RenovaCare, Inc.
Form 10-K
March 13, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended **December 31, 2017**

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

For the transition period from _____ to _____

Commission file number **000-30156**

RENOVACARE, INC.

(Exact name of registrant as specified in its charter)

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

Pittsburgh Life Sciences Greenhouse

2425 Sidney Street

Pittsburgh, PA 15203

(Address of principal executive offices)

(888) 398-0202

(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price of the registrant's common stock on June 30, 2017, as reported on the OTCQB was $73,220,246. Common stock held by each officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 6, 2018, there were 76,840,522 shares of the registrant's common stock outstanding.

Documents incorporated by reference: None.

RENOVACARE, INC.

FORM 10-K

For The Fiscal Year Ended December 31, 2017

TABLE OF CONTENTS

		Page
	PART I	
Item 1.	Business	4
Item 1A.	Risk Factors	9
Item 1B.	Unresolved Staff Comments	9
Item 2.	Properties	9
Item 3.	Legal Proceedings	9
Item 4.	Mine Safety Disclosures	9
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	10
Item 6.	Selected Financial Data	11
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	14
Item 8.	Financial Statements and Supplementary Data	15
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	16
Item 9A.	Controls and Procedures	16
Item 9B.	Other Information	16
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	17
Item 11.	Executive Compensation	21
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	24
Item 13.	Certain Relationships and Related Transactions, and Director Independence	26
Item 14.	Principal Accounting Fees and Services	28
	PART IV	
Item 15.	Exhibits, Financial Statement Schedules	30
	Signatures	31

2

PART I

Forward-Looking Statements

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

- our ability to meet requisite regulations or receive regulatory approvals in the United States, and our ability to retain any regulatory approvals that we may obtain; and the absence of adverse regulatory developments in the United States and abroad;

- new entrance of competitive products or further penetration of existing products in our markets;

- the effect on us from adverse publicity related to our products or the company itself; and

- any adverse claims relating to our intellectual property.

The safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, apply to forward-looking statements made by the Company. The reader is

cautioned that no statements contained in this Form 10-K should be construed as a guarantee or assurance of future performance or results. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks described in this report and matters described in this report generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur.

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

Table of Contents

ITEM 1. BUSINESS

Overview

RenovaCare, Inc. (formerly Janus Resources, Inc.) (together with its wholly owned subsidiary, "**RenovaCare**" the "**Company**" "**we**" "**us**" and "**our**") was incorporated under the laws of the State of Nevada and has an authorized capital o 500,000,000 shares of $0.00001 par value common stock, of which 76,840,522 shares are outstanding as of February 28, 2018, and 10,000,000 shares of $0.0001 par value preferred stock, of which none are outstanding.

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

Our principal executive offices are located at Pittsburgh Life Sciences Greenhouse, 2425 Sidney Street, Pittsburgh, PA 15203. Our telephone number is (888) 398-0202.

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

Description of Business

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

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

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

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

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

Table of Contents

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

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

Our Market Opportunity

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

Burn Wounds

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

The prevalence of patients with severe burns is even higher in emerging economies. For example, according to the World Health Organization over 1,000,000 people in India are moderately to severely burnt every year and approximately 265,000 people worldwide die from burn related injuries (see World Health Organization "*Burns: Fact Sheet No. 365*," reviewed September 2016, available at: http://www.who.int/mediacentre/factsheets/fs365/en/). According to Critical Care, an international clinical medical journal, burns are also among the most expensive traumatic injuries because of long and costly hospitalization, rehabilitation and wound and scar treatment (see 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).

5

Table of Contents

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 able to develop a commercially viable product based upon the CellMist™ System and its underlying technology.*

Domestic Regulation

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

regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application in the U.S. for pre-market approval, or for foreign regulatory approvals outside the U.S.. The process of obtaining foreign approvals, can be expensive, time consuming and uncertain.

