

RenovaCare, Inc.  
Form S-1/A  
April 07, 2017

As filed with the U.S. Securities and Exchange Commission on April 7, 2017

Registration No. 333-215661

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

**Washington, D.C. 20549**

**AMENDMENT NO. 1 TO**

**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**

**Thomas Bold**  
**RenovaCare, Inc.**  
**430 Park Avenue, Suite 702**  
**New York, New York 10022**  
**(888) 398-0202**

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(Address and telephone number  
of principal executive offices)

(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.

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

(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 (1)</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>\$ 369.97<sup>(6)</sup></b>

- (1) 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.
- (2) Represents shares of our common stock previously acquired by and issued to the Selling Stockholders in a private transaction directly with us.
- (3) The proposed maximum offering price per share is estimated solely for the purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act, using the closing price of our common stock as reported on the OTC Markets Group, Inc. QB tier on January 13, 2017, a date within five business days prior to the date of the filing of the original registration statement.
- (4) Represents shares of our common stock issuable upon exercise of Series D Stock Purchase Warrants (each a “Series D Warrant” and collectively, the “Series D Warrants”) that were purchased by the Selling Stockholders in a private transaction 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 Warrants may be exercised on a “cashless basis”.
- (5) The proposed maximum offering price per share is estimated solely for the purposes of calculating the registration fee in accordance with Rule 457(g) using the price at which the Series D Warrants may be exercised.
- (6) Previously paid.

**PROSPECTUS**

**SUBJECT TO COMPLETION, DATED APRIL 7, 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 April 4, 2017, the closing price of our common stock, as reported on the OTCQB was \$2.96 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 April 7, 2017

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**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 74,650,675 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."

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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.

## **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.

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**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:** 74,650,675

**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 76,606,675 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.

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The following tables set forth a summary of certain selected consolidated financial data for the fiscal years ended December 31, 2016 and 2015. 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 Year Ended</b>	<b>For the Year Ended</b>
	<b>December 31, 2016</b>	<b>December 31, 2015</b>
<b>Statements of Operations Data</b>		
Revenue	\$ 0	\$ 0
Loss from operations	\$ (1,898,222)	\$ (1,318,507)
Basic and diluted net loss per share	\$ (0.03)	\$ (0.02)
Weighted average shares outstanding used in basic and diluted net loss per share calculation	69,772,485	67,233,254

	<b>As of</b>	<b>As of</b>
	<b>December 31,</b>	<b>December 31,</b>
	<b>2016</b>	<b>2015</b>
<b>Balance Sheet Data</b>		
Cash and cash equivalents	\$ 418,031	\$ 397,589
Working capital	\$ 85,575	\$ 172,099
Total assets	\$ 603,318	\$ 560,736
Total liabilities	\$ 363,991	\$ 335,783
Total stockholders' equity	\$ 239,327	\$ 224,953

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**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 \$1,898,222 and \$1,318,507 for our fiscal years ended December 31, 2016 and 2015, respectively, and we have incurred a cumulative deficit of \$11,051,584 million through December 31, 2016. 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 December 31, 2016, we had cash and cash equivalents of \$418,031. 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 to 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.



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***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);
- the CellMist™ System may ultimately prove to be ineffective, unsafe or otherwise fail to receive necessary regulatory approvals;
- the CellMist™ System (or any derivatives), even if safe and effective, may be difficult to manufacture on a large scale or uneconomical to market;
- our marketing license or proprietary rights to products derived from the CellMist™ System may not be sufficient to protect our products from competitors;
- the proprietary rights of third parties may preclude us or our collaborators from making, using or marketing products utilizing the CellMist™ System; or,
- third parties may market superior, more effective, or less expensive technologies or products having comparable results to the CellMist™ System (or any derivatives).

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***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.

***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.

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***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.

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.

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***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.

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.



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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.

***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.

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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;

- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

***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.

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***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:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or the validation of our caregiver and patient reported outcome instruments;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our CellMist™ System and its underlying technology may not be sufficient to satisfy the FDA or comparable foreign regulatory authorities to support our submission or to obtain regulatory approval in the U.S. or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

***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.

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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.

***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.



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*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.

**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 74,650,675 shares issued and outstanding, of which 50,434,347 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.

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***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 quoted 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;
- submit an application to OTCQB and pay an application and annual fee; and

- submit an OTCQB Annual Certification confirming the Company Profile displayed on [www.otcmarkets.com](http://www.otcmarkets.com) is current and complete and providing additional information on officers, directors, and controlling shareholders.

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.

***Kalen Capital Corporation (“KCC”), a private corporation solely owned by Mr. Harmel Rayat, beneficially owns approximately 66% of our issued and outstanding stock. This ownership interest may permit KCC to influence significant corporate decisions.***

As of March 16, 2017, KCC, a private corporation solely owned by Harmel S. Rayat, a former officer and director of ours, beneficially owned approximately 50,008,783 shares (including shares issuable upon exercise of outstanding warrants and convertible notes), or approximately 66%, 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.

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*There are convertible loans in the aggregate principal amount of \$1,145,000 outstanding that we do not currently have the funds to repay.*

On September 9, 2016, we entered into a loan agreement (the “**KCC 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, which was evidenced by a convertible promissory note convertible 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 convert the note, subject to a floor price of \$1.23. On February 23, 2017, we entered into loan agreements with KCC and a member of our Board (the “**February Loan Agreements**”) pursuant to which we received \$420,000, at an annual interest rate of 7% per year, compounded quarterly and a maturity date of February 23, 2018, which was evidenced by convertible promissory notes convertible at the lesser of (i) \$3.45 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 convert the note, subject to a floor price of \$2.76. On March 6, 2017, we entered into a loan agreement with an investor (the “**March Loan Agreement**”) pursuant to which we received \$25,000, at an annual interest rate of 7% per year, compounded quarterly and a maturity date of February 23, 2018, which was evidenced by convertible promissory note. We do not currently have the funds to repay these loans.

*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 235,000 shares of our common stock. The exercise prices of these options range from \$0.80 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 2,343,401 shares of common stock. The exercise prices of these warrants are: (1) \$0.35 per share for the 720,000 Series A Warrant through July 12, 2019. The Series A Warrant vests in equal installments of 240,000 on July 12, 2014-2018 and expires on July 12, 2019; (2) \$1.10 for the 910,000 shares issuable upon exercise of the Series D Warrants through June 5, 2020; (3) 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 Warrant. the Series E Warrant may not be exercised prior to September 9, 2017 and expires on September 9, 2021; (4) the lesser of (i) \$3.45 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 128,985 shares issuable upon exercise of the Series F Warrants. The Series F Warrants may be exercised beginning on the one month anniversary of their issuance; 121,739 Series F Warrants expire on February 23, 2022 and the remaining 7,246 expire on March 9, 2022. 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. Each of the warrants may be exercised on a "cashless basis" using the formula set forth therein.

*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.

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***We have entered into a registration rights agreement (the “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.



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**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;
- new entrance of competitive products or further penetration of existing products in our markets;
- the effect on us from adverse publicity related to our products or the company itself; and
- any adverse claims relating to our intellectual property.

The 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.

Table of Contents**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."**

**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 April 4, 2017, was \$2.96.

As of the date of this prospectus there were 74,650,675 shares of our common stock outstanding and held by approximately 357 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, 2016</b>	<b>High</b>	<b>Low</b>
First Quarter (January 1 - March 31, 2016)	\$ 2.35	\$ 0.96
Second Quarter (April 1 – June 30, 2016)	\$ 2.58	\$ 1.96
Third Quarter (July 1 – September 30, 2016)	\$ 2.48	\$ 1.25
Fourth Quarter (October 1 – December 31, 2016)	\$ 2.81	\$ 0.88

<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

## 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.

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**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.*

**Results of Operations***Year Ended Year Ended December 31, 2016 versus December 31, 2015*

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

***Research and Development***

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

***General and Administrative***

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

***Other Income (Expense)***

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

**Liquidity and Capital Resources**

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

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

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America and applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. As discussed in Note 1 to the consolidated financial statements, we have incurred recurring operating losses since inception of \$11,051,584. We require additional funds to meet our obligations and maintain our operations. Subsequent to December 31, 2017, the Company received \$445,000 upon the sale of three convertible promissory notes. As a result, we have sufficient cash on hand to pay our administrative and general operating expenses through June 30, 2017. We do not currently have cash flow from operations as we have no commercialized products; without cash flow from operations, we will need to obtain additional funds (presumably through equity offerings, debt borrowing or through the exercise of outstanding warrants, which, if exercised in total for cash would result in proceeds of \$6,562,000; all of our outstanding warrants currently include a “cashless exercise” feature) in order to implement our current research and development programs for the CellMist™ System. If we are unable to obtain adequate funds, or if such funds are not available to us on acceptable terms, our ability to continue our business as planned will be significantly impaired and it may cause us to curtail operations.

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

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

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

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

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

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

## **Dividends**

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

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

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



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**Plans for Next Twelve Months**

During the next twelve months we intend to continue our research and development efforts on the CellMist™ System. As part of these efforts we intend to make certain filings with regulatory bodies, including, but not limited to, the FDA, in order to obtain regulatory approval for the clinical use of the CellMist™ System. Our cash position, relative to our cash requirements with respect to our research and development, raises substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should we be unable to continue as a going concern. Our actual results could differ materially from those anticipated in these forward-looking statements.

**Share Capital**

At December 31, 2016, we had:

- Authorized share capital of 10,000,000 preferred shares with par value of \$0.0001.
- Authorized share capital of 500,000,000 common shares with par value of \$0.00001 each.
- 70,069,693 common shares were issued and outstanding.

**Market Risk Disclosures**

We have not entered into derivative contracts either to hedge existing risks or for speculative purposes during the years ended December 31, 2016 and 2015, and the subsequent period through the date of this annual report.

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

We do not have any off-balance sheet arrangements or contractual obligations at December 31, 2016, and the subsequent period through the date of this annual report, that are likely to have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that have not been disclosed in our

consolidated financial statements.

### **Critical Accounting Policies**

See "**Note 2. Significant Accounting Policies**" in the Notes to the Consolidated Financial Statements attached hereto.

## **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 United States 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."

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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>).

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>).

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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.

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**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.



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*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.

### **Employees**

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

Table of Contents**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>Position</b>	<b>Director / Officer Since</b>
Thomas Bold	56	President, Chief Executive Officer and Interim Chief Financial Officer	December 2013
Patsy Trisler	69	Vice-President, Regulatory & Clinical Affairs	April 1, 2014
Kenneth Kirkland	74	Director	August 2013
Joseph Sierchio	67	Director	August 2010

**Biographical Information**

Set forth below are the names of all of our executive officers and directors, 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 Officers and Directors

**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.

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**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.

### **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.

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**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.

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

During the fiscal year ended December 31, 2016, the Board held a total of eleven (11) 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, 2016.

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.



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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.

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

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

Name		Fees earned or paid in cash <sup>(1)</sup> (\$)	Option awards	Total (\$)
			Aggregate Grant Date Fair Value <sup>(2)</sup> (\$)	
Joseph Sierchio <sup>(3)</sup>	2016	6,000	69,830	75,830
	2015	6,000	-	6,000
Kenneth Kirkland	2016	6,000	69,830	75,830
	2015	6,000	-	6,000

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

Table of Contents**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	Year	Salary/ consulting fee	Bonus	Stock awards	Option awards	All other compensation	Total
	December	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Thomas Bold <sup>(1)</sup>	2016	100,000	-	-	83,796	-	183,796
President, CEO and Interim CFO	2015	100,000	-	-	-	-	100,000
Rhonda B. Rosen <sup>(2)</sup>	2016	30,100	-	-	27,932	-	58,032
	2015	46,800	-	-	-	-	46,800

## Former CFO

Patsy Trisler <sup>(3)</sup>	2016	60,000	-	-	-	-	60,000
VP – Clinical & Regulatory Affairs	2015	60,000	-	-	-	-	60,000

(1) On December 1, 2013, we appointed Mr. Bold as our President & CEO. On October 8, 2016, Mr. Bold assumed the role of Chief Financial Officer commensurate with the resignation of Rhonda Rosen. On December 1, 2013 we entered into the Consulting Agreement with Mr. Bold. Pursuant to the terms of the Consulting Agreement, Mr. Bold is expected to serve on a part-time basis and will receive an annual fee of \$100,000, payable in 12 equal installments, which is prorated for any partial months during the term of the Consulting Agreement. In addition to Mr. Bold's fee, he was issued a stock option to purchase up to 40,000 shares of common stock at an exercise price of \$0.75 per share, the closing price of our common stock as quoted on the OTCQB on November 29, 2013, and a stock option to purchase up to 60,000 shares of common stock at an exercise price of \$1.91 per share, the closing price on March 15, 2016. The options may be exercised on a "cashless basis" using the formula contained therein and vest as follows: (a) 20,000 vested on December 1, 2014; (b) 20,000 vested on December 1, 2015; and (c) 60,000 vested on March 16, 2016.

