

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

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

Registration No. 333-215661

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

RenovaCare, Inc.

(Exact name of registrant as specified in its charter)

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

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

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(Address and telephone number
of principal executive offices)

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number of agent for service)

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

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

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

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

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

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934. (Check one):

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

(Do not check if a smaller reporting company)

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered⁽¹⁾	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, par value \$0.00001 ⁽²⁾	946,000	\$ 2.20 ⁽³⁾	\$ 2,081,200	\$ 241.21
Common stock, par value \$0.00001 ⁽⁴⁾	1,010,000	\$ 1.10 ⁽⁵⁾	\$ 1,111,000	\$ 128.76
Total	1,956,000		\$ 3,192,200	\$ 369.97⁽⁶⁾

- (1) In the event of a stock split, stock dividend or similar transaction involving our common stock, in order to prevent dilution, the number of shares registered shall be automatically increased to cover the additional shares in accordance with Rule 416(a) under the Securities Act of 1933, as amended.
- (2) Represents shares of our common stock previously acquired by and issued to the Selling Stockholders in a private transaction directly with us.
- (3) The proposed maximum offering price per share is estimated solely for the purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act, using the closing price of our common stock as reported on the OTC Markets Group, Inc. QB tier on January 13, 2017, a date within five business days prior to the date of the filing of the original registration statement.
- (4) Represents shares of our common stock issuable upon exercise of Series D Stock Purchase Warrants (each a “Series D Warrant” and collectively, the “Series D Warrants”) that were purchased by the Selling Stockholders in a private transaction allowing the holders to purchase shares of common stock at an exercise price of \$1.10 per share through June 5, 2020; the Series D Warrants may be exercised on a “cashless basis”.
- (5) The proposed maximum offering price per share is estimated solely for the purposes of calculating the registration fee in accordance with Rule 457(g) using the price at which the Series D Warrants may be exercised.
- (6) Previously paid.

PROSPECTUS

SUBJECT TO COMPLETION, DATED APRIL 7, 2017

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

1,956,000 SHARES

RENOVACARE, INC. COMMON STOCK

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

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

Our common stock is presently quoted for trading under the symbol "**RCAR**" on the OTC Markets Group Inc. QBTM tier (the "**OTCQB**"). On April 4, 2017, the closing price of our common stock, as reported on the OTCQB was \$2.96 per share. The Selling Stockholders have advised us that they will sell the shares of common stock registered hereunder from time to time in the open market, on the OTCQB, in privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or otherwise as described under the section of this prospectus titled "**Plan of Distribution.**"

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

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

The date of this prospectus is April 7, 2017

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

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

PROSPECTUS SUMMARY

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

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

Overview

We were incorporated under the laws of the State of Utah on July 14, 1983, under the name "Far West Gold, Inc." On May 9, 1996, our stockholders authorized a name change to "Far West Resources, Inc." On June 30, 1997, the stockholders authorized a name change to "American Alliance Corporation" and authorized a change in the state of domicile from Utah to Nevada. On May 20, 1999, we changed our name to "WhatsOnline.Com, Inc.," effective as of August 3, 2000, we changed our name to Entheos Technologies, Inc. and effective as of January 5, 2011, we changed our name to Janus Resources, Inc. On January 7, 2014, we filed a Certificate of Amendment to Articles of Incorporation changing our name from "Janus Resources, Inc." to "RenovaCare, Inc." so as to more fully reflect our operations. We have an authorized capital of 500,000,000 shares of common stock, par value \$0.00001 of which 74,650,675 shares are outstanding as of the date of this prospectus, and 10,000,000 shares of \$0.0001 par value preferred stock, of which none are outstanding.

