RenovaCare, Inc.
Form S-1/A
April 06, 2018

As filed with the U.S. Securities and Exchange Commission on April 5, 2018

Registration No. 333-222974

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

PRE-EFFECTIVE 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.

Pittsburgh Life Sciences Greenhouse

2425 Sidney Street

Pittsburgh, PA 15203

(888) 398-0202

Thomas Bold

RenovaCare, Inc.

Pittsburgh Life Sciences Greenhouse

2425 Sidney Street

Pittsburgh, PA 15203

(888) 398-0202

(Address and telephone number of principal executive offices)

(Name, address and telephone number of agent for service)

Copies to:

Joseph Sierchio, Esq.

Satterlee Stephens LLP

230 Park Avenue

Suite 1130

New York, New York 10169

Telephone: (212) 818-9200

Facsimile: (212) 818-9606

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

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

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. ¨

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	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	x
(Do not check if a smaller reporting company)		Emerging growth company	¨

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 to Section 7(a)(2)(B) of the Securities Act. ¨

This filing constitutes a Post-Effective Amendment to the Registration Statement on Form S-1 (File No. 333-215661), which was declared effective on July 5, 2017. This Post-Effective Amendment shall hereafter become effective in accordance with Section 8(c) of the Securities Act of 1933 on such date as the Securities and Exchange Commission, acting pursuant to Section 8(c), may determine.

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)	460,250	$ 6.05(3)	$ 2,784,513	$ 346.67
Common stock, par value $0.00001 (4)	460,250	$ 2.68(5)	$ 1,233,470	$ 153.57
Common stock, par value $0.00001 (6)	640,000	$ 6.05(7)	$ 3,872,000	$ 482.06
Common stock, par value $0.00001 (8)	910,000	$ 2.75(9)	$ 2,502,500	$ 311.57
Common stock, par value $0.00001 (10)	1,933,636	$ 6.05	$ 11,698,498	$ 1,456.46
Total	4,404,136	-	$ 22,090,981	$ 2,750.33
Less amount previously paid				$ 761.13(11)
Registration fee aid with this filing				$ 1,989.20

_____

(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 460,250 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 February 5, 2018, a date within five trading days prior to the date of the filing of this registration statement.

(4) Represents shares of our common stock, par value $0.00001 per share, which have vested and may be issued upon exercise of an outstanding Series G Stock Purchase Warrant (the "**Series G Warrant**"), allowing the holder to purchase shares of our common stock at an exercise price of $2.68 per share through July 21, 2022.

(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 warrants may be exercised.

(6) Represents shares of our common stock that were previously purchased by certain of the Selling Stockholders in private transactions, 140,000 of which were purchased in June 2013 from an unaffiliated third-party who purchased the shares from us in an unregistered offering, pursuant exemptions from the registration requirements of the Securities Act, which we completed in July 2008, and 500,000 of which were purchased from an affiliate of ours in September 2008.

(7) 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 February 2, 2018, a date within five trading days prior to the date of the filing of this registration statement.

(8) Represents shares of our common stock, par value $0.00001 per share, which have vested and may be issued upon exercise of an outstanding Series H Stock Purchase Warrant (the "**Series H Warrant**"), allowing the holder to purchase shares of our common stock at an exercise price of $2.75 per share through October 16, 2022.

(9) 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 H Warrants may be exercised.

(10) Pursuant to Rule 429 under the Securities Act this Registration Statement includes Pursuant to Rule 429 under the Securities Act of 1933, the prospectus included in this Registration Statement is a combined prospectus relating to (i) this Registration Statement pursuant to which an aggregate of 2,310,142 shares are being registered for resale as set forth above and (ii) 1,933,636 Common Shares previously registered by the Company on its Registration Statements on Form S-1 (Registration No. 333-215661 previously filed by the Registrant on Form S-1 on January 23, 2017 and declared effective by the Securities and Exchange Commission July 5, 2017 (the "**Prior Registration Statement**"), which related to the resale of up to 2,856,000 shares of common stock of the Registrant from time to time by the Selling Stockholders named therein. The 1,933,636 shares represent the remaining balance after taking into account the removal of the sold shares registered on behalf of one Selling Stockholder (none of which were sold) and the shares sold by the Selling Stockholders. An aggregate filing fee of $761.13 was previously paid in connection with the Prior Registration Statement.

(11) The $ 1,989.20 being paid contemporaneously with this filing is net of the $761.13 previously paid with respect to the Prior Registration Statement.

The registrant hereby amends this registration statement on such date or date(s) 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(c) of the Securities Act, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(c), may determine.