Premarket Approval

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

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

Table of Contents

Investigational Device Exemption ("IDE")

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

HIPAA Requirements

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

Other U.S. Regulatory Requirements

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

rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

International Regulation

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

Competition

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

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

Intellectual Property

General

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

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

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

Strategy

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

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

Table of Contents

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.

Operations

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

Employees

We currently have one full time employee, Mr. Andrew Danielson, Director of Operations, and three consultants, two of whom provide services as officers: 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. Mr. Bold is also one of our directors. From time to time we use additional independent contractors to provide us with services. None of the consultants are required to expend all of their time and efforts on our behalf and may engage in other activities.

ITEM 1A. RISK FACTORS

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any properties. Our corporate offices are located at Pittsburgh Life Sciences Greenhouse, 2425 Sidney Street Pittsburgh, PA 15203. Rent is $800 per month on a month-to-month basis.

ITEM 3. 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 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 did not file a Notice of Appeal with the Federal Circuit Court to review the PTAB Final Written Decision prior to the appeal deadline on February 21, 2018.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

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

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2017 – High	$ 5.50	$ 2.49	$ 3.95	$ 4.95
2017 – Low	$ 2.10	$ 4.75	$ 2.87	$ 2.99
2016 – High	$ 2.35	$ 2.58	$ 2.48	$ 2.81
2016 – Low	$ 0.96	$ 1.96	$ 1.25	$ 0.88

The closing price of our common stock on March 5, 2018, was $5.01 As of March 5, 2018, there were approximately 360 stockholders of record (this number does not include stockholders who hold their stock through brokers, banks and other nominees).

Transfer Agent

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

Penny Stock

The Securities and Exchange Commission has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document prepared by the Commission, which: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation to such duties or other requirements of Securities' laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form as the Commission shall require by rule or regulation. The broker-dealer also must provide to the customer, prior to effecting any transaction in a penny stock: (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitably statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our stock if it becomes subject to these penny stock rules.

Table of Contents

Rule 144

There were 76,840,522 shares of our common stock issued and outstanding at March 6, 2018, of which 51,513,687 shares are deemed "restricted securities" or "control securities" within the meaning of Rule 144. Absent registration under the Securities Act, the sale of such shares is subject to Rule 144, as promulgated under the Securities Act.

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

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

Dividend Policy

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

- ωε ωουλδ νοτ βε αβλε το παψ ουρ δεβτσ ασ τηεψ βεχομε δυε ιν τηε υσυαλ χουρσε οφ βυσινεσσ; ορ

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

ITEM 6. SELECTED FINANCIAL DATA

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

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Discussion and Analysis

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

Results of Operations

Year Ended Year Ended December 31, 2017 versus December 31, 2016

	Year Ended December 31, 2017	2016	Increase / (Decrease)	Percentage 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.

Table of Contents

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.

Table of Contents

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:

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- 76,145,418 χομμον σηαρεσ ωερε ισσυεδ ανδ ουτστανδινγ.

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 in this Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

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

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

Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets as of December 31, 2017 and 2016	F-2
Consolidated Statements of Operations for the years ended December 31, 2017 and 2016	F-3
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2017 and 2016	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016	F-5
Notes to the Consolidated Financial Statements	F-6

Table of Contents

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

Table of Contents

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)

F-2

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)

Table of Contents

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

	Common Stock		Additional Paid-in	Retained	Total Stockholders'
	Shares	Amount	Capital	Deficit	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

July 2017 Private Placement units issued	460,250	4	1,122,606		1,122,610
Stock based compensation due to common stock purchase options	-	-	904,004	-	904,004
Discount on convertible promissory note due to detachable warrants and beneficial conversion feature	-	-	443,286	-	443,286
Net loss for the year ended December 31, 2017	-	-	-	(3,689,338)	(3,689,338)
Balance, December 31, 2017	76,145,418	$ 762	$ 16,404,673	$ (14,740,922)	$ 1,664,513

(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)

F-5

Table of Contents

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.

Table of Contents

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.

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.

Table of Contents

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.

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.

Table of Contents

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.

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.

Table of Contents

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: