, employee, or agent is successful on the merits or otherwise in defending any action or proceeding referred to in Section 78.7502(1) or 78.7502(2), Section 78.7502(3) of the NRS requires that he be indemnified "against expenses, including attorneys' fees, actually and reasonably incurred by him in connection with the defense."

Unless ordered by a court or advanced pursuant to Section 78.751(2), Section 78.751(1) of the NRS limits indemnification under Section 78.7502 to situations in which either (1) the stockholders, (2) the majority of a disinterested quorum of directors, or (3) independent legal counsel determine that indemnification is proper under the circumstances.

Section 78.751(2) authorizes a corporation's articles of incorporation, bylaws or agreement to provide that directors' and officers' expenses incurred in defending a civil or criminal action must be paid by the corporation as incurred, rather than upon final disposition of the action, upon receipt by the director or officer to repay the amount if a court ultimately determines that he is not entitled to indemnification.

Section 78.751(3)(a) provides that the rights to indemnification and advancement of expenses shall not be deemed exclusive of any other rights under any bylaw, agreement, stockholder vote or vote of disinterested directors. Section 78.751(3)(b) extends the rights to indemnification and advancement of expenses to former directors, officers, employees and agents, as well as their heirs, executors, and administrators.

Regardless of whether a director, officer, employee or agent has the right to indemnity, Section 78.752 allows the corporation to purchase and maintain insurance on his behalf against liability resulting from his or her corporate role.

Our Bylaws also contain broad indemnification provisions.

Table of Contents

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors or officers pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities Exchange Commission, this indemnification is against public policy as expressed in the Securities Act, and is therefore unenforceable.

There is no pending litigation or proceeding involving any of our directors, officers, employees, or other agents as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director, officer, employee, or other agent.

**ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES**

Set forth below in chronological order is a description of the Registrant's sales of unregistered securities since January 1, 2014:

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 and may be exercised on a cashless basis.

The offering was conducted pursuant to exemptions from the registration requirements afforded by, among others, Rule 506(b) of Regulation D and Regulation S, as promulgated under the Securities Act of 1933, as amended. Accordingly, the securities were sold only to investors who were either "accredited investors," as such term is defined in Rule 501(a) of Regulation D or up to 35 purchasers who are not "accredited investors," or who are not U.S. Persons, as such term is defined in Rule 902 of Regulation S.

On September 9, 2016, we entered into a loan agreement (the "**Loan Agreement**") with Kalen Capital Corporation ("**KCC**"); KCC is wholly owned by Mr. Harmel S. Rayat, our majority shareholder. 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 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 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.

Per the Loan Agreement, we issued KCC a Series E 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. 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 securities were sold pursuant to exemptions from the registration requirements afforded by, among others, Regulation S as the investor was not a U.S. Person, as such term is defined in Rule 902 of Regulation S.

We used the proceeds from the above transaction for research and development and general corporate purposes.

Table of Contents**ITEM 16. EXHIBITS****Exhibit**

<b>No.</b>	<b>Description of Exhibit</b>
3.1	Articles of Incorporation, as amended, of the Company, incorporated by reference and included in the Company's Registration Statement on Form 10-SB 12g filed on May 11, 1999, SEC file number 000-30156-99616992.
3.2	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	Bylaws 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 0156-131300357.
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 KCC 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 Stock Purchase Warrant, incorporated by reference and included in the Company's Form 8-K filed on June 10, 2015, SEC file number 000-30156-1592367.
4.5	Convertible Promissory Note dated September 9, 2016, between KCC 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
<u>5.1</u>	<u>Opinion of Satterlee Stephens LLP*</u>
10.1§	Employment Agreement dated June 20, 2013, between Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156-131259657.

- 10.2† Asset Purchase Agreement dated as of June 21, 2013, between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on July 18, 2013, as amended on November 21, 2013 and December 27, 2013, SEC file number 000-30156-131300357.
- 10.3§ Form of Stock Option Agreement, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156- 131259657.
- 10.4 Finder's Agreement dated August 13, 2013, between Vector Asset Management, Inc. and the Company, incorporated by reference and included in the Company's Form 10-Q filed on August 14, 2013, SEC file number 000-30156-13109753.



Table of Contents

10.5	At-Will Executive Services Agreement dated October 1, 2013, between Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 10-Q filed on November 14, 2013, SEC file number 000-30156-13129717.
10.6	Subscription Agreement for 3,500,000 units dated November 29, 2013, between Kalen Capital Corporation and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657.
10.7§	At-Will Consulting Agreement effective as of December 1, 2013, between Thomas Bold and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657.
10.8	Stock Purchase Agreement dated December 31, 2013, between Duke Mountain Resources, Inc., Fostung Resources Ltd. and the Company, incorporated by reference and included in the Company's Form 8-K filed on January 7, 2014, SEC file number 000-30156-14513586.
10.9§	At-Will Consulting Agreement effective as of April 1, 2014, between Patsy Trisler and the Company, incorporated by reference and included in the Company's Form 8-K filed on April 7, 2014, SEC file number 000-30156-14838542.
10.10§	Stock Option Agreement dated April 1, 2014, between Patsy Trisler and the Company, incorporated by reference and included in the Company's Form 8-K filed on April 7, 2014, SEC file number 000-30156-14838542.
10.11§	Stock Option Agreements dated August 14, 2014, between Kenneth Kirkland, Joseph Sierchio, Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 8-K filed on August 20, 2014, SEC file number 000-30156-141054256.
10.12	Post-Closing Amendment to Asset Purchase Agreement between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on September 15, 2014, SEC file number 000-30156-141102510.
10.13	Option Agreement 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 000-30156-15833270.
10.14	Form of Subscription Agreement, incorporated by reference and included in the Company's Form 8-K filed on June 10, 2015, SEC file number 000-30156-1592367.
10.15	Loan Agreement between KCC 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
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.



Table of Contents

23.1	Consent of Satterlee Stephens LLP*
23.2	<u>Consent of Peterson Sullivan LLP*</u>
24.1	<u>Power of Attorney*</u>
99.1§	2013 Incentive Stock Option Plan, incorporated by reference and included in the Company's Form 10-Q filed on November 14, 2013, SEC file number 000- 30156-13129717.
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension - Schema Document**
101.CAL	XBRL Taxonomy Extension - Calculation Linkbase Document**
101.DEF	XBRL Taxonomy Extension - Definition Linkbase Document**
101.LAB	XBRL Taxonomy Extension - Label Linkbase Document**
101.PRE	XBRL Taxonomy Extension - Presentation Linkbase Document**

---

\* Filed herewith.

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

§ Indicates a management contract or compensatory plan or arrangement.

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

Table of Contents

**ITEM 17. UNDERTAKINGS**

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any Prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness.

Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Table of Contents

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of New York, State of New York, on January 23, 2017.

**RenovaCare, Inc.**

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

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

Dated: January 23, 2017

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

Dated: January 23, 2017

By: */s/ Patsy Trisler*  
Name: Patsy Trisler  
Title: Vice President – Clinical  
& Regulatory Affairs

Dated: January 23, 2017

By: */s/ Kenneth Kirkland*  
Name: Kenneth Kirkland  
Title: Director

Dated: January 23, 2017

By: */s/ Joseph Sierchio*

Name: Joseph Sierchio

Title: Director