Description of Business

We are a development-stage company focusing on the acquisition, research, development and, if warranted, commercialization of autologous (using a patient's own cells) cellular therapies that can be used for medical and aesthetic applications. On July 12, 2013, we, through our wholly owned subsidiary, RenovaCare Sciences Corp., completed the acquisition of our flagship technologies (collectively, the "**CellMist™ System**") along with the associated United States patent applications and two foreign patents, the first of which expires on August 22, 2027 and the second of which expires on April 26, 2031. One of the two US patent applications was granted to us on November 29, 2016 (Patent No.: US 9,505,000) and expires on or about March 3, 2035. The CellMist™ System is comprised of (a) a treatment methodology for cell isolation for the regeneration of human skin cells (the "**CellMist™ Solution**") and (b) a solution sprayer device (the "**SkinGun™**") for delivering the cells to the treatment area. Based on these technologies the Company has recently filed two additional patent applications, one with the United States Patent and Trademark Office titled "Modular Device for Cell Spraying," and one with the European Patent Office titled "Disposable Apparatus and Device with Unsterile Reusable Apparatus for Sterile Application of a Liquid."

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

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

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

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

Corporate Information

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

Risk Factors

Our business operations are subject to numerous risks, including the risk of delays in, or discontinuation of, our research and development due to lack of financing, poor results, inability to commercialize our technologies or to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider, you are urged to carefully review and consider the section titled "**Risk Factors**" beginning on page 9 of this prospectus.

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THE OFFERING

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

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

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

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

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

Shares Outstanding Prior to Completion of the Offering: 74,650,675

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

Shares Outstanding upon Closing of the Offering: Upon completion of the offering, we will have 76,606,675 shares outstanding, assuming the full exercise of all outstanding Series D Warrants, without giving effect to the exercise of any other outstanding warrants or options.

OTCQB Symbol: RCAR

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

Risk Factors: Our business operations are subject to numerous risks, including the risk of delays in, or discontinuation of, our research and development due to lack of financing, poor results, inability to commercialize our technologies or to obtain necessary regulatory

approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider, you are urged to carefully review and consider the section titled "**Risk Factors**" beginning on page 9 of this prospectus.

Use of Proceeds:

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

Duration of Offering:

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

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

	For the Year Ended	For the Year Ended
	December 31, 2016	December 31, 2015
Statements of Operations Data		
Revenue	\$ 0	\$ 0
Loss from operations	\$ (1,898,222)	\$ (1,318,507)
Basic and diluted net loss per share	\$ (0.03)	\$ (0.02)
Weighted average shares outstanding used in basic and diluted net loss per share calculation	69,772,485	67,233,254

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

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RISK FACTORS

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

Risks Related To Our Business

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

We are a development-stage company. We do not have any commercialized products and have not generated any revenue since inception and do not expect to generate any revenue for the foreseeable future. We had a net loss from continuing operations of \$1,898,222 and \$1,318,507 for our fiscal years ended December 31, 2016 and 2015, respectively, and we have incurred a cumulative deficit of \$11,051,584 million through December 31, 2016. We anticipate incurring losses through at least December 31, 2017.

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

As of December 31, 2016, we had cash and cash equivalents of \$418,031. We anticipate that we will remain engaged in research and product development activities through at least December 31, 2017. Based upon our current level of operations and expenditures, we believe that absent any modification or expansion of our existing research, development and testing activities, cash on hand should be sufficient to enable us to continue operations to March 31, 2017. There is no assurance that we will be able to generate revenue and achieve profitability or secure additional financing once our current cash balance is depleted. Any significant expansion in scope or acceleration in timing of our current research and development activities, or commencement of any marketing and sales activities, will require additional funds.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These companies enjoy numerous competitive advantages, including:

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

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

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

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

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

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

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

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

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

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

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

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

Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. We may

experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process. Even if preclinical or clinical trials are successful, we still may be unable to commercialize the product, as success in preclinical trials, early clinical trials, or previous clinical trials, does not ensure commercial acceptance.

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

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

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

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

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

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

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

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval for our product candidates for any or all targeted indications. Any related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may withdraw approvals of such product;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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