RenovaCare, Inc. Form 10-K March 28, 2014

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, 2013

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

For the transition period from ______ to _____

Commission file number 000-30156

RENOVACARE, INC.

(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation) 98-0170247

(I.R.S. Employer Identification No.)

430 Park Avenue Suite 702 New York, NY 10022 (Address of principal executive offices)

800-755-5815

(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:

Common Stock, \$0.00001 par value per share (Title of Class)

OTC Markets Group, Inc. QB tier ("OTCQB") (Name of exchange on which registered)

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. Yes x No o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting company x

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 28, 2013, as reported on the OTCQB was \$20,585,780. 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 24, 2014, there were 66,575,122 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, 2013

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PART I

Forward-Looking Statements

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

- our ability to meet requisite regulations or receive regulatory approvals in the United States, and our ability to retain any regulatory approvals that we may obtain; and the absence of adverse regulatory developments in the United States and abroad;
- new entrance of competitive products or further penetration of existing products in our markets;
- •the effect on us from adverse publicity related to our products or the company itself; and
- any adverse claims relating to our intellectual property

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.

Item 1. Business

Overview

RenovaCare, Inc. (formerly Janus Resources, Inc.) (together with its wholly owned subsidiary, "RenovaCare" "the Company" "we" "us" and "our") was incorporated under the laws of the State of Nevada and has an authorized capital of 500,000,000 shares of \$0.00001 par value common stock, of which 66,575,122 shares are outstanding as of March 24, 2014, 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 "Januar Resources, Inc." to "RenovaCare, Inc." so as to more fully reflect our operations. The Financial Industry Regulatory Authority ("FINRA") declared the name change effective as of January 9, 2014. In conjunction with the name change, we changed our stock symbol on the OTCQB from "JANI" to "RCAR".

Our principal executive offices are located at 430 Park Avenue, Suite 702, New York, NY 10022. Our telephone number is (800) 755-5815.

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

Description of Business

We are a development-stage company focusing on the acquisition, research, development and, if warranted, commercialization of autologous (using a patient's own cells) cellular therapies that can be used for medical and aesthetic applications. On July 12, 2013, we, through our wholly owned subsidiary, RenovaCare Sciences Corp., completed the acquisition of our flagship technology, a treatment methodology for skin isolation, spraying and associated equipment for the regeneration of human skin cells (the "Cell Deposition Device"), which has been shown in early human clinical use in the United States to naturally regenerate and heal skin for burn victims, along with the associated United States and foreign patents and patent applications. The development of our Cell Deposition Device 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, since the ratio between the size of the wound area and the size of the donor site is quite low, i.e. the size of the skin removed must be substantially equal in size to the size of the damaged skin, the mesh-grafting approach is in many cases limited. Donor and injury sites can take weeks to heal, requiring expensive hospital stays, ongoing wound dressing management, and ever-changing anti-infection strategies.

We are currently evaluating the efficacy and potential of our Cell Deposition Device, in combination with our unique cell isolation method, in the treatment of tissue that has been subject to severe trauma such as second and third degree burns. In small scale clinical trials, the Cell Deposition Device and cell isolation methodology has shown the ability to regenerate a more natural and thicker skin. The Cell Deposition Device utilizes the patient's own skin stem cells and is able to address much larger treatment areas and at the same time reduce the size of the donor site. Furthermore, we believe the Cell Deposition Device enables the effective treatment of other skin disorders with minimal scarring compared to skin grafting.

Governmental Regulations

Domestic Regulation

Governmental authorities in the United States, 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 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States, and to any approvals required by foreign governmental entities prior to their marketing outside the United States. 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 for 510(k) clearance, pre-market approval or foreign regulatory approvals.

The 510(k) clearance and pre-market approval processes, as well as the process of obtaining foreign approvals, can be expensive, time consuming and uncertain. It generally takes from four to twelve months from submission to obtain 510(k) clearance, and from one to three years from submission to obtain pre-market approval; however, it may take longer, and 510(k) clearance or pre-market approval may never be obtained. Delays in receipt of, or failure to obtain, clearances or approvals for future products, including tests that are currently in design or development, would result in delayed, or no, realization of revenues from such products and in substantial additional costs which could decrease our profitability. We have not yet submitted any devices for 510(k) approval and there are no guarantees that we will make such a submission or that if we do our submission will be approved.

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. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

Other U.S. Regulatory Requirements

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

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

International Regulation

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

Competition

The pharmaceutical and wound care industries are characterized by intense competition, rapid product development and technological change. Our Cell Deposition Device 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 offers ReCell® Spray-On SkinTM, 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 mesh-grafted tissue. Other competitors include Fibrocell Science, Inc., Shire Plc and Organogenesis, Inc.

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

Strategy

Our ultimate goal is to leverage the potential of our Cell Deposition Device, 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 Cell Deposition Device's efficacy for treating wounds and burns;
- expanding the range of possible applications;
- formalizing collaborations with universities and scientific partners;
- creating a network of clinical and research partners; and
- achieving Food and Drug Administration (the "FDA") and other regulatory approval.

Additionally, we will likely be required to raise significant capital in order to fund our ongoing research and development operations, and there is no guarantee that we will be able to raise on acceptable terms, if at all.

Discontinued Operations

Sale of Fostung Resources Ltd.

On December 31, 2013, we entered into a stock purchase agreement with Duke Mountain Resources, Inc. ("Duke"), a Nevada corporation, pursuant to which we sold to Duke 100% of the issued and outstanding shares of Fostung Resources Ltd. ("Fostung Resources"), a corporation organized under the laws of Ontario, Canada and a wholly owned subsidiary of ours, in exchange for a promissory note in the amount of \$80,000, which amount approximated the fair

value of the leases and mining claims controlled by Fostung Resources, as concluded by an independent third-party geological consultant.

Sale of Oil and Gas Properties

On February 18, 2013, we completed the sale of our working interest in the Onnie Ray #1, Haile #1, Pearce #1 and Stahl #1 oil wells. We entered into an Assignment Agreement with Leexus Oil LLC, the wells operator, whereby we assigned our right, title and interest in the oil, gas and mineral leases and the oil and gas wells. Payment for the assignment was the assumption of all outstanding liabilities and assumption of all future payments for any and all work performed on the wells. On February 19, 2013, we completed the sale of our working interest in the Cooke #6 well. We entered into an Assignment Agreement with Millennium Petro-Physics, the well operator, whereby we assigned our right, title and interest in the oil, gas and mineral leases and the oil and gas wells. Payment for the assignment was \$3,000 cash.

Operations

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

Employees

We currently have two part-time contractors providing services to us, Mr. Thomas Bold, our President and Chief Executive Officer and Ms. Rhonda B. Rosen, our Chief Financial Officer.

Item 1A. Risk Factors

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We do not own any properties. Our corporate offices are located at 430 Park Avenue, Suite 702, New York, NY 10022 and it provided to us free of charge by one of our directors; we do not have a lease agreement for our corporate office.

Item 3. Legal proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

On January 7, 2014, we filed a Certificate of Amendment to Articles of Incorporation changing our name from "January Resources, Inc." to "RenovaCare, Inc." 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".

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
2013 – High	\$0.38	\$0.80	\$0.74	\$1.37
2013 – Low	\$0.33	\$0.37	\$0.55	\$0.56
2012 – High	\$0.55	\$0.58	\$0.43	\$0.37
2012 – Low	\$0.28	\$0.40	\$0.37	\$0.33

The closing price of our common stock on March 24, 2014, was \$1.25.

As of March 24, 2014, there were approximately 324 stockholders of record.

Transfer Agent

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

Penny Stock

The Securities and Exchange Commission has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Our stock is currently a "penny stock." Penny stocks are generally equity securities with a price of less than \$5.00, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document prepared by the Commission, which: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation to such duties or other requirements of Securities' laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form as the Commission shall require by rule or regulation. The broker-dealer also must provide to the customer, prior to effecting any transaction in a penny stock: (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable

information relating to the depth and liquidity of the market for such stock; and (d) monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written 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.

Rule 144

There were 66,575,122 shares of our common stock issued and outstanding at March 24, 2014, of which 42,921,800 shares are deemed "restricted securities," within the meaning of Rule 144. Absent registration under the Securities Act, the sale of such shares is subject to Rule 144, as promulgated under the Securities Act.

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

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

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: