

RenovaCare, Inc.
Form 424B4
April 25, 2018

PROSPECTUS

**Filed pursuant to Rule
424(b)(4)**

**Registration No.
333-222974**

RENOVACARE, INC.

4,404,136 SHARES OF 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 4,404,136 shares (collectively, the “**Shares**”) of our common stock, par value \$0.00001. The Shares being offered under this prospectus are comprised of:

- (a) 2,223,886 shares of common stock that were purchased by the Selling Stockholder in private placements with us pursuant to exemptions from the registration requirements of the Securities Act of 1933, as amended (the “**Securities Act**”);
- (b) 810,000 shares of common stock issuable upon exercise of a Series D Warrants allowing the holder to purchase shares of common stock at an exercise price of \$1.10 per share through June 5, 2020;
- (c) 460,250 shares of common stock issuable upon exercise of a Series G Warrants that vested on July 12, 2014 allowing the holder to purchase shares of common stock at an exercise price of \$2.68 per share through July 21, 2022; and
- (d) 910,000 shares of common stock issuable upon exercise of a Series H Warrants allowing the holder to purchase shares of common stock at an exercise price of \$2.75 per share through October 16, 2022.

Although we will pay substantially all the expenses incident to the registration of the Shares, we will not receive any proceeds from the sales of the Shares 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. Pink Marketplace-Current Information (the “**OTCPINC**”). On April 3, 2018, the closing price of our common stock, as reported on the **OTCPINC** was \$4.34 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 **OTCPINC**, 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 8.**

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 17, 2018

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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.

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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.

Organizational History

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 77,536,626 shares are outstanding as of April 3, 2018, and 10,000,000 shares of \$0.0001 par value preferred stock, of which none are outstanding.

Overview of Business

We are a development-stage company focusing on the acquisition, development and commercialization of autologous (using a patient’s own cells) cellular therapies for medical and aesthetic applications. On July 12, 2013, we, through our wholly owned subsidiary, RenovaCare Sciences Corp., completed the acquisition of our flagship technologies (collectively, the “CellMistTM System”) along with associated United States patent applications and two foreign patent

applications, the first of which was filed on August 23, 2007 (DE 10 2007 040 252.1) and the second of which was filed on April 27, 2011 (DE 10 2011 100 450.9), both of which have been granted. One of the US patent applications was granted to us on November 29, 2016 (Patent No. US 9,505,000) and the other patent application was granted to us on April 4, 2017 (Patent No. US 9,610,430). Two additional patent applications are pending.

On or about April 11, 2017, we received from Avita Medical Limited (“**Avita Medical**”) a petition For *Inter Partes* Review purporting to challenge the validity of the claims in U.S. Patent No. 9,610,430 (the “**Petition**”) before the Patent Trial and Appeal Board (“**PTAB**”) of the U.S. Patent & Trademark Office. Upon consideration of the arguments and evidence set forth by us and Avita, on December 18, 2017, the PTAB rendered a “**Final Written Decision**” dismissing the Petition in its entirety and, accordingly, confirming all such claims. Avita Medical’s right to file an appeal expired on February 21, 2018.

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

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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. We have filed additional patent applications related to the CellMist™ Solution and SkinGun™ technologies.

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

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

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

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

Corporate Information

We recently relocated our corporate headquarters to:

Pittsburgh Life Sciences Greenhouse

2425 Sidney Street

Pittsburgh, PA 15203

Our telephone number is (888) 398-0202. Our website is 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 8 of this prospectus.

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THE OFFERING

| | |
|--|---|
| Securities Being Offered: | 4,404,136 shares of common stock, consisting of: |
| | (a) 2,223,886 shares of common stock that were purchased by the Selling Stockholder in private placements with us pursuant to exemptions from the registration requirements of the Securities Act; |
| | (c) 810,000 shares of common stock issuable upon exercise of a Series D Warrants allowing the holder to purchase shares of common stock at an exercise price of \$1.10 per share through June 5, 2020; the Series D Warrants contain cashless exercise provisions. |
| | (b) 460,250 shares of common stock issuable upon exercise of a Series G Warrants that vested on July 12, 2014 allowing the holder to purchase shares of common stock at an exercise price of \$2.68 per share through July 21, 2022; the Series D Warrants contain cashless exercise provisions. |
| | (d) 910,000 shares of common stock issuable upon exercise of a Series H Warrants allowing the holder to purchase shares of common stock at an exercise price of \$2.75 per share through October 16, 2022; the Series D Warrants contain cashless exercise provisions. |
| | The Series D, G, and H Warrants are referred to collectively as the “Warrants.” |
| 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 Commencement of the Offering: | On April 3, 2018 there were 77,536,626 issued and outstanding. |
| 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 | Assuming all of the Warrants are exercised on a cash basis upon |

| | |
|---------------------------------------|---|
| <i>Offering:</i> | completion of this offering there will be 79,716,876 shares issued and outstanding. |
| <i>OTC Pink Market Symbol:</i> | RCAR |
| <i>Transfer Agent:</i> | Worldwide Stock Transfer, LLC, One University Plaza, Suite 505, Hackensack, NJ 07601. |

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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 8 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 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:

Pursuant to the terms of Registration Rights Agreements (collectively, the “**Registration Rights Agreement**”) we entered into with the Selling Stockholders, we agreed to keep the registration statement, of which this prospectus is a part of, effective until the earlier of:

(a) the date the investor’s securities have been sold in accordance with Rule 144, as promulgated under the Securities Act (“**Rule 144**”) or this prospectus as the same may be amended, modified or supplemented from time to time;

(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 investor pursuant to an exemption from the registration requirements of the Securities Act.

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The following tables set forth a summary of certain selected consolidated financial for the fiscal years ended December 31, 2017 and 2016. 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.

| | For the Year Ended December 31, 2017 | For the Year Ended December 31, 2016 |
|--|---|---|
| Statements of Operations Data | | |
| Revenue | \$ - | \$ - |
| Loss from operations | \$ (2,695,823) | \$ (1,898,222) |
| Basic and diluted net loss per share | \$ (0.05) | \$ (0.03) |
| Weighted average shares outstanding used in basic and diluted net loss per share calculation | 74,386,340 | 69,772,485 |

| | As of December 31, 2017 | As of December 31, 2016 |
|----------------------------|--|--|
| Balance Sheet Data | | |
| Cash and cash equivalents | \$ 2,906,237 | \$ 418,031 |
| Working capital | \$ 2,638,318 | \$ 85,575 |
| Total assets | \$ 3,060,422 | \$ 603,318 |
| Total liabilities | \$ 1,395,909 | \$ 363,991 |
| Total stockholders’ equity | \$ 1,664,513 | \$ 239,327 |

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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, expect losses to continue for the foreseeable future and may never achieve or maintain profitability.

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 loss from operations of 2,695,823 and \$1,898,222 for our fiscal years ended December 31, 2017 and 2016, respectively. We have incurred a cumulative deficit of \$14,740,922 through December 31, 2017. We anticipate incurring losses through at least December 31, 2018. We may not be able to successfully achieve or sustain profitability. Successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure.

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, 2017, we had cash and cash equivalents of \$2,906,237. We anticipate that we will remain engaged in research and product development activities through at least December 31, 2018. Based upon our current level of operations and expenditures, we believe that absent any modification or expansion of our existing research, development and testing activities, cash on hand should be sufficient to enable us to continue operations through at least December 31 2018. The Company expects to incur losses as it continues development of its products and technologies and expects that it will need to raise additional capital through the sale of its securities to accomplish its business plan and failing to secure such additional funding before achieving sustainable revenue and profit from

operations poses a significant risk. The Company's ability to fund the development of its cellular therapies will depend on the amount and timing of cash receipts from future financing activities. There can be no assurance as to the availability or terms upon which such financing and capital might be available.

If adequate funds, including proceeds, if any, from the exercise of the Warrants 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.

We may need additional capital to reach and maintain a sustainable level of positive cash flow and if we raise such additional capital through the issuance of equity or convertible debt securities, your ownership will be diluted, and equity securities issued may have rights, preferences and privileges superior to the shares of common stock.

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If we are unable to achieve profitability sufficient to permit us to fund our operations and other planned actions, we may be required to raise additional capital. There can be no assurance that such capital would be available on favorable terms, or at all. If we raise additional capital through the issuance of equity or convertible debt securities, the percentage ownership held by existing stockholders may be reduced, and the market price of our common stock could fall due to an increased number of shares available for sale in the market. Further, our board has the authority to establish the designation of additional shares of preferred stock that may be convertible into common stock without any action by our stockholders, and to fix the rights, preferences, privileges and restrictions, including voting rights, of such shares. Any such additional shares of preferred stock may have rights, preferences and privileges senior to those of outstanding common stock, and the issuance and conversion of any such preferred stock would further dilute the percentage ownership of our stockholders. Debt financing, if available, may involve restrictive covenants, which may limit our operating flexibility with respect to certain business matters. If we are unable to secure additional capital as circumstances require, we may not be able to fund our planned activities or continue our operations.

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.

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 31, 2018.

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, if possible, 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.

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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).

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.

We may be adversely affected if we violate privacy and security regulations or suffer a data breach.

Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the unauthorized use and disclosure of such information. In particular, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing privacy, security, and breach notification regulations, collectively, HIPAA Standards, govern the use and disclosure of protected health information by "covered entities," which are healthcare providers that submit electronic claims, health plans and healthcare clearinghouses, as well as their "business associates" and their subcontractors. Our employee health benefit plans are considered "covered entities" and, therefore, are subject to the HIPAA Standards.

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We may be adversely affected if our internal control over financial reporting fails or is circumvented.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. We are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting, but as a smaller reporting company we are exempt from the requirement to have our independent accountants attest to our internal control over financial reporting. If it were to be determined that our internal control over financial reporting is not effective, such shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively affect the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The effect of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board and our board committees and as executive officers.

If we are unable to protect effectively our intellectual property, we may not be able to operate our business and third parties may use our technology, both of which would impair our ability to compete in our markets.

Our success will depend in significant part on our ability to obtain and maintain meaningful patent protection for certain of our technologies and products throughout the world. Patent law relating to the scope of claims in the technology fields in which we will operate is still evolving. The degree of future protection for our proprietary rights is uncertain. We will rely on patents to protect a significant part of our intellectual property and to enhance our competitive position. However, our presently pending or future patent applications may not issue as patents, and any patent previously issued to us or our subsidiaries may be challenged, invalidated, held unenforceable or circumvented. Furthermore, the claims in patents that have been issued to us or our subsidiaries or that may be issued to us in the future may not be sufficiently broad to prevent third parties from producing competing products similar to our products. In addition, the laws of various foreign countries in which we plan to compete may not protect our intellectual property to the same extent as do the laws of the United States. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive will be materially impaired.

If third parties make or file claims of intellectual property infringement against us, or otherwise seek to establish their intellectual property rights, we may have to spend time and money in response and cease some of our operations.

Third parties may claim that we are employing their proprietary technology without authorization or that we are infringing on their patents. We could incur substantial costs and diversion of management and technical personnel in defending against any of these claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively block our ability to further develop, commercialize and sell products. In the event of a successful claim of infringement, courts may order us to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing available products.

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Lawsuits against us by third-parties that allege we infringe their intellectual property rights could harm our potential business and operating results.

There is considerable patent and other intellectual property activity in the industry in which we operate. We may be unaware of intellectual property rights of others that may cover some or all of our technology. Additionally, notwithstanding our receipt of a patent, a third-party may nevertheless challenge the validity of one or more claims included in the patent, which may require us to expend significant funds to defend our claims. For example, As an example, or about April 11, 2017, we received from Avita Medical a Petition For *Inter Partes* Review purporting to challenge, before the PTAB of the U.S. Patent & Trademark Office, the validity of the claims in U.S. Patent No. 9,610,430 (the “**Proceeding**”). Upon consideration of the arguments and evidence set forth by us and Avita Medical, on December 18, 2017, the PTAB rendered a Final Written Decision dismissing the Petition in its entirety and, accordingly, confirming all such claims. Avita Medical’s right to file an appeal expired on February 21, 2018.

In 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.

Our proprietary rights may not adequately protect our technologies and products.

Our commercial success will depend on our ability to obtain patents and/or regulatory exclusivity and maintain adequate protection for our technologies and products in the United States and other countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We intend to apply for additional patents covering both our technologies and products, as we deem appropriate. We may, however, fail to apply for patents on important technologies or products in a timely fashion, if at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, the patent positions of life science industry companies are highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, we cannot guarantee that:

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- we were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our patents will be valid or enforceable;
- any patents issued to us will provide us with any competitive advantages, or will not be challenged by third parties; and
- we will develop additional proprietary technologies that are patentable, or the patents of others will not have an adverse effect on our business.

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. Our ability to maintain and solidify our proprietary position for our products will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, unenforceable or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. We also rely on trade secrets to protect some of our technology, especially where it is believed that patent protection is inappropriate or unobtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our products in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products. These products may compete with our products, and may not be covered by any patent claims or other intellectual property rights.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in

foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against us.

Our success will depend to a significant degree on our ability to secure and protect intellectual property rights and enforce patent and trademark protections relating to our technology. While we believe that the protection of patents and trademarks is important to our business, we also rely on a combination of copyright, trade secret, nondisclosure and confidentiality agreements, know-how and continuing technological innovation to maintain our competitive position. From time to time, litigation may be advisable to protect our intellectual property position. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any litigation in this regard could be costly, and it is possible that we will not have sufficient resources to fully pursue litigation or to protect our intellectual property rights. This could result in the rejection or invalidation of our existing and future patents. Any adverse outcome in litigation relating to the validity of our patents, or any failure to pursue litigation or otherwise to protect our patent position, could materially harm our business and financial condition. In addition, confidentiality agreements with our employees, consultants, customers, and key vendors may not prevent the unauthorized disclosure or use of our technology. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Enforcement of these agreements may be costly and time consuming. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity or enforceability of these patents is upheld, the court will refuse to stop the other party on the grounds that such other party's activities do not infringe our rights.

If we wish to use the technology claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity or enforceability of the patents or incur the risk of litigation in the event that the owner asserts that we infringed its patents. The failure to obtain a license to technology or the failure to challenge an issued patent that we may require to discover, develop or commercialize our products may have a material adverse effect on us.

If a third party asserts that we infringed its patents or other proprietary rights, we could face a number of risks that could seriously harm our results of operations, financial condition and competitive position, including:

- patent infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not the claims have merit, and which could delay a product and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our product or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and
- if a license is available from a third party, we may have to pay substantial royalties or lump-sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license.

The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent, and/or that the patent claims are invalid, and/or that the patent is unenforceable and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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U.S. patent laws as well as the laws of some foreign jurisdictions provide for provisional rights in published patent applications beginning on the date of publication, including the right to obtain reasonable royalties, if a patent subsequently issues and certain other conditions are met.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology.

Patent applications filed by third parties that cover technology similar to ours may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party files a U.S. patent application on an invention similar to ours, we may elect to participate in or be drawn into an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. We cannot predict whether third parties will assert these claims against us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit and whether they are resolved in favor of or against us, we may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

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.

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

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

- customer acceptance of our products;
- obtaining third-party coverage or reimbursement for our products;
- performance and reliability of our products as compared with other alternative products;
- the ability to offer our products for sale at an attractive value and the willingness of physicians to administer our products and their acceptance as part of the medical department routine;
- the prevalence and severity of any side effects;
- the efficacy, potential advantages and timing of introduction to the market of alternative treatments; and
- our failure to develop and maintain successful relationships with health care professionals, manufacturers, distributors, and other resellers, as well as strategic partners.

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

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

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

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

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.

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

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

- regulators may not authorize us to conduct a clinical trial within a country or at a prospective trial site or may change the design of a study;
- delays may occur in reaching agreement on acceptable clinical trial terms with regulatory authorities or prospective sites, or obtaining institutional review board approval;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional trials or to abandon strategic projects;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we expect, or patients may not participate in necessary follow-up visits to obtain required data, any of which would result in significant delays in our clinical testing process;
- our third-party contractors, such as a research institution, may fail to comply with regulatory requirements or meet their contractual obligations to us;
- we may be forced to suspend or terminate our clinical trials if the participants are being exposed, or are thought to be exposed, to unacceptable health risks or if any participant experiences an unexpected serious adverse event;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;
- the cost of our clinical trials may be significantly greater than we anticipate;
- an audit of preclinical or clinical studies by regulatory authorities may reveal noncompliance with applicable protocols or regulations, which could lead to disqualification of the results and the need to perform additional studies; and
- delays may occur in obtaining our clinical materials.

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

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.

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

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

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

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

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

- 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;
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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.

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

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

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

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

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

perform other corrective actions at our respective facilities. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents.

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.

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

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

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

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

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

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

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

any failure to effectively integrate new personnel could prevent us from successfully growing our company.

We have not yet identified or hired a complete management, operations or sales and marketing team and if it takes longer than anticipated or if costs are more than anticipated to do so, the Company could be adversely affected.

We have not yet identified a complete management, sales or marketing team. As a result, aside from the directors, officers and key employees referenced in this Prospectus, investors will not have the benefit of knowing the identities and backgrounds of such team members in making their investment decisions. In addition, we have estimated the compensation we will have to pay to recruit a qualified management, operations and sales and marketing team and have not engaged a compensation consultant or other professional to estimate such costs, but have relied solely on the judgment of our directors. If the budgeted compensation expense is not adequate to retain a qualified management, operations, and sales and marketing team, we may need to scale back other aspects of our proposed operations or we may need to raise additional capital to commence operations. In addition, if it takes longer than anticipated to recruit a qualified team, the commencement of operations could be delayed. All of these potential issues could have a material adverse impact on the Company.

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Risks Related To Ownership of Our Common Stock and This Offering

We are not a fully reporting company under the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act; therefore, we are subject only to the reporting requirements of Section 15(d) of the Exchange Act.

We are not a fully reporting company under the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”); therefore, we are subject only to the reporting requirements of Section 15(d) of the Exchange Act. Until our Common Stock is registered under the Exchange Act, we will be subject only to the reporting obligations imposed by Section 15(d) of the Exchange Act, which we refer to as Section 15(d). Section 15(d) requires that issuers file periodic and current reports with the U.S. Securities and Exchange Commission (the “**Commission**” or the “**SEC**”) when they have issued any class of securities for which a registration statement was filed and became effective pursuant to the Securities Act. The purpose of Section 15(d) is to ensure that investors who buy securities in registered offering are provided with the same information on an ongoing basis that they would receive if the securities they purchased were listed on a securities exchange or the issuer were otherwise subject to periodic reporting obligations. However, companies that are required to report only under Section 15(d) are not subject to some of the Exchange Act reporting requirements. For example, companies that are required to report only under Section 15(d) are not subject to the short-swing profit reporting requirements contained in Section 16 of the Exchange Act, the beneficial ownership reporting requirements contained in Section 13 of the Exchange Act, the institutional investor reporting rules or the third-party tender offer rules, or the Exchange Act’s proxy rules contained in Section 14 of the Exchange Act.

The reporting obligations under Section 15(d) of the Exchange Act are automatically suspended when: (i) any class of securities of the issuer reporting under Section 15(d) is registered under Section 12 of the Exchange Act; or (ii) at the beginning of the issuer’s fiscal year, other than the year in which the applicable registration statement became effective, if the class of securities covered by the registration statement is held of record by fewer than 300 persons. In the latter case, the Company would no longer be subject to periodic reporting obligations so long as the number of holders remained below 300 unless we filed a registration statement with the Securities and Exchange Commission under Section 12 of the Exchange Act. If our obligation to file reports under Section 15(d) is suspended (other than due to our having registered our common stock under Section 12 of the Exchange Act), then investors will have reduced visibility with respect to the Company, its financial condition and results of operations.

Until our Common Stock is listed on an exchange, we expect to remain eligible for quotation on the OTCBB, on another over-the-counter quotation system or in the “pink sheets.” In those venues, however, an investor may find it difficult to obtain accurate quotations for our common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect the liquidity of your shares. This would also make it more difficult for us to raise additional capital or attract qualified employees or partners. Please refer to “***Our common stock is currently quoted on the OTC PINK which may make it more difficult for you to purchase or sell***”

shares of the Company's Common Stock" below.

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 beyond 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.

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Since our common stock is thinly traded its trading price is likely to be highly volatile and could be subject to extreme fluctuations in response to various factors, many of which are beyond our control, including ,but not limited to:

- the trading volume of our common stock;
- the number of securities analysts, market-makers and brokers following our common stock;
- new products or services introduced or announced by us or our competitors;
- actual or anticipated variations in quarterly operating results;
- conditions or trends in our business industries;
- announcements by us of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- sales of our common stock and
- general stock market price and volume fluctuations of publicly-traded, and particularly microcap, companies.

Should our common stock become subject to the “penny stock rules,” the market for our common stock, as well as a stockholder’s ability to sell his shares, would be adversely affected.

The SEC has also adopted rules that regulate broker-dealer practices in connection with transactions in “penny stocks” as such term is defined by Rule 15c-9. Penny stocks are generally equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or quoted on the Nasdaq system provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). As of the date of this prospectus, shares of our common stock were quoted for trading at a price above \$5.00 per share. Under FINRA guidelines and rules, the actual transaction price is used or, in the absence of a transaction, the price is the inside bid quotation for the security displayed on an automated interdealer quotation system having characteristics specified by the Exchange Act, including dissemination of last-sale information. If there is no inside bid quotation, the price will be determined by the average of three or more bid quotations by market makers in an interdealer quotation system, which includes the OTCQB and other quotation media of general circulation such as the OTC PINK.

The classification of our shares as penny stocks makes it more difficult for a broker-dealer to sell the stock into a secondary market, which makes it more difficult for a purchaser to liquidate his or her investment. Any broker-dealer engaged by the purchaser for the purpose of selling his or her shares in Renovacare will be subject to the penny stock rules.

The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document approved by the SEC, which: (i) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (ii) contains a description of the broker’s or dealer’s duties to the customer and of the rights and remedies available to the customer

with respect to a violation to such duties or other requirements of the Securities Act; (iii) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and significance of the spread between the bid and ask price; (iv) contains a toll-free telephone number for inquiries on disciplinary actions; (v) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (vi) contains such other information and is in such form as the SEC shall require by rule or regulation. The broker-dealer also must provide to the customer, prior to effecting any transaction in a penny stock, (i) bid and offer quotations for the penny stock; (ii) the compensation of the broker-dealer and its salesperson in the transaction; (iii) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (iv) monthly account statements showing the market value of each penny stock held in the customer's account.

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In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitability statement.

We expect that if our common stock is subsequently classified as a "penny stock" the foregoing disclosure requirements will have the effect of reducing the trading activity in the secondary market for our stock because it will be subject to these penny stock rules; and, therefore, stockholders may have difficulty selling those securities.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may also limit a stockholder's ability to buy and sell our common stock, which could depress the price of our common stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require a broker-dealer to have reasonable grounds for believing that the investment is suitable for that customer before recommending an investment to a customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives, and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. Thus, the FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares of common stock, have an adverse effect on the market for our shares of common stock, and thereby depress our price per share of common stock.

Sales of a substantial number of shares of our common stock into the public market by the Selling Stockholders may result in significant downward pressure on the price of our common stock and may affect the ability of our stockholders to realize any trading price of our common stock.

Sales of a substantial number of shares of our common stock into the public market by the Selling Stockholders may result in significant downward pressure on the price of our common stock and may affect the ability of our stockholders to realize any trading price of our common stock when and if a trading market develops for our common stock.

Any significant downward pressure on the price of our common stock as the Selling Stockholders sell their shares of our common stock could encourage other stockholders to sell as well as short sales by the Selling Stockholders or others. Any such short sales could place further downward pressure on the 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 April 3, 2018 we had 77,536,626 shares issued and outstanding, of which 51,513,687 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 re-sales could decrease our stock price and because of the availability of resale shares to those interested in investing in our common stock.

Our common stock is currently quoted on the OTC PINK which may make it more difficult for you to purchase or sell shares of the Company's Common Stock.

Prior to February 26, 2018, our stock was included for trading on the OTCQB; on February 23, 2018 we received an email notification from OTC Markets Group, Inc. (the “**OTC Markets**”) which regulates the OTCQB informing us that effective immediately, our stock would be quoted on the OTC PINK and that a caveat emptor designation would be assigned to our stock. This action was taken by OTC Markets pursuant to Section 4.2 of the OTCQB Standards, which generally provide that the OTC Markets may remove the Company's securities from trading on the OTCQB market immediately and at any time, without notice, if OTC Markets, in its sole and absolute discretion, believes that the continued inclusion of the Company's securities would impair the reputation or the integrity of OTC Markets or be detrimental to the interests of investors. Such concerns may include but are not limited to promotion, spam or disruptive corporate actions even when adequate current information is available.

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During the time it is labeled caveat emptor, any stock that is not in OTC Pink will also have its quotes blocked on www.otcm Markets.com. Although facts and circumstances may differ, generally, OTC Markets Group will remove the caveat emptor designation once an issuer demonstrates that it meets the qualifications for OTC Pink (which we believe we do), has updated and verified the information in its profile on www.otcm Markets.com (which we have done), and demonstrates that there is no longer a public interest concern (which we are endeavoring to demonstrate to the OTC Markets). We cannot, at this time, state with any certainty if or when the caveat emptor designation we received will be removed.

Removal of the caveat emptor designation does not mean that trading in our stock will automatically be resumed on the OTCQB. Once removed, we will need to reapply for listing on the OTCQB, which application may or may not be approved. If not approved, we expect that our stock will continue to trade on the OTC Pink.

To be eligible for OTCQB, companies will be required to at least:

- 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.otcm Markets.com is current and complete and providing additional information on officers, directors, and controlling shareholders.

While the Company is addressing the OTC Markets concerns, there is no assurance that it will be able to do so to the satisfaction of the OTC Markets. In the event we do not submit an application for listing on the OTCQB or if we do and the application is not approved, we expect that our stock will continue to trade on 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 January 17, 2018, KCC, a private corporation solely owned by Harmel S. Rayat, our director and Chairman, beneficially owned approximately 51,894,709 shares (including shares issuable upon exercise of outstanding warrants and convertible notes or approximately 66%, of our outstanding common stock. See footnote 7 to the beneficial ownership table in the section of this prospectus titled “SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.”

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 \$1,095,000 outstanding that we do not currently have the funds to repay.

On September 9, 2016, we entered into the Loan Agreement with KCC pursuant to which KCC agreed to loan us up to \$900,000 at an annual interest rate of 7% per year, compounded quarterly. KCC provided an initial loan in the amount of \$700,000, which was evidenced by a convertible promissory note (the “**Note**”); the remaining \$200,000 needed to be loaned prior to December 31, 2017. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matured on December 31, 2017, but was extended to December 31, 2019 pursuant to the Amendment No. 1, dated as of January 26, 2018, to the Note. Except for the extension of the maturity date, the Note was not otherwise amended and continues in full force and effect. Beginning on September 9, 2017, the Note became convertible, at KCC’s sole discretion, into shares of our common stock at conversion rate equal to the lesser of: (i) \$1.54, the closing price of our common stock on the day prior to the issuance of the Note or (ii) a 20% discount to the average closing price of our common stock for the five days prior to the date on which KCC elects to convert the Note.

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 (\$395,000 from KCC and \$25,000 from Mr. Sierchio) at an annual interest rate of 7% per year, compounded quarterly, which was evidenced by the February Notes. On October 19, 2017, the Company repaid the February Note of Mr. Sierchio in full. The maturity date of the February Note was extended from February 23, 2018, to December 31, 2019 pursuant to the Amendment No. 1, dated as of January 26, 2018, to the Note. Except for the extension of the maturity date, the February Note was not otherwise amended and continues in full force and effect. The KCC February Note can be converted, at KCC’s 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 February 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 February Note, subject to a floor price of \$2.76.

If foregoing notes are converted and the shares issued, such shares will 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 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 545,000 shares of our common stock. The exercise prices of these options range from \$0.80 to \$4.20 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 3,011,912 shares of common stock. Each of the warrants may be exercised on a “cashless basis” using the formula set forth therein at prices ranging from \$0.35 to \$3.45 per share. If exercised the shares issuable may be resold immediately pursuant to Rule 144, to the extent available. Such sales could exert downward pressure on the market price of our common stock and may cause other stockholders and others to sell their stock or to enter into short sales transactions which will further exacerbate the downward pressure on the stock price.

We may sell additional equity securities in the future and your ownership interest in the Company may be diluted as a result of such sales.

We intend to sell additional equity securities in order to fully implement our business plan. Such sales will be made at prices determined by our board of directors based on factors deemed appropriate at the time; accordingly, such sales by us could be made at prices less than the price of the shares of our common stock purchased pursuant to this prospectus or prevailing market prices at the time, in which case, investors could experience dilution of their investment.

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

Our Articles of Incorporation allow our Board of Directors 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.

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.

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 that 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 have timely filed the initial registration statement that we were required to file on behalf of KCC. At the request of KCC we recently, except for the Shares registered for resale on behalf of KCC pursuant to the registration statement of which this prospectus is part, deregistered all of the shares previously registered for resale 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.

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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 pursuant to this prospectus.

Our articles of incorporation provide for indemnification of officers and directors at our expense and limit their liability, which may result in a major cost to us and hurt the interests of our stockholders because corporate resources may be expended for the benefit of officers and/or directors.

Our articles of incorporation and applicable Nevada law provide for the indemnification of our directors, officers, employees, and agents, under certain circumstances, against attorney's fees and other expenses incurred by them in any litigation to which they become a party arising from their association with or activities on our behalf. We will also bear the expenses of such litigation for any of our directors, officers, employees, or agents, upon such person's promise to repay us if it is ultimately determined that any such person shall not have been entitled to indemnification. This indemnification policy could result in substantial expenditures by us, which we will be unable to recoup.

We have been advised that, in the opinion of the SEC, indemnification for liabilities arising under federal securities laws is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against these types of liabilities, other than the payment by us of expenses incurred or paid by a director, officer or controlling person in the successful defense of any action, suit or proceeding, is asserted by a director, officer or controlling person in connection with the securities being registered, we will (unless in the opinion of our counsel, the matter has been settled by controlling precedent) submit to a court of appropriate jurisdiction, the question whether indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue. The legal process relating to this matter, if it were to occur, is likely to be very costly and may result in us receiving negative publicity, either of which factors is likely to materially reduce the market and price for our common stock.

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 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:

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- 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 that may be issued to the Selling Stockholders upon exercise of outstanding warrants. We will not receive any proceeds from the sale of shares of our common stock in this offering. We may receive proceed from the exercise of warrants and or options and to the extent we do receive any such proceeds they will be used to fund the research, development and commercialization of the CellMist SystemTM and for general working capital.

DETERMINATION OF OFFERING PRICE

The Selling Stockholders will determine at what price they may sell the offered shares, and such sales may be made at prevailing market prices, or at privately negotiated prices. **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 OTCPIPC under the symbol “RCAR.” Our warrants are not currently traded on any market. The closing price of our common stock as quoted on the OTCPIPC on April 3, 2018, was \$4.34.

As of April 3, 2018 there were 77,536,626 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.

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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, and since February 26, 2018 on the OTCPIPC:

| Fiscal Year Ending December 31, 2018 | High | Low |
|---|-------------|------------|
| First Quarter (January 1 – March 31, 2017) | \$ 12.82 | \$ 4.28 |

| Fiscal Year Ended December 31, 2017 | High | Low |
|--|-------------|------------|
| First Quarter (January 1 – March 31, 2017) | \$ 5.50 | \$ 2.10 |
| Second Quarter (April 1 – June 30, 2017) | \$ 4.75 | \$ 2.49 |
| Third Quarter (July 1 – September 30, 2017) | \$ 3.95 | \$ 2.87 |
| Fourth Quarter (October 1 – December 31, 2017) | \$ 4.95 | \$ 2.99 |

| Fiscal Year Ended December 31, 2016 | High | Low |
|--|-------------|------------|
| 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 |

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, 2017 versus December 31, 2016*

| | Year Ended December 31, | | Increase / | Percentage |
|----------------------------|--------------------------------|--------------|-------------------|-------------------|
| | 2017 | 2016 | (Decrease) | Change |
| Operating expense: | | | | |
| Research and development | \$ 473,461 | \$ 302,503 | \$ 163,958 | 53 |
| General and administrative | 1,318,357 | 1,306,457 | 11,900 | 1 |
| Stock compensation | 904,004 | 282,262 | 621,742 | 220 |
| Total operating expense | \$ 2,695,822 | \$ 1,898,222 | \$ 797,600 | 42 |

Research and Development

Research and development (“**R&D**”) costs represent costs incurred to develop our CellMist™ System and are incurred pursuant to agreements with third party providers and certain internal R&D cost allocations. Payments under these agreements include salaries and benefits for R&D personnel, allocated overhead, contract services and other costs. R&D costs are expensed when incurred. R&D costs, excluding stock based compensation, increased during the year ended December 31, 2017 compared to 2016, as a result of the timing of our R&D expenses.

General and Administrative

General and administrative (“**G&A**”) costs include all expenditures incurred other than research and development related costs, including costs related to personnel, professional fees, travel and entertainment, public company costs, insurance and other office related costs. 2017 G&A costs, excluding stock based compensation, remained flat compared to 2016 and included an increase of \$294,000 related to professional fees and \$4,000 of other costs offset by a \$61,000 decrease in personnel costs and \$225,000 decrease in investor communications costs.

Stock Compensation

Expense associated with equity based transactions is calculated and expensed in our financial statements as required pursuant to various accounting rules and is non-cash in nature. Stock compensation represents the expense associated with the amortization of our stock options. Stock compensation expense increased during 2017 compared to 2016 due to the May 11, 2017 grant of 310,000 stock options with a weighted average grant date fair value of \$3.38 per share of which 160,000 vested on the date of grant whereas in 2016, 187,500 stock options were granted with a fair value of \$1.40 and were fully vested upon grant.

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Other Income (Expense)

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

Liquidity and Capital Resources

The Company does not have any commercialized products, has not generated any revenue since inception and has sustained recurring losses and negative cash flows since inception. The Company has incurred recurring operating losses since inception of \$14,740,922. The Company expects to incur losses as it continues development of its products and technologies. Over the past year, the Company has been funded through the sale of equity securities and proceeds from convertible promissory notes. As of December 31, 2017, the Company had \$2,906,237 of cash. The Company believes that it currently has sufficient cash to meet its funding requirements over the next year.

Net cash used in operating activities was \$1,674,028 during the year ended December 31, 2017, compared to net cash used in operating activities of \$1,788,608 during the year ended December 31, 2016. The decrease in cash used in operating activities is primarily due to the timing of payments made against accounts payable where the Company had a higher accounts payable balance in 2017 compared to 2016.

Net cash used in investing activities was \$0 during the year ended December 31, 2017, compared to \$951 during the year ended December 31, 2016.

Net cash provided by financing activities was \$4,162,234 during the year ended December 31, 2017, compared to \$1,810,001 during the year ended December 31, 2016.

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

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

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

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

On December 6, 2016, the Company issued 100,000 shares of common stock upon the exercise of a Series D Warrant at an exercise price of \$1.10 per share resulting in \$110,000 of proceeds to the Company.

On 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.

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.

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Fair Value of Financial Instruments and Risks

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

Plans for Next Twelve Months

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

Share Capital

At December 31, 2017, 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; and
- 76,145,418 common shares 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, 2017 and 2016, 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, 2017, 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 included in this prospectus.

DESCRIPTION OF OUR BUSINESS AND PROPERTY

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

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On or about April 11, 2017, we received from Avita Medical a Petition For *Inter Partes* Review purporting to challenge the validity of the claims in U.S. Patent No. 9,610,430 before the PTAB of the U.S. Patent & Trademark Office . Upon consideration of the arguments and evidence set forth by us and Avita, on December 18, 2017, the PTAB rendered a Final Written Decision dismissing the Petition in its entirety and, accordingly, confirming all such claims. Avita Medical's right to file an appeal expired on February 21, 2018.

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

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

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

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

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

System could enable treatment of other skin disorders with minimal scarring.

Our Market Opportunity

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

Burn Wounds

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

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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 Brusselaers, N., Monstrey, et al, “*Severe Burn Injury in Europe: A systematic Review of the Incidence, Etiology, Morbidity, and Mortality*” available at: <http://ccforum.com/content/14/5/R188>).

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

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

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

Our Technology

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

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

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

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

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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.

Premarket Approval

We may be required to file for premarket approval (“**PMA**”) for the SkinGumTM 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.

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Other U.S. Regulatory Requirements

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

International Regulation

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

Competition

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

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

Intellectual Property

General

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

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

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

Strategy

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

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

Additionally, we will likely be 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 capital 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. From time to time we use additional independent contractors to provide us with services

Our Office Facilities

Our corporate office is located at Pittsburgh Life Sciences Greenhouse, 2425 Sidney Street Pittsburgh, PA 15203. Rent is \$800 per month on a month-to-month basis.

Legal Proceedings

On or about April 11, 2017, we received from Avita Medical Limited a paper copy of what was labeled a Petition For *Inter Partes* Review purporting to challenge the validity of the claims in U.S. Patent No. 9,610,430 (the before the PTAB of the U.S. Patent & Trademark Office.

Upon consideration of the arguments and evidence set forth by us and Avita, on December 18, 2017, the PTAB rendered a “**Final Written Decision**” dismissing the Petition in its entirety and, accordingly, confirming all such claims. Avita Medical’s right to file an appeal expired on February 21, 2018.

Table of Contents**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 four 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.

| Name | Age | Position | Director / Officer Since |
|------------------|------------|--|---|
| Thomas Bold | 56 | President, Chief Executive Officer, Interim Chief Financial Officer and Director | CEO: December 2013 Interim CFO: September 2016 Director: May 2017 |
| Harmel S. Rayat | 56 | Chairman and Director | March 21, 2018 |
| Patsy Trisler | 69 | Vice-President, Regulatory & Clinical Affairs | April 1, 2014 |
| Kenneth Kirkland | 75 | Director | August 2013 |
| Joseph Sierchio | 68 | 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.

Harmel S. Rayat. Since the 1990s, Mr. Rayat has provided strategic capital and managerial guidance to a number of entities in various industries, including advertising, biotechnology, news distribution, alternative energy and commercial real estate. Mr. Rayat is also a founder and director of SolarWindow Technologies Inc., which is engaged in the research and development of renewable energy technology. Mr. Rayat was invited to join the Board due to his experience in finance, marketing, management and technology start-ups generally.

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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.

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Corporate Governance and 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. We have also 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 Code of Ethics and Corporate Governance Guidelines may be obtained at no charge by sending a written request to our President and Chief Executive Officer, Thomas Bold, at:

RenovaCare, Inc.

Pittsburgh Life Sciences Greenhouse

2425 Sidney Street

Pittsburgh, PA 15203

Consideration of Director Nominees/ Director Qualifications

We believe that our Board, to the extent that our limited resources permit, should encompass a diverse range of talent, skill and expertise sufficient to provide sound and prudent guidance with respect to our operations and interests. Each director also is expected to: exhibit high standards of integrity, commitment and independence of thought and judgment; use his or her skills and experiences to provide independent oversight to our business; participate in a constructive and collegial manner; be willing to devote sufficient time to carrying out their duties and responsibilities effectively; devote the time and effort necessary to learn our business; and, represent the long-term interests of all shareholders.

The Board has determined that the Board as a whole must have the right diversity, mix of characteristics and skills for the optimal functioning of the Board in its oversight of our affairs. The Board believes it should be comprised of persons with skills in areas such as: finance; real estate; banking; strategic planning; human resources and diversity; leadership of business organizations; and legal matters. The Board may also consider in its assessment of the Board's

diversity, in its broadest sense, reflecting, but not limited to, age, geography, gender and ethnicity.

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

- **Strategy**—knowledge of our business model, the formulation of corporate strategies, knowledge of key competitors and markets;
- **Leadership**—skills in coaching and working with senior executives and the ability to assist the Chief Executive Officer;
- **Organizational Issues**—understanding of strategy implementation, change management processes, group effectiveness and organizational design;
- **Relationships**—understanding how to interact with investors, accountants, attorneys, management companies, analysts, and communities in which we operate;
- **Functional**—understanding of finance matters, financial statements and auditing procedures, technical expertise, legal issues, information technology and marketing; and
- **Ethics**—the ability to identify and raise key ethical issues concerning our activities and those of senior management as they affect the business community and society.

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Director Independence

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

Board Leadership Structure

We currently have three executive officers and four 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.

Legal Proceedings

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

- the subject of any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- convicted in a criminal proceeding or is subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
- found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law;
- the subject of any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of

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1. Any Federal or State securities or commodities law or regulation; or
 2. Any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order; or
 3. Any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity.
- any federal or state judicial or administrative proceedings based on violations of federal or state securities, commodities, banking or insurance laws and regulations, or any settlement to such actions (excluding settlements between private parties); and
 - any disciplinary sanctions or orders imposed by a stock, commodities or derivatives exchange or other self-regulatory organization.

Directors' and Officers' Liability Insurance

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

Compliance with Section 16(a) of the Exchange Act

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

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

During the fiscal year ended December 31, 2017, the Board held a total of eleven (11) meetings, inclusive of 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, 2017.

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

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

While the Board is solely responsible for the selection and nomination of directors, the Board may consider nominees recommended by stockholders as it deems appropriate. The Board evaluates each potential nominee in the same manner regardless of the source of the potential nominee's recommendation. Although we do not have a policy regarding diversity, the Board does take into consideration the value of diversity among Board members in background, experience, education and perspective in considering potential nominees for recommendation to the Board for selection.

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Stockholders who wish to recommend a nominee should send nominations to our Chief Executive Officer, Thomas Bold, Pittsburgh Life Sciences Greenhouse, 2425 Sidney Street, Pittsburgh, PA 15203, and include all information relating to such person that is required to be disclosed in solicitations of proxies for the election of directors. The recommendation must be accompanied by a written consent of the individual to stand for election if nominated by the Board and to serve if elected.

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, Pittsburgh Life Sciences Greenhouse, 2425 Sidney Street, Pittsburgh, PA 15203

The Board will review and respond to all correspondence received, as appropriate.

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.

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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 fiscal years ending December 31, 2017 and 2016 (“Named Executive Officers”).

| Name and principal position | Year | Salary/ consulting fee | Bonus | Stock awards | Option awards | All other compensation | Total |
|--|--------------|------------------------------|-------|-----------------|------------------|---------------------------|---------|
| | December 31, | (\$) | (\$) | (\$) | (\$) | (\$) | (\$) |
| Thomas Bold ⁽¹⁾ President, CEO and Interim CFO | 2017 | 100,000 | - | - | 248,700 | - | 348,700 |
| | 2016 | 100,000 | - | - | 83,796 | - | 183,796 |
| Rhonda B. Rosen ⁽²⁾ Former CFO | 2016 | 30,100 | - | - | 27,932 | - | 58,032 |
| Patsy Trisler ⁽³⁾ V P Clinical & Regulatory Affairs | 2017 | 60,000 | - | - | - | - | 60,000 |
| | 2016 | 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, a stock option to purchase up to 60,000 shares of common stock at an exercise price of \$1.91 per share, the closing price on March 15, 2016, and a stock option to purchase up to 75,000 shares of common stock at an exercise price of \$4.20 per share, the closing price on May 11, 2017. The options may be exercised on a “cashless basis” using the formula contained therein and vest as follows: (a) 20,000 vested on December 1, 2014; (b) 20,000 vested on December 1, 2015; (c) 60,000 vested on March 16, 2016; (d) 37,500 vested on May 11, 2017; and (e) 37,500 vest on May 11, 2018.

(2) On October 1, 2013, we appointed Ms. Rosen to serve as our CFO on a part-time basis, for which she was 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.

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

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, 2017.

| 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 | 60,000 | - | 1.91 | March 15, 2026 |
| | 37,500 | 37,500 | 4.20 | May 11, 2028 |
| Rhonda B. Rosen | 10,000 | - | 0.80 | October 8, 2018 |
| | 20,000 | - | 1.91 | October 8, 2018 |
| Patsy Trisler | 30,000 | 20,000 | 1.05 | April 2, 2025 |

Long-Term Incentive Plans

On June 20, 2013, our Board adopted our 2013 Long-Term Incentive Plan and on November 15, 2013, a stockholder owning a majority of our issued and outstanding stock approved adoption to the 2013 Plan. Pursuant to the terms of the 2013 Plan, an aggregate of 20,000,000 shares of our common stock are reserved for issuance to our officers, directors, employees and consultants in order to attract and hire key technical personnel and management. Options granted to employees under the 2013 Plan, including directors and officers who are employees, may be incentive stock options or non-qualified stock options; options granted to others under the Incentive Plan are limited to non-qualified stock options. As of December 31, 2017, there were 19,338,572 shares available for grant.

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

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

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

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Employment Contracts

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

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

Change of Control Agreements

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

Compensation of Directors

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

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

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

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

| Name | | Fees earned or paid in cash ⁽¹⁾ (\$) | Option awards | Total (\$) |
|--------------------------------|------|---|--|------------|
| | | | Aggregate Grant Date Fair Value (\$) ⁽²⁾ | |
| Joseph Sierchio ⁽³⁾ | 2017 | 6,000 | 248,700 | 254,700 |
| | 2016 | 6,000 | 69,830 | 75,830 |
| Kenneth Kirkland | 2017 | 6,000 | 248,700 | 254,700 |
| | 2016 | 6,000 | 69,830 | 75,830 |

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

⁽²⁾ The amounts in this column represent the total fair value assigned to options granted in 2017 and 2016 to Messrs. Kirkland and Sierchio.

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

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 ⁽¹⁾ | Number of | |
|---|----------------------|----------------------|
| | shares | |
| | Beneficially | % of Class |
| | Owned ⁽²⁾ | Owned ⁽²⁾ |
| Directors and Officers | | |
| Thomas Bold ⁽³⁾ | 125,879 | * |
| Harmel S. Rayat ⁽⁴⁾ | 51,894,709 | 66.03 |
| Patsy Trisler ⁽⁵⁾ | 30,000 | * |
| Kenneth Kirkland ⁽⁶⁾ | 108,175 | * |
| Joseph Sierchio ⁽⁷⁾ | 647,516 | * |
| All Directors and Officers as a Group (5 people) | | 67.28 |
| 5% Shareholders | | |
| Kalen Capital Corporation ⁽⁸⁾ | | |
| The Kalen Capital Building | | |
| 688 West Hastings St. | | |
| Suite 700 | | |
| Vancouver, BC V6B 1P1 | 51,894,709 | 66.03 |
| Jatinder Singh Bhogal ⁽⁹⁾ | | |
| 1962 Knox Road | | |
| Vancouver, BC V6T 1S6 | 5,038,061 | 6.62 |

* 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 Pittsburgh Life Sciences Greenhouse, 2425 Sidney Street Pittsburgh, PA 15203

(2) Calculated pursuant to Rule 13d-3(d) of the Exchange Act. Beneficial ownership is calculated based on 77,535,626 shares of common stock issued and outstanding as of April 3, 2018. Under Rule 13d-3(d) of the Exchange Act, shares not outstanding which are subject to options, warrants, rights or conversion privileges exercisable within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person, but are not deemed outstanding for the purpose of calculating the percentage owned by each other person listed.

(3) Consists of 5,000 shares of common stock and a Series D Warrant to purchase 5,000 shares of common stock purchased by Mr. Bold in a private placement we conducted in 2015; 78,379 shares received upon the cashless exercise of 100,000 options and vested options to purchase up to 37,500 shares of common stock. Does not include 37,500 shares issuable upon exercise of issued warrants scheduled to vest on May 11, 2018.

(4) Mr. Rayat is the sole owner and President of Kalen Capital Corporation, which beneficially owns 51,894,709 of our issued and outstanding shares. As such Mr. Rayat may be deemed to be the beneficial owner of such shares. Please refer to footnote 8 of this table for more information regarding the holdings of Kalen Capital Corporation.

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(5) Ms. Trisler was appointed as our Vice President – Clinical & Regulatory Affairs on April 1, 2014; as part of her appointment she was granted a stock option to purchase up to 50,000 shares of common stock. The option vests in five equal installments of 10,000 on April 1, 2015-2019, subject to her continued service with the Company.

(6) Consists of 70,675 shares issued upon the cashless exercise of options and vested options to purchase 37,500 shares of common stock. Does not include 37,500 shares issuable upon exercise of issued warrants scheduled to vest on May 11, 2018.

(7) Includes (a) 550,000 shares of common stock owned by Mr. Sierchio; (b) 75,199 shares of common stock issued upon the cashless exercise of vested stock options; (c) 10,000 shares of common stock purchased pursuant to the October 2017 private placement; (d) 4,899 shares of common stock issued upon the cashless exercise of a Series F Warrant; and (e) 7,418 shares of common stock issued upon the cashless exercise of a Series H Warrant. Does not include 37,500 shares issuable upon exercise of issued warrants scheduled to vest on May 11, 2018.

(8) Kalen Capital Corporation is a private Alberta corporation wholly owned by Mr. Harmel Rayat. In such capacity, Mr. Rayat may be deemed to have beneficial ownership of these shares. Consists of (a) 49,449,037 shares of common stock; (b) a Series D Warrant to purchase up to 800,000 shares of common stock at an exercise price of \$1.10 per share through June 5, 2020; (c) a Series E Warrant to purchase up to 584,416 shares of common stock at an exercise price of the lesser of \$1.54, or a 20% discount to the average closing price of our common stock for the five days prior to the date on which the Series E Warrant is exercised, through September 9, 2021; (d) a Series G Warrant to purchase up to 410,000 shares of common stock at an exercise price of \$2.68 per share through July 21, 2022; (e) 122,845 shares issuable upon conversion of the February 2017 Loan Agreement (assuming the February Loan Agreement was converted as of April 3, 2018, at a conversion price of \$3.45); and (f) 502,950 shares issuable upon conversion of the note issued pursuant to the Loan Agreement (assuming the Loan Agreement was converted as of April 3, 2018, at a conversion price of \$1.54). As of the date of this report we have not received a notice of conversion from Kalen Capital Corporation for the Loan Agreement or the February 2017 Loan Agreement. Each of KCC's warrants may be exercised on a cashless basis. For tax purposes, a portion of the debt and equity securities of owned by KCC have been assigned to Kalen Capital Holdings, LLC, its wholly owned subsidiary.

(9) Includes (a) 2,529,425 shares of common stock held by Boston Financial Group, Ltd., and (b) 2,508,636 shares of common stock held by 1420527 Alberta Ltd., Mr. Bhogal is the sole principal of each entity and in such capacity, Mr. Bhogal may be deemed to have beneficial ownership of these shares. Does not include 30,800 shares of stock owned by Mr. Bhogal's wife, of which he disclaims beneficial ownership. Mr. Bhogal is the President and sole shareholder of Vector Asset Management, Inc., which provides us with consulting services.

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.

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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.

The following are related party transactions for the fiscal years ended December 31, 2017 and 2016:

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

The law firm of Satterlee Stephens LLP ("Satterlee"), of which Joseph Sierchio, one of the Company's directors, is a partner, provides counsel to the Company. Mr. Sierchio is the Company's primary attorney. During the years ended December 31, 2017 and 2016, the Company recognized \$277,933 and \$168,775 of fees for legal services billed by firms associated with Mr. Sierchio. At December 31, 2017 and 2016, the Company owed Satterlee \$30,000 and \$11,750 which is included in accounts payable. Mr. Sierchio continues to serve as a director of the Company.

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In connection with the Company's anticipated FDA and other regulatory filings, the Company engaged StemCell Systems to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$219,806 and \$184,517 during the years ended December 31, 2017 and 2016, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

Dr. Gerlach is entitled to payments for consulting services. During the years ended December 31, 2017 and 2016, the Company recognized expenses related to Dr. Gerlach services of \$38,540 and \$42,480, respectively. Accounts payable to Dr. Gerlach amounted to \$17,640 and \$18,540 at December 31, 2017 and 2016, respectively.

On August 1, 2013, the Company entered into a consulting agreement, as amended on May 1, 2016, with Jatinder Bhogal to provide consulting services to the Company through his wholly owned company, Vector Asset Management, Inc., Mr. Bhogal is an individual owning in excess of 5% of our issued and outstanding shares of common stock. Pursuant to the Consulting Agreement, as amended, Mr. Bhogal received compensation of \$81,600 and \$74,400 during the years ended December 31, 2017 and 2016 in connection with the consulting agreement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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 April 3, 2018, there were 77,535,626 shares of our common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Common Stock

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

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

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

Preferred Stock

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

Table of Contents**Warrants**

The following table summarizes information about warrants outstanding at December 31, 2017 and 2016:

| Description | Shares of Common Stock Issuable from Warrants Outstanding as of | | Weighted Average Exercise Price | Expiration |
|--------------|--|-------------------------|--|--------------------------------------|
| | December 31, 2017 | December 31, 2016 | | |
| Series A | 720,000 | 960,000 | \$ 0.35 | July 12, 2019 |
| Series B | - | 1,326,087 | \$ 0.46 | November 29, 2018 |
| Series C | - | 3,500,000 | \$ 0.49 | November 29, 2018 |
| Series D | 910,000 | 910,000 | \$ 1.10 | June 5, 2020 |
| Series E | 584,416 | 584,416 | \$ 1.54 | September 8, 2021 |
| Series F | 14,492 | - | \$ 3.45 | February 23, 2022 & March 9, 2022 |
| Series G | 460,250 | - | \$ 2.68 | July 21, 2022 |
| Series H | 920,000 | - | \$ 2.75 | October 16, 2022 |
| Total | 3,609,158 | 7,280,503 | | |

Since January 1, 2018 an aggregate of 597,246 warrants have been exercised; accordingly, as of the date of this prospectus, there were 3,011,912 issued and outstanding ranging in prices from \$0.35 to \$3.45. If issued, the shares underlying these warrants would increase the number of shares of our common stock currently outstanding and will dilute the holdings and voting rights of our then-existing shareholders.

Options

As at December 31, 2017 there were 545,000 stock options issued and outstanding. Since January 1, 2018, an aggregate of 187,500 options have been exercised; accordingly, as of the date of this prospectus there remain 357,500 options outstanding. If issued, the shares underlying these options would increase the number of shares of our common stock currently outstanding and will dilute the holdings and voting rights of our then-existing shareholders.

Debt

On September 9, 2016, we entered into the Loan Agreement with KCC pursuant to which KCC agreed to loan us up to \$900,000 at an annual interest rate of 7% per year, compounded quarterly. KCC provided an initial loan in the amount of \$700,000, which was evidenced by a convertible promissory note (the “**Note**”); the remaining \$200,000 needed to be loaned prior to December 31, 2017. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matured on December 31, 2017, but was extended to December 31, 2019 pursuant to the Amendment No. 1, dated as of January 26, 2018, to the Note. Except for the extension of the maturity date, the Note was not otherwise amended and continues in full force and effect. Beginning on September 9, 2017, the Note became convertible, at KCC’s sole discretion, into shares of our common stock at conversion rate equal to the lesser of: (i) \$1.54, the closing price of our common stock on the day prior to the issuance of the Note or (ii) a 20% discount to the average closing price of our common stock for the five days prior to the date on which KCC elects to convert the Note.

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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 (\$395,000 from KCC and \$25,000 from Mr. Sierchio) at an annual interest rate of 7% per year, compounded quarterly, which was evidenced by the February Notes. On October 19, 2017, the Company repaid the February Note of Mr. Sierchio in full. The maturity date of the February Note was extended from February 23, 2018, to December 31, 2019 pursuant to the Amendment No. 1, dated as of January 26, 2018, to the Note. Except for the extension of the maturity date, the February Note was not otherwise amended and continues in full force and effect. The KCC February Note can be converted, at KCC's 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 February 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 February Note, subject to a floor price of \$2.76.

On March 6, 2017, we entered into the March Loan Agreement with an investor, pursuant to which we borrowed \$25,000 at an annual interest rate of 7% per year, compounded quarterly, which was evidenced by a convertible promissory note (the "**March Note**"). On July 27, 2017, the Company repaid the March Note in full.

Shares Eligible for Resale

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

Rule 144

As of April 3, 2018 there were 77,535,626 shares of our common stock issued and outstanding, of which 51,513,687 shares are deemed "restricted securities," within the meaning of Rule 144. Absent registration under the Securities Act, the sale of such shares is subject to Rule 144, as promulgated under the Securities Act.

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

Rule 144 also permits a person who presently is not and who has not been an affiliate of ours for at least three months immediately preceding the sale and who has beneficially owned the shares of common stock for at least nine months to sell such shares without restriction other than the requirement that there be current public information as set forth in Rule 144. To the extent that Rule 144 is otherwise available, this provision is currently applicable to all of the restricted shares. If a non-affiliate has held the shares for more than one year, such person may make unlimited sales pursuant to Rule 144 without restriction.

The possibility that substantial amounts of our common stock may be sold under Rule 144 into the public market may adversely affect prevailing market prices for the common stock and could impair our ability to raise capital in the future through the sale of equity securities. Please refer to “**Risk Factors.**”

Registration Rights Agreements

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

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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.

Per the September, February and March Loan Agreements, we have provided the investors registration rights for all shares issued upon conversion of the respective notes and the warrants issued pursuant to the loan agreements beginning on the first anniversary of the respective loan agreement.

Currently, as requested by KCC, the only shares registered on behalf of KCC are those registered pursuant to the registration statement of which this prospectus is part.

THE SELLING STOCKHOLDERS

The following table presents information regarding the Selling Stockholders. The Selling Stockholders may sell up to 4,404,136 shares of common stock (including shares issuable upon exercise of the Warrants). The percentage of outstanding shares beneficially owned is based on 77,535,626 shares of common stock issued and outstanding as of April 3, 2018. Information with respect to beneficial ownership is based upon information provided to us by the Selling Stockholders. Except as may be otherwise described below, to the best of our knowledge, the named Selling Stockholders beneficially own and have sole voting and investment authority as to all of the shares set forth opposite his name, none of the Selling Stockholders is known to us to be a registered broker-dealer or an affiliate of a registered broker-dealer. Each of the Selling Stockholders has acquired his, hers or its shares solely for investment and not with a view to or for resale or distribution of such securities.

| Selling Stockholders | # of Shares Beneficially Owned Prior to the Offering | % of Issued and Outstanding Shares Owned Prior to the Offering (1) | # of Shares Registered and to be Sold in this Offering (2) | Estimated No. of Shares Beneficially Owned After this Offering (2) |
|-----------------------------|---|---|---|---|
| Cindy Bains | 900,000 (3) | * | 900,000 | 0 |

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| | | | | |
|-----------------------------|-----------------|-------|----------------|------------|
| Thomas Bold | 141,796 (4) | * | 10,000 (5) | 136,796 |
| Rhonda Rosen | 40,000 (6) | * | 10,000 (7) | 30,000 |
| Rajeev Mehta | 80,000 (8) | * | 80,000 (8) | 0 |
| Michael Emmott | 4,100 (9) | * | 4,100 (9) | 0 |
| Calderwood Investments Ltd. | 16,400 (10) | * | 16,400 (10) | 0 |
| 1420527 Alberta Ltd. | 5,038,061 (11) | 6.62 | 508,636 (12) | 4,529,425 |
| Jeetenderjit Singh Sidhu | 2,584,456 (13) | 3.39 | 355,000 (14) | 2,229,456 |
| Kalen Capital Holdings, LLC | 51,894,709 (15) | 66.03 | 2,420,000 (16) | 49,474,709 |
| Narinder Thouli | 100,000 (17) | * | 100,000 (18) | 0 |
| Total | 60,799,522 | | 4,404,136 | 56,400,386 |

* Represents beneficial ownership of less than one percent of the issued and outstanding shares of our common stock.

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- (1) Calculated pursuant to Rule 13d-3(d) of the Exchange Act. Beneficial ownership is calculated based on 77,535,626 shares of common stock issued and outstanding as of April 3, 2018. Under Rule 13d-3(d) of the Exchange Act, shares not outstanding which are subject to options, warrants, rights or conversion privileges exercisable within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person, but are not deemed outstanding for the purpose of calculating the percentage owned by each other person listed.

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

- (2) The Selling Stockholders may offer and sell, from time to time, any or all of our common stock issued to them and registered for resale. Because the Selling Stockholders may offer all or only some portion of the 4,404,136 shares of common stock registered, no exact number can be given as to the amount or percentage of these shares of common stock that will be held by the Selling Stockholders upon termination of the offering. We can only make estimates and assumptions. The number of shares listed in the category titled "Estimated Number of Shares Beneficially Owned After This Offering," in the table above represents an estimate of the number of shares of common stock that will be held by the Selling Stockholders after the offering. To arrive at this estimate, we have assumed that the Selling Stockholders will sell all of the shares to be registered pursuant to this offering and will not be acquiring any additional shares. Please refer to "**Plan of Distribution.**"
- (3) Represents 900,000 shares of common stock issuable upon exercise of a Series H Warrant purchased by the Selling Stockholder in a private transaction with us completed on October 16, 2017.
- (4) Consists of 5,000 shares of common stock and a Series D Warrant to purchase 5,000 shares of common stock purchased by Mr. Bold in a private placement we conducted in 2015; 34,296 shares received upon the cashless exercise of 40,000 options and vested options to purchase up to 97,500 shares of common stock.
- (5) Consists of 5,000 shares of common stock and a Series D Warrant to purchase 5,000 shares of common stock purchased by Mr. Bold in a private placement we conducted in 2015.
- (6) Includes 5,000 shares of common stock and a Series D Warrant allowing Ms. Rosen to purchase up to an additional 5,000 shares of common stock, which Ms. Rosen purchased from us as part of a private placement completed on June 5, 2015 and 30,000 shares of common stock reserved for issuance upon the exercise of stock options granted to Ms. Rosen, our former Chief Financial Officer, which vested as of the date hereof. On

September 9, 2016, we terminated Ms. Rosen's at-will executive services agreement.

- (7) Represents 5,000 shares of common stock and 5,000 shares issuable upon exercise of a series D Warrant purchased by the Selling Stockholder in a private transaction with us completed on June 5, 2015.
- (8) Includes 40,000 shares of common stock and 40,000 shares issuable upon exercise of a series G Warrant purchased by the Selling Stockholder in a private transaction with us completed on July 21, 2017.

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- (9) Includes 2,050 shares of common stock and 2,050 shares issuable upon exercise of a series G Warrant purchased by the Selling Stockholder in a private transaction with us completed on July 21, 2017.
- (10) Includes 8,200 shares of common stock and 8,200 shares issuable upon exercise of a series G Warrant purchased by the Selling Stockholder in a private transaction with us completed on July 21, 2017.
- (11) Includes (a) 2,529,425 shares of common stock held by Boston Financial Group, Ltd. and (b) 2,508,636 shares of common stock held by 1420527 Alberta Ltd. (collectively, the “**JSB Holdings**”). Mr. Bhogal is the sole principal of each entity and in such capacity, Mr. Bhogal may be deemed to have beneficial ownership of these shares. For additional information regarding Mr. Bhogal’s share ownership see footnote 9 to the beneficial ownership table.
- (12) Consists of 508,636 shares of the JSB Holdings.
- (13) Represents shares of common stock owned by Mr. Sidhu and entities wholly owned by him of which he is deemed to be the beneficial owner, and is inclusive of 10,000 shares issuable upon exercise of a Series H Stock Warrant acquired by Mr. Sidhu in a private placement we conducted in 2017 (collectively, the “**Sidhu Shares**”). .
- (14) Represents 355,000 Sidhu Shares..
- (15) Kalen Capital Corporation is a private Alberta corporation wholly owned by Mr. Harmel Rayat. In such capacity, Mr. Rayat may be deemed to have beneficial ownership of these shares. Consists of (a) 49,449,037 shares of common stock; (b) a Series D Warrant to purchase up to 800,000 shares of common stock at an exercise price of \$1.10 per share through June 5, 2020; (c) a Series E Warrant to purchase up to 584,416 shares of common stock at an exercise price of the lesser of \$1.54, or a 20% discount to the average closing price of our common stock for the five days prior to the date on which the Series E Warrant is exercised, through September 9, 2021; (d) a Series G Warrant to purchase up to 410,000 shares of common stock at an exercise price of \$2.68 per share through July 21, 2022; (e) 151,838 shares issuable upon conversion of the February 2017 Loan Agreement (assuming the February Loan Agreement was converted as of April 4, 2018, at a conversion price of \$2.76); and (f) 499,418 shares issuable upon conversion of the note issued pursuant to the Loan Agreement (assuming the Loan Agreement was converted as of April 4, 2018, at a conversion price of \$1.54). As of the date of this prospectus we have not received a notice of conversion from Kalen Capital Corporation for the Loan Agreement or the February 2017 Loan Agreement. Each of KCC’s warrants may be exercised on a cashless basis. For tax purposes, a portion of the debt and equity securities of owned by KCC have been assigned to Kalen Capital Holdings, LLC, its wholly owned subsidiary.
- (16) Consists of 1,210,000 shares of common stock; 800,000 shares issuable upon exercise of a Series D Warrant exercise price of \$1.10 per share through June 5, 2020; and 410,000 shares of common stock issuable upon the exercise of a Series G Warrant at an exercise price of \$2.68 per share through July 21, 2022.
- (17) Consists of 100,000 shares issued upon exercise of a Series D Warrant exercise price of \$1.10 per share through June 5, 2020.

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

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

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PLAN OF DISTRIBUTION

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

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

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

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

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

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

The SEC has also adopted rules that regulate broker-dealer practices in connection with transactions in “penny stocks” as such term is defined by Rule 15g-9. Penny stocks are generally equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or quoted on the Nasdaq system provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system).

The shares offered by this prospectus may constitute penny stocks under the Exchange Act. The shares may remain penny stocks throughout the offering period. The classification of our shares as penny stocks makes it more difficult for a broker-dealer to sell the stock into a secondary market, which makes it more difficult for a purchaser to liquidate his or her investment.

The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document approved by the SEC, which: (i) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (ii) contains a description of the broker’s or dealer’s duties to the customer and of the rights and remedies available to the customer with respect to a violation to such duties or other requirements of the Securities Act; (iii) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and significance of the spread between the bid and ask price; (iv) contains a toll-free telephone number for inquiries on disciplinary actions; (v) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (vi) contains such other information and is in such form as the SEC shall require by rule or regulation. The broker-dealer also must provide to the customer, prior to effecting any transaction in a penny stock, (i) bid and offer quotations for the penny stock; (ii) the compensation of the broker-dealer and its salesperson in the transaction; (iii) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (iv) monthly account statements showing the market value of each penny stock held in the customer’s account.

In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitability statement. These disclosure requirements will have the effect of reducing the trading activity in the secondary market for our stock because it will be subject to these penny stock rules. Therefore, stockholders may have difficulty selling those

securities.

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

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

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

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

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

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**DISCLOSURE OF COMMISSION POSITION ON
INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS**

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

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

Section 78.751(2) authorizes a corporation’s articles of incorporation, bylaws or agreement to provide that directors’ and officers’ expenses incurred in defending a civil or criminal action must be paid by the corporation as incurred, rather than upon final disposition of the action, upon receipt by the director or officer to repay the amount if a court ultimately determines that he is not entitled to indemnification. Section 78.751(3)(a) provides that the rights to indemnification and advancement of expenses shall not be deemed exclusive of any other rights under any bylaw, agreement, stockholder vote or vote of disinterested directors. Section 78.751(3)(b) extends the rights to indemnification and advancement of expenses to former directors, officers, employees and agents, as well as their heirs, executors, and administrators. Our bylaws require us to indemnify our directors to the fullest extent permitted under Nevada law or any other applicable law in effect.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable.

LEGAL MATTERS

The validity of the shares of common stock offered hereby has been passed upon for us by Satterlee Stephens, LLP. Joseph Sierchio, a partner at Satterlee Stephens LLP, is one of our directors and the beneficial owner of 654,957 shares of our common stock.

EXPERTS

Our consolidated financial statements for the fiscal years ended December 31, 2017 and 2016, appearing herein, have been audited by Peterson Sullivan LLP, an independent registered public accounting firm, as set forth in its report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file periodic reports with the SEC, including quarterly reports and annual reports which include our audited financial statements. This registration statement, including exhibits hereto, and all of our periodic reports may be inspected without charge at the Public Reference Room maintained by the SEC at 100 F Street, NE, Washington, D.C. 20549. You may obtain copies of this registration statement, including the exhibits hereto, and all of our periodic reports after payment of the fees prescribed by the SEC. For additional information regarding the operation of the Public Reference Room, you may call the SEC at 1-800-SEC-0330. The SEC also maintains a website which provides on-line access to reports and other information regarding registrants that file electronically with the SEC at: www.sec.gov. In addition, you may request a copy of any of our periodic reports filed with the Securities and Exchange Commission at no cost, by writing us at: RenovaCare, Inc., Pittsburgh Life Sciences Greenhouse, 2425 Sidney Street, Pittsburgh, PA 15203

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| <u>Consolidated Statements of Operations for the years ended December 31, 2017 and 2016</u> | F-3 |
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors

RenovaCare, Inc.

Pittsburgh, Pennsylvania

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of RenovaCare, Inc. and Subsidiaries ("the Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States.

Basis for Opinion

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

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

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

/S/ PETERSON SULLIVAN LLP

We have served as the Company's auditor since 2006.

Seattle, Washington

March 13, 2018

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RENOVACARE, INC
CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2017 AND 2016

| | December 31, | |
|---|---------------------|-------------------|
| | 2017 | 2016 |
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 2,906,237 | \$ 418,031 |
| Prepaid expenses | 750 | 31,535 |
| Total current assets | 2,906,987 | 449,566 |
| Equipment, net of accumulated depreciation of \$370 and \$53, respectively | 581 | 898 |
| Intangible assets | 152,854 | 152,854 |
| Total assets | \$ 3,060,422 | \$ 603,318 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ 107,336 | \$ - |
| Accounts payable - related parties | 61,333 | 33,290 |
| Contract payable | 100,000 | 150,000 |
| Interest payable to related parties | - | 15,220 |
| Convertible promissory note payable to related party, net of discount of \$534,519 | - | 165,481 |
| Total current liabilities | 268,669 | 363,991 |
| Interest payable to related parties | 90,678 | - |
| Convertible promissory notes payable to related party, net of discount of \$58,438 | 1,036,562 | - |
| Total liabilities | 1,395,909 | 363,991 |
| Commitments and contingencies | | |
| Stockholders' equity | | |
| Preferred stock: \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding | - | - |
| Common stock: \$0.00001 par value; 500,000,000 shares authorized, 76,145,418 and 70,069,693 shares issued and outstanding at December 31, 2017 and 2016, respectively | 762 | 702 |
| Additional paid-in capital | 16,404,673 | 11,290,209 |
| Retained deficit | (14,740,922) | (11,051,584) |
| Total stockholders' equity | 1,664,513 | 239,327 |
| Total liabilities and stockholders' equity | \$ 3,060,422 | \$ 603,318 |

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

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

| | Years Ended December 31, | |
|---|-------------------------------------|----------------|
| | 2017 | 2016 |
| Revenue | \$ - | \$ - |
| Operating expense | | |
| Research and development | 574,091 | 309,503 |
| General and administrative | 2,121,732 | 1,588,719 |
| Total operating expense | 2,695,823 | 1,898,222 |
| Loss from operations | (2,695,823) | (1,898,222) |
| Other income (expense) | | |
| Interest income | 3,136 | 1,034 |
| Interest expense | (77,284) | (15,220) |
| Accretion of debt discount | (919,367) | (165,481) |
| Total other income (expense) | (993,515) | (179,667) |
| Net loss | \$ (3,689,338) | \$ (2,077,889) |
| Basic and Diluted Loss per Common Share | \$ (0.05) | \$ (0.03) |
| Weighted average number of common shares outstanding - basic and diluted | 74,386,340 | 69,772,485 |

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

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RENOVACARE, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

| | Common Stock | | Additional | Retained | Total |
|--|--------------|--------|--------------------|----------------|-------------------------|
| | Shares | Amount | Paid-in Capital | Deficit | Stockholders' Equity |
| Balance, December 31, 2015 | 67,781,934 | \$ 678 | \$ 9,197,970 | \$ (8,973,695) | \$ 224,953 |
| Issuance of common stock from the exercise of warrants | 2,273,913 | 24 | 1,109,977 | - | 1,110,001 |
| Issuance of common stock from the exercise of stock options | 13,846 | - | - | - | - |
| Stock based compensation due to common stock purchase options | - | - | 296,123 | - | 296,123 |
| Reversal of stock based compensation due to forfeiture of stock options | - | - | (13,861) | - | (13,861) |
| Discount on convertible promissory note due to detachable warrants and beneficial conversion feature | - | - | 700,000 | - | 700,000 |
| Net loss for the year ended December 31, 2016 | - | - | - | (2,077,889) | (2,077,889) |
| Balance, December 31, 2016 | 70,069,693 | 702 | 11,290,209 | (11,051,584) | 239,327 |
| Issuance of common stock from the exercise of warrants | 4,592,895 | 46 | 344,578 | - | 344,624 |
| Issuance of common stock from the exercise of stock options | 102,580 | 1 | (1) | - | - |
| October 2017 Private Placement units issued | 920,000 | 9 | 2,299,991 | - | 2,300,000 |
| | 460,250 | 4 | 1,122,606 | - | 1,122,610 |

| | | | | | |
|--|------------|----|---------|--------------|-------------|
| July 2017 Private Placement units issued | | | | | |
| Stock based compensation due to common stock purchase options | - | - | 904,004 | - | 904,004 |
| Discount on convertible promissory note due to detachable warrants and beneficial conversion feature | - | - | 443,286 | - | 443,286 |
| Net loss for the year ended December 31, 2017 | - | - | - | (3,689,338) | (3,689,338) |
| Balance, December 31, 2017 | 76,145,418 | \$ | 762 | \$ | 16,404,673 |
| | | | | (14,740,922) | \$ |
| | | | | | 1,664,513 |

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

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

| | Years Ended December 31, | |
|--|-------------------------------------|-------------------|
| | 2017 | 2016 |
| Cash flows from operating activities | | |
| Net loss | \$ (3,689,338) | \$ (2,077,889) |
| Adjustments to reconcile net loss to net cash flows from operating activities | | |
| Depreciation | 317 | 53 |
| Stock based compensation expense | 904,004 | 282,262 |
| Accretion of debt discount | 919,367 | 165,481 |
| Changes in operating assets and liabilities: | | |
| Decrease (increase) in prepaid expenses | 30,785 | (21,242) |
| Increase (decrease) in accounts payable | 107,336 | (71,563) |
| Increase (decrease) in accounts payable - related parties | 28,043 | 3,195 |
| Increase (decrease) in interest payable - related parties | 75,458 | 15,220 |
| Increase (decrease) in contract payable | (50,000) | (84,125) |
| Net cash flows from operating activities | (1,674,028) | (1,788,608) |
| Cash flows from investing activity | | |
| Purchase of equipment | - | (951) |
| Net cash flows from investing activity | - | (951) |
| Cash flows from financing activities | | |
| Proceeds from exercise of warrants and issuance of common stock | 3,767,234 | 1,110,001 |
| Proceeds from the issuance of convertible promissory notes | 445,000 | 700,000 |
| Payments of convertible promissory notes | (50,000) | - |
| Net cash flows from financing activities | 4,162,234 | 1,810,001 |
| Increase in cash and cash equivalents | 2,488,206 | 20,442 |
| Cash and cash equivalents at beginning of period | 418,031 | 397,589 |
| Cash and cash equivalents at end of period | \$ 2,906,237 | \$ 418,031 |
| Supplemental disclosure of cash flow information: | | |
| Interest paid in cash | \$ 1,825 | \$ - |
| Income taxes paid in cash | \$ - | \$ - |
| Supplemental disclosure of non-cash transactions: | | |
| Discount on convertible promissory note due to detachable warrants and beneficial conversion feature | \$ 443,286 | \$ 700,000 |

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

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RENOVACARE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization, Nature and Continuance of Operations

Organization

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

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

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

Nature and Continuance of Operations

The Company does not have any commercialized products. The Company's activities have consisted principally of performing research and development activities and raising capital. These development activities are subject to significant risks and uncertainties, including possible failure of preclinical testing. The Company has not generated any revenue since inception and has sustained recurring losses and negative cash flows from operations since inception. The Company expects to incur losses as it continues development of its products and technologies and expects that it will need to raise additional capital through the sale of its securities to accomplish its business plan and failing to secure such additional funding before achieving sustainable revenue and profit from operations poses a

significant risk. The Company's ability to fund the development of its cellular therapies will depend on the amount and timing of cash receipts from future financing activities. There can be no assurance as to the availability or terms upon which such financing and capital might be available.

As of December 31, 2016, the Company had approximately \$418,031 of cash on hand. On March 9, 2017, the Company completed the sale of three convertible promissory notes and warrants and received \$445,000. On June 28, 2017, the Company received \$344,624 upon the exercise of 114,493 Series F Warrants. On July 21, 2017, the Company completed a private placement, whereby the Company received proceeds of \$1,122,610 from the sale of common stock and warrants. On October 16, 2017, the Company completed a private placement, whereby the Company received proceeds of \$2,300,000 from the sale of common stock and warrants. On January 26, 2018, the Company entered into the first amendment to the convertible promissory note dated September 9, 2016 and the Company entered into the first amendment to the convertible promissory note dated February 23, 2017 both with KCC pursuant to which both notes were amended (with a combined principal balance of \$1,095,000) to extend the maturity date to December 31, 2019. The Company believes that, as a result of the financings and note maturity date extensions, it currently has sufficient cash to meet its funding requirements over the next year and these events alleviate the conditions which initially indicated substantial doubt about the Company's ability to continue as a going concern.

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

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Note 2. Significant Accounting Policies

Principles of Consolidation

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

Applicable Accounting Guidance

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

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

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for public business entities for reporting periods for which financial statements have not yet been issued. Management is currently assessing the impact the adoption of ASU 2017-09 will have on the Company's Consolidated Financial Statements.

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

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

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

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

Accounting Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. Actual results, as determined by future events, may differ from these estimates.

Cash and Cash Equivalents

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

Fair Value Measurement

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

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

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

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

Fair Value of Financial Instruments

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

Table of Contents*Research and Development Costs*

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

Equipment

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

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

| | Estimated Useful Lives |
|-----------------------|---------------------------------------|
| Office equipment | 3-5 years |
| Furniture & equipment | 5 - 7 years |

Intangible Assets

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

and prioritized. If the totality of the relevant events and circumstances indicate that the intangible asset is not impaired, additional impairment tests are not necessary.

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

Stock Options

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

Table of Contents*Income Taxes*

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

Earnings (Loss) Per Share

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

Following is the computation of basic and diluted net loss per share for the years ended December 31, 2017 and 2016:

| | Years Ended December 31, | |
|--|-------------------------------------|----------------|
| | 2017 | 2016 |
| Basic and Diluted EPS Computation | | |
| Numerator: | | |
| Loss available to common stockholders' | \$ (3,689,338) | \$ (2,077,889) |
| Denominator: | | |
| Weighted average number of common shares outstanding | 74,386,340 | 69,772,485 |
| Basic and diluted EPS | \$ (0.05) | \$ (0.03) |

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

| | | |
|---------------|---------|---------|
| Stock options | 545,000 | 385,000 |
|---------------|---------|---------|

| | | |
|--|-----------|-----------|
| Warrants | 3,609,158 | 7,280,503 |
| Convertible debt | 619,266 | 464,428 |
| Total shares not included in the computation of diluted losses per share | 4,773,424 | 8,129,931 |

Related Party Transactions

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

Table of Contents**Note 3. Assets – Intellectual Property**

On July 12, 2013, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an asset purchase agreement (“APA”) with Dr. Jörg Gerlach, MD, PhD, pursuant to which RenovaCare Sciences purchased all of Dr. Gerlach’s rights, title and interest in the CellMist™ System. Acquisition related costs amounted to \$52,852 and were capitalized together with the cash payment upon the closing of the transaction in July 2013 of \$100,002. Intangible assets amounted to \$152,854 at December 31, 2017 and 2016.

Note 4. Contract Payable

On June 9, 2014, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an amended asset purchase agreement (the “Amended APA”) with Dr. Jörg Gerlach, MD, PhD, pursuant to which RenovaCare Sciences purchased all of Dr. Gerlach’s rights, title and interest in the CellMist™ System. The Amended APA provided for cash payments of \$300,000 as partial consideration for the purchase which are payable as follows: (a) \$100,000 on December 31, 2014; (b) \$50,000 on December 31, 2015; (c) \$50,000 on December 31, 2016; and (d) \$100,000 on December 31, 2017. At December 31, 2017, \$100,000 of the amount payable to Dr. Gerlach was recorded as current liabilities in the accompanying consolidated balance sheet and was paid on January 24, 2018.

See also “Note 9. Related Party Transactions.”

Note 5. Debt

As of December 31, 2017 and 2016, the Company had the following outstanding debt balances:

| | Issue Date | Maturity Date | Principal | Debt Discount | Balance | Interest Payable |
|---------------------------------|-----------------------|--------------------------|------------------|--------------------------|----------------|-----------------------------|
| As of December 31, 2017: | | | | | | |
| February 2017 Note as amended | 2/23/2017 | 12/31/2019 | \$ 395,000 | \$ (58,438) | \$ 336,562 | \$ 24,074 |
| September 2016 Note as amended | 9/9/2016 | 12/31/2019 | 700,000 | - | 700,000 | 66,604 |
| | | | \$ 1,095,000 | \$ (58,438) | \$ 1,036,562 | \$ 90,678 |

**As of December
31, 2016:**

| | | | | | | | | | | |
|-----------------|----------|------------|----|---------|----|-----------|----|---------|----|--------|
| September 2016 | 9/9/2016 | 12/31/2019 | \$ | 700,000 | \$ | (534,519) | \$ | 165,481 | \$ | 15,220 |
| Note as amended | | | | | | | | | | |

February 2017 Convertible Promissory Notes

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

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

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

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

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

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

On January 29, 2018, KCC and the Company entered into an Amendment No. 1 to the February 2017 Note whereby the maturity date of the KCC February Note was extended from February 23, 2018 to December 31, 2019. Except for the extension of the maturity date, the February Note was not otherwise amended and continues in full force and effect.

During the year ended December 31, 2017, the Company recognized \$25,899 of interest expense and \$384,848 of accretion related to the debt discount. The remaining debt discount of \$58,438 will be amortized over the next quarter through March 31, 2018.

September 9, 2016 Convertible Promissory Note

On September 9, 2016, the Company entered into a loan agreement (the “**Loan Agreement**”) with KCC. Pursuant to the terms of the Loan Agreement, KCC agreed to loan the Company up to \$900,000 at an annual interest rate of 7% per year, compounded quarterly. KCC provided the Company with an initial loan in the amount of \$700,000, which was evidenced by a convertible promissory note (the “**Note**”); the remaining \$200,000 needed to be loaned prior to December 31, 2017. The Note, including any interest due thereon, may be prepaid at any time without penalty. The Note matured on December 31, 2017, but was extended to December 31, 2019 pursuant to the Amendment No. 1, dated as of January 29, 2018, to the Note. Except for the extension of the maturity date, the Note was not otherwise amended and continues in full force and effect. Beginning on September 9, 2017, the Note became convertible, at KCC’s sole discretion, into shares of our common stock at conversion rate equal to the lesser of: (i) \$1.54, the closing price of our common stock on the day prior to the issuance of the Note or (ii) a 20% discount to the average closing price of our common stock for the five days prior to the date on which KCC elects to convert the Note, subject to a floor price of \$1.23 per share.

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

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The Loan Agreement provides KCC with registration rights for all of the shares issuable upon conversion of the Note and exercise of the Series E Warrant, beginning on the first anniversary of the Loan Agreement.

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

During the years ended December 31, 2017 and 2016, the Company recognized \$51,385 and \$15,220, respectively, of interest expense and \$534,519 and \$165,481, respectively, of accretion related to the debt discount.

Note 6. Common Stock and Warrants

Common Stock

At December 31, 2017, the Company had 500,000,000 authorized shares of common stock with a par value of \$0.00001 per share, 76,145,418 shares of common stock outstanding and 19,338,572 shares reserved for issuance under the Company's 2013 Long-Term Incentive Plan (the "2013 Plan") as adopted and approved by the Company's Board of Directors (the "Board") on June 20, 2013 that provides for the grant of stock options to employees, directors, officers and consultants. See "Note 7. Stock Options" for further discussion.

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

- On October 16, 2017, the Company completed a self-directed offering of 920,000 shares of the Company common stock at a price of \$2.50 per share for \$2,300,000 in aggregate proceeds (the "**October 2017 Private Placement**"). Additionally, each purchaser, in a concurrent private placement, received one stock purchase warrant for each share of stock purchased for no additional consideration (the "**Series H Warrant**"). Each Series H Warrant is exercisable at a price of \$2.75 per share for a period of five years. The warrants may be exercised on a cashless basis. The relative fair value of the common stock was estimated to be \$1,309,458.

The relative fair value of the Series H Warrants was estimated to be \$990,542 as determined based on the relative fair value allocation of the proceeds received. The Series H Warrants were valued using the Black-Scholes option pricing model using the following variables: market price of common stock - \$3.10 per share; exercise price of \$2.75; estimated volatility – 98.25%; 5-year risk free interest rate – 1.95%; expected dividend rate - 0% and expected life - 5 years.

- On July 21, 2017, the Company completed a self-directed offering of 460,250 units of the Company’s equity securities (the “Units”) at a price of \$2.44 per unit for \$1,122,610 in aggregate proceeds (the “**July 2017 Private Placement**”). Each unit consists of (a) one share of common stock and one Series G Stock Purchase Warrant (the “**Series G Warrants**”) allowing the holder to purchase one share of the Company’s common stock at a price of \$2.68 per share for a period of five years. The warrants may be exercised on a cashless basis. The relative fair value of the common stock was estimated to be \$634,782. The relative fair value of the Series G Warrants was estimated to be \$487,828 as determined based on the relative fair value allocation of the proceeds received. The Series G Warrants were valued using the Black-Scholes option pricing model using the following variables: market price of common stock - \$2.92 per share; estimated volatility – 102.23%; 5-year risk free interest rate – 1.81%; expected dividend rate - 0% and expected life - 5 years.
- On June 28, 2017, KCC exercised 114,493 Series F Warrants for \$3.01 per share resulting in the issuance of 114,493 shares of common stock and proceeds of \$344,624.

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- March 1, 2017, KCC exercised 1,326,087 Series B Warrants and 3,500,000 Series C Warrants, on a cashless basis, resulting in the issuance of 4,273,831 shares of common stock.
- On February 17, 2017, Thomas Bold, the Company's President, CEO and Interim Chief Financial Officer exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 34,296 shares of common stock.
- On February 10, 2017, Joseph Sierchio, a member of the Company's board of directors, exercised options to purchase up to 70,000 shares, on a cashless basis, resulting in the issuance of 38,642 shares of common stock.
- On February 2, 2017, Kenneth Kirkland, a member of the Company's board of directors, exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 29,642 shares of common stock.
- On January 10, 2017, Dr. Gerlach exercised a Series A Warrant to purchase up to 240,000 shares, on a cashless basis, resulting in the issuance of 204,571 shares of common stock.

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

- issued 100,000 shares of common stock, upon the exercise of a Series D Warrant at an exercise price of \$1.10 per share resulting in \$110,001 of proceeds to the Company.
- issued 2,173,913 shares of common stock to KCC on February 2, 2016, upon the exercise of a portion of its Series B Warrant at an exercise price of \$0.46 per share resulting in \$1,000,000 of proceeds to the Company.
- issued 13,846 shares of common stock upon the cashless exercise of an option to purchase 20,000 shares by Joseph Sierchio, a director.

Warrants

The following table summarizes information about warrants outstanding at December 31, 2017 and 2016:

| Description | Shares of Common Stock Issuable from Warrants Outstanding as of | | Weighted Average Exercise Price | Expiration |
|-------------|---|----------------------|---------------------------------------|------------|
| | December 31, 2017 | December 31, 2016 | | |

| | | | | | |
|----------|-----------|-----------|----|------|--|
| Series A | 720,000 | 960,000 | \$ | 0.35 | July 12, 2019 |
| Series B | - | 1,326,087 | \$ | 0.46 | November 29, 2018 |
| Series C | - | 3,500,000 | \$ | 0.49 | November 29, 2018 |
| Series D | 910,000 | 910,000 | \$ | 1.10 | June 5, 2020 |
| Series E | 584,416 | 584,416 | \$ | 1.54 | September 8, 2021 |
| Series F | 14,492 | - | \$ | 3.45 | February 23, 2022 & March 9, 2022 |
| Series G | 460,250 | - | \$ | 2.68 | July 21, 2022 |
| Series H | 920,000 | - | \$ | 2.75 | October 16, 2022 |
| Total | 3,609,158 | 7,280,503 | | | |

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

A Series B Warrant with an exercise price of \$0.46 to purchase 3,500,000 shares of common stock was issued on November 29, 2013 to KCC in connection with the 11/29 Financing. On February 2, 2016, KCC exercised a portion of its Series B Warrant for 2,173,913 shares of the Company's common stock resulting in proceeds of \$1,000,000. On March 1, 2017, KCC exercised, in full, on a cashless basis, the remaining 1,326,087 Series B Warrants resulting in the issuance of 1,181,194 shares of common stock.

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

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

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

Three Series F Warrants to purchase 128,985 shares of common stock were issued between February 22, 2017 and March 9, 2017 in connection with the February 2017 Loan Agreements. On June 28, 2017, KCC exercised 114,493 Series F Warrants for \$3.01 per share resulting in the issuance of 114,493 shares of common stock and proceeds of \$344,624. See "Note 5. Debt" for further discussion.

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

The Series H Warrants to purchase 920,000 shares of common stock were issued on October 16, 2017 in connection with the sale of units pursuant to the October 2017 Private Placement. See “Note 6. Common Stock and Warrants” for further discussion.

Note 7. Stock Options

On June 20, 2013, the Company’s Board adopted the 2013 Long-Term Incentive Plan and on November 15, 2013, a stockholder owning a majority of the Company’s issued and outstanding stock approved adoption to the 2013 Plan. Pursuant to the terms of the 2013 Plan, an aggregate of 20,000,000 shares of the Company’s common stock are reserved for issuance to the Company’s officers, directors, employees and consultants in order to attract and hire key technical personnel and management. Options granted to employees under the 2013 Plan, including directors and officers who are employees, may be incentive stock options or non-qualified stock options; options granted to others under the 2013 Plan are limited to non-qualified stock options. As of December 31, 2017, there were 19,338,572 shares available for grant.

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

The exercise price per share of common stock for options granted under the 2013 Plan will be the fair market value of the Company's common stock on the date of grant, using the closing price of the Company's common stock on the last trading day prior to the date of grant, except for incentive stock options granted to a holder of ten percent or more of the Company's common stock, for whom the exercise price per share will not be less than 110% of the fair market value. No option can be granted under the 2013 Plan after June 20, 2023. The Company adopted ASU 2016-09 effective January 1, 2017 with no effect on retained deficit or other components of equity as of the beginning of the period.

Stock Option Activity

The following table summarizes stock option activity for the period ended December 31, 2017:

| | Number of Options | Weighted Average Exercise Price (\$) | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value (\$) |
|--|------------------------------|---|--|---|
| Outstanding at December 31, 2015 | 257,500 | 1.07 | | |
| Grants | 187,500 | 1.92 | | |
| Forfeitures | (40,000) | 1.65 | | |
| Exercises | (20,000) | 0.80 | | |
| Outstanding at December 31, 2016 | 385,000 | 1.42 | | |
| Grants | 310,000 | 4.20 | | |
| Exercises | (150,000) | 1.12 | | |
| Outstanding at December 31, 2017 | 545,000 | 3.09 | 8.61 years | 972,325 |
| Exercisable at December 31, 2017 | 390,000 | 2.80 | 8.47 years | 805,475 |
| Available for grant at December 31, 2017 | 19,338,572 | | | |

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. There were 310,000 stock options granted during the year ended December 31, 2017 with a weighted-average grant date fair value of \$3.38. There were 187,500 stock options granted during the year ended December 31, 2016 with a weighted-average grant date fair value of \$1.41. During the year ended December 31, 2017, there were 150,000 options exercised on a cashless basis resulting in the issuance of 102,582 shares of common stock, with an aggregate intrinsic value of \$397,100. During the year ended December 31, 2016, there were 20,000 options exercised on a cashless basis resulting in the issuance of 13,846 shares of common stock, with an aggregate intrinsic value of \$36,000. Assumptions regarding volatility, expected term, dividend yield and risk-free interest rate are required for the Black-Scholes model. The volatility assumption is based on the Company's historical experience. The risk-free interest rate is based on a U.S. treasury note with maturity similar to the option award's expected life. The expected life represents the average period of time that options granted are expected to be outstanding. The assumptions for volatility, expected life, dividend yield and risk-free interest rate for options granted are presented in the table below:

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| | Years Ended December 31, | |
|-----------------------------------|--------------------------|-------------|
| | 2017 | 2016 |
| Risk-free interest rate | 1.93%-2.39% | 1.23%-1.41% |
| Expected life in years | 5.5 – 10.0 | 5.5 |
| Weighted Avg. Expected Volatility | 98%-106% | 92% |
| Expected dividend yield | 0 | 0 |

The share-based compensation cost resulting from stock option grants, including those previously granted and vesting over time is expensed ratably over the respective vesting periods. During the years December 31, 2017 and 2016, the Company recognized \$904,004 and \$282,262, respectively, in share-based compensation. As of December 31, 2017, the Company had approximately \$165,000 of unrecognized compensation cost related to unvested stock options which is expected to be recognized over a period of 1.0 years. Stock-based compensation has been included in the Consolidated Statement of Operations as follows:

| | Years Ended December 31, | |
|----------------------------|--------------------------|------------|
| | 2017 | 2016 |
| Research and development | \$ 100,630 | \$ - |
| General and administrative | 803,374 | 282,262 |
| Total | \$ 904,004 | \$ 282,262 |

The following table summarizes information about stock options outstanding and exercisable at December 31, 2017:

| Range of Exercise Prices | Stock Options Outstanding | | | Stock Options Exercisable | | |
|--------------------------|---|---|---------------------------------|--|---|---------------------------------|
| | Number of Shares Subject to Outstanding Options | Weighted Average Contractual Life (years) | Weighted Average Exercise Price | Number of Shares Subject To Exercise Options | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price |
| 0.80 | 10,000 | 6.62 | 0.80 | 10,000 | 6.62 | 0.80 |
| 1.05 | 55,000 | 6.25 | 1.05 | 35,000 | 6.25 | 1.05 |
| 1.25 | 7,500 | 7.46 | 1.25 | 7,500 | 7.46 | 1.25 |
| 1.34 | 7,500 | 7.50 | 1.34 | 7,500 | 7.50 | 1.34 |
| 1.65 | 10,000 | 7.84 | 1.65 | 10,000 | 7.84 | 1.65 |
| 1.70 | 7,500 | 7.79 | 1.70 | 7,500 | 7.79 | 1.70 |
| 1.91 | 130,000 | 8.21 | 1.91 | 130,000 | 8.21 | 1.91 |
| 2.28 | 7,500 | 8.55 | 2.28 | 7,500 | 8.55 | 2.28 |
| 4.20 | 310,000 | 9.36 | 4.20 | 175,000 | 9.36 | 4.20 |
| Total | 545,000 | 8.61 | \$ 3.09 | 390,000 | 8.47 | \$ 2.80 |

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Note 8. Commitments

Effective March 1, 2015, the Company entered into a lease agreement (the “Lease”) in the Pittsburgh Life Sciences Greenhouse at a monthly rate of \$750. The Lease was renewed effective March 1, 2016 at a monthly rate of \$800 through August 30, 2018. Rent expense for the years ended December 31, 2017 and 2016 was \$9,600 and \$9,500, respectively.

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

In connection with the Company’s anticipated regulatory filings, the Company has engaged StemCell Systems GmbH (“StemCell Systems”) to provide it with prototypes and related documents under various agreements. Pursuant to these engagements the Company incurred expenses of \$219,806 and \$184,517 in during the years ended December 31, 2017 and 2016, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

On August 1, 2017, the Company and the University of Pittsburgh entered into a Corporate Research Agreement whereby the University of Pittsburgh will perform academic research related to the Company’s technologies in exchange for \$171,595 with \$42,899 due on August 1, 2017; \$42,899 due on November 1, 2017; \$42,899 due on February 1, 2018 and \$42,898 due on May 31, 2018. As of December 31, 2017, the Company had paid one advance and \$42,899 is recorded as accounts payable in the accompanying consolidated balance sheets as of December 31, 2017.

See also “Note 9. Related Party Transactions.”

Note 9. Related Party Transactions

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

The law firm of Satterlee Stephens LLP ("Satterlee"), of which Joseph Sierchio, one of the Company's directors, is a partner, provides counsel to the Company. Mr. Sierchio is the Company's primary attorney. During the years ended December 31, 2017 and 2016, the Company recognized \$277,933 and \$168,775 of fees for legal services billed by firms associated with Mr. Sierchio. At December 31, 2017 and 2016, the Company owed Satterlee \$30,000 and \$11,750 which is included in accounts payable. Mr. Sierchio continues to serve as a director of the Company.

In connection with the Company's anticipated FDA and other regulatory filings, the Company engaged StemCell Systems to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$219,806 and \$184,517 during the years ended December 31, 2017 and 2016, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

Dr. Gerlach is entitled to payments for consulting services. During the years ended December 31, 2017 and 2016, the Company recognized expenses related to Dr. Gerlach services of \$38,540 and \$42,480, respectively. Accounts payable to Dr. Gerlach amounted to \$17,640 and \$18,540 at December 31, 2017 and 2016, respectively.

On August 1, 2013, the Company entered into a consulting agreement, as amended on May 1, 2016, with Jatinder Bhogal to provide consulting services to the Company through his wholly owned company, Vector Asset Management, Inc., Mr. Bhogal is an individual owning in excess of 5% of our issued and outstanding shares of common stock. Pursuant to the Consulting Agreement, as amended, Mr. Bhogal received compensation of \$81,600 and \$74,400 during the years ended December 31, 2017 and 2016 in connection with the consulting agreement.

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

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

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

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

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

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

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

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

discussion.

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

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

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

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

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

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Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. A valuation allowance is established to reduce deferred tax assets if all, or some portion, of such assets will more than likely not be realized.

On December 22, 2017, the President of the United States signed into law H.R. 1, "An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for Fiscal Year 2018" (the "Tax Cuts and Jobs Act"). ASC Topic 740, Accounting for Income Taxes, requires companies to recognize the effect of tax law changes in the period of enactment. The Tax Cuts and Jobs Act made significant changes to existing U.S. tax law, including, but not limited to, a permanent reduction to the U.S. federal corporate income tax rate from 35% to 21%, imposition of a one-time tax on deferred foreign income ("Repatriation Transition Tax"), adoption of a participation exemption system with respect to the taxation of future dividends received from foreign corporations, and repeal of the corporate alternative minimum tax system. Other significant changes in the Tax Cuts and Jobs Act include taxing payments made to foreign related parties that are deemed to be excessive, imposing a minimum tax on certain foreign earnings, requiring (beginning after December 31, 2021) the capitalization and subsequent amortization of certain research and development related expenses, and placing additional limits on the use of net operating losses and the deductibility of certain executive compensation. The reduction of the Company's deferred tax assets resulting from the Tax Cuts and Jobs Act's reduction in the U.S. federal corporate income tax rate from 35% to 21% amounted to \$1,831,000 during 2017.

There is no current or deferred tax expense for 2017 and 2016, due to the Company's loss position. Realization of the future tax benefits related to the deferred tax assets is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Management has considered these factors in reaching its conclusion as to the valuation allowance for financial reporting purposes and has recorded a full valuation allowance against the deferred tax asset. The income tax effect of temporary differences comprising the deferred tax assets and deferred tax liabilities is a result of the following at December 31:

| | 2017 | 2016 |
|---|--------------|--------------|
| Deferred tax assets: | | |
| Net operating loss and contribution carryforwards | \$ 2,480,000 | \$ 3,217,000 |
| Intangible asset | 85,000 | 158,000 |
| Capital loss carryforward | 146,000 | 236,000 |
| Stock-based compensation | 247,000 | 139,000 |
| | 2,958,000 | 3,750,000 |
| Valuation allowance | (2,958,000) | (3,750,000) |
| Net deferred tax assets | \$ - | \$ - |

The 2017 decrease in the valuation allowance was \$792,000 compared to an increase of \$974,000 in 2016.

The Company has available net operating loss and contribution carryforwards of approximately \$11,810,000 for tax purposes to offset future taxable income which expire commencing 2018 through to the year 2037. The capital loss carryforward expires during 2018. Pursuant to the Tax Reform Act of 1986, annual utilization of the Company's net operating loss and contribution carryforwards may be limited if a cumulative change in ownership of more than 50% is deemed to occur within any three-year period. The tax years 2015 through 2017 remain open to examination by federal agencies and other jurisdictions in which it operates.

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

| | 2017 | 2016 |
|--|-------|-------|
| Statutory federal income tax rate | 34% | 34% |
| Permanent differences and other | (5)% | 13% |
| Deferred tax impact from tax rate change | (50)% | |
| Valuation allowance | 21% | (47)% |
| | 0% | 0% |

Note 11. Subsequent Events

Management has reviewed material events subsequent of the period ended December 31, 2017 and prior to the filing of financial statements in accordance with FASB ASC 855 “Subsequent Events”.

On January 26, 2018, the Company entered into the first amendment to the convertible promissory note dated September 9, 2016 and the Company entered into the first amendment to the convertible promissory note dated February 23, 2017 both with KCC pursuant to which both notes were amended (with a combined principal balance of \$1,095,000) to extend the maturity date to December 31, 2019.

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

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

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

On February 13, 2018, a Series D Warrant to purchase 100,000 shares of common stock with an exercise price of \$1.10 per share was exercised resulting in \$110,000 to the Company.

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

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

On January 25, 2018, the Company paid the University of Pittsburgh \$85,798 pursuant to the Corporate Research Agreement dated August 1, 2017.

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RENOVACARE, INC.

4,404,136 SHARES

OF

COMMON STOCK

PROSPECTUS

April 17, 2018

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