(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 vest as follows: (a) 5,000 vested on the grant date; (b) 5,000 vested on August 14, 2015, and (c) 20,000 vested on March 16, 2016. On September 9, 2016, we terminated the at-will executive services agreement with Ms. Rosen.

Table of Contents**OUTSTANDING EQUITY AWARDS AT FISCAL-YEAR END**

The following table sets forth information regarding equity awards that have been previously awarded to each of the Named Executives and which remained outstanding as of December 31, 2016.

Name	Option Awards		Option Exercise Price (\$)	Option Expiration Date
	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable		
Thomas Bold	40,000	-	0.75	November 30, 2023
	60,000	-	1.91	March 15, 2026
Rhonda B. Rosen (former CFO)	10,000	-	0.80	October 8, 2018
	20,000	-	1.91	October 8, 2018
Patsy Trisler	20,000	30,000	1.05	March 31, 2025

**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, 2016 and 2015, stock-based compensation expense of \$282,262 and \$59,122, respectively, was recognized as general and administrative expenses. As of December 31, 2016 we had \$8,404 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.

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

At December 31, 2016 we had 385,000 (2015 – 257,500) 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.

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

\* less than 1%

(1) Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Each of the beneficial owners listed above has direct ownership of and sole voting power and investment power with respect to the shares of our common stock and except as indicated the address of each beneficial owner is 430 Park Avenue, Suite 702, New York, New York 10022.





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**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 10% stockholder of the company since the beginning of the previous fiscal year, and their immediate family members. We are required to report any transaction or series of transactions in which we or a subsidiary is a participant, the amount involved exceeds \$120,000, and a related person has a direct or indirect material interest.

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

- 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.

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The following are related party transactions for the past two fiscal years and in the period between December 31, 2016 and the date of this prospectus:

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

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

On February 23, 2017, we entered into the February Loan Agreements with KCC and Joseph Sierchio, a member of our Board, pursuant to which we borrowed an aggregate of \$420,000 at an annual interest rate of 7% per year, compounded quarterly, which was evidenced by convertible promissory notes (the "**February Notes**"). The February Notes mature on February 23, 2018, and, beginning on the one month anniversary, the February Notes can be converted, at the holders' sole discretion, into shares of our common stock at conversion rate equal to the lesser of: (i) \$3.45, 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 the holders elect to convert the February Notes, subject to a floor price of \$2.76.

Per the February Loan Agreements, we issued Series F Warrants to purchase up to 121,739 shares of our common stock at a purchase price of the lesser of: (i) \$3.45, the closing price of our common stock on the day prior to issuance of the Series F Warrants; or (ii) a 20% discount to the average closing price of our common stock for the five days prior to the date on which the holders elect to exercise the Series F Warrants. The Series F Warrants are exercisable for a period of five years from the date of issuance and may be exercised on a cashless basis. The Series F Warrants are exercisable beginning on the one month anniversary of their issuance.

On September 9, 2016, we entered into the KCC Loan Agreement 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 us with an initial loan in the amount of \$700,000, which was evidenced by the Note; the remaining \$200,000 may be loaned prior to December 31, 2017, upon the mutual agreement. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matures on December 31, 2017, and, beginning on the first anniversary of the Note, can be

converted, at KCC's sole discretion, into shares of our common stock at conversion rate equal to the lesser of: (i) \$1.54, the closing price of our common stock on the day prior to the issuance of the Note or (ii) a 20% discount to the average closing price of our common stock for the five days prior to the date on which KCC elects to convert the Note, subject to a floor price of \$1.23.

Per the Loan Agreement, we issued KCC a Series E 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 Series E Warrant may not be exercised prior to September 9, 2017.

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

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**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 74,650,675 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 af