EXPLANATORY NOTE

Pursuant to Rule 429 under the Securities Act of 1933, the prospectus included in this Registration Statement is a combined prospectus relating to the resale of up to an aggregate of 4,404,136 shares of the Company's common stock, consisting of (i) 2,470,500 additional shares that being registered for resale pursuant to this Registration Statement and (ii) 1,933,636 Common Shares previously registered by the Company on its Registration Statements on Form S-1 (Registration No. 333-215661 previously filed by the Registrant on Form S-1 on January 23, 2017 and declared effective by the Securities and Exchange Commission July 5, 2017 (the "**Prior Registration Statement**"), which related to the resale of up to 2,856,000 shares of common stock of the Registrant from time to time by the Selling Stockholders named therein. The 1,933,636 shares represent the remaining balance of the shares registered for resale by the Selling Stockholders named in the Prior Registration Statement.

This Registration Statement constitutes Post-Effective Amendment No. 1 to the Prior Registration Statement. Such post-effective amendments shall hereafter become effective concurrently with the effectiveness of this Registration Statement in accordance with Section 8(c) of the Securities Act.

PROSPECTUS

SUBJECT TO COMPLETION, DATED April 5, 2018

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.

RENOVACARE, INC.

4,404,136 SHARES OF COMMON STOCK

This prospectus relates to the resale by certain of our stockholders and holders of warrants to purchase our stock named in the section of this prospectus titled "Selling Stockholders" (collectively, the "**Selling Stockholders**") of up to 4,404,136 shares (collectively, the "**Shares**") of our common stock, par value $0.00001. The Shares being offered under this prospectus are comprised of:

(a) 2,223,886 shares of common stock that were purchased by the Selling Stockholder in private placements with us pursuant to exemptions from the registration requirements of the Securities Act of 1933, as amended (the "**Securities Act**");

(b) 810,000 shares of common stock issuable upon exercise of a Series D Warrants allowing the holder to purchase shares of common stock at an exercise price of $1.10 per share through June 5, 2020;

(c) 460,250 shares of common stock issuable upon exercise of a Series G Warrants that vested on July 12, 2014 allowing the holder to purchase shares of common stock at an exercise price of $2.68 per share through July 21, 2022; and

(d) 910,000 shares of common stock issuable upon exercise of a Series H Warrants allowing the holder to purchase shares of common stock at an exercise price of $2.75 per share through October 16, 2022.

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

Our common stock is presently quoted for trading under the symbol "**RCAR**" on the OTC Markets Group Inc. Pink Marketplace-Current Information (the "**OTCPINC**"). On April 3, 2018, the closing price of our common stock, as reported on the **OTCPINC** was $4.34 per share. The Selling Stockholders have advised us that they will sell the shares of common stock registered hereunder from time to time in the open market, on the **OTCPINC**, in privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or otherwise as described under the section of this prospectus titled "**Plan of Distribution**." The purchase of the Shares offered through this prospectus involves a high degree of risk. **Please refer to "Risk Factors" beginning on page** 8**.**

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

The date of this prospectus is [ ], 2018

TABLE OF CONTENTS

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.

5

Table of Contents

PROSPECTUS SUMMARY

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

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

Organizational History

We were incorporated under the laws of the State of Utah on July 14, 1983, under the name "Far West Gold, Inc." On May 9, 1996, our stockholders authorized a name change to "Far West Resources, Inc." On June 30, 1997, the stockholders authorized a name change to "American Alliance Corporation" and authorized a change in the state of domicile from Utah to Nevada. On May 20, 1999, we changed our name to "WhatsOnline.Com, Inc.," effective as of August 3, 2000, we changed our name to Entheos Technologies, Inc. and effective as of January 5, 2011, we changed our name to Janus Resources, Inc. On January 7, 2014, we filed a Certificate of Amendment to Articles of Incorporation changing our name from "Janus Resources, Inc." to "RenovaCare, Inc." so as to more fully reflect our operations.

We have an authorized capital of 500,000,000 shares of common stock, par value $0.00001 of which 77,536,626 shares are outstanding as of April 3, 2018, and 10,000,000 shares of $0.0001 par value preferred stock, of which none are outstanding.

Overview of Business

We are a development-stage company focusing on the acquisition, development and commercialization of autologous (using a patient's own cells) cellular therapies for medical and aesthetic applications. On July 12, 2013, we, through our wholly owned subsidiary, RenovaCare Sciences Corp., completed the acquisition of our flagship technologies (collectively, the "**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 Limited ("**Avita Medical**") a petition For *Inter Partes* Review purporting to challenge the validity of the claims in U.S. Patent No. 9,610,430 (the "**Petition**") before the Patent Trial and Appeal Board ("**PTAB**") of the U.S. Patent & Trademark Office. Upon consideration of the arguments and evidence set forth by us and Avita, on December 18, 2017, the PTAB rendered a "**Final Written Decision**" dismissing the Petition in its entirety and, accordingly, confirming all such claims. Avita Medical's right to file an appeal expired on February 21, 2018.

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

Table of Contents

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

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

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

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

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

Corporate Information

We recently relocated our corporate headquarters to:

Pittsburgh Life Sciences Greenhouse

2425 Sidney Street

Pittsburgh, PA 15203

Our telephone number is (888) 398-0202. Our website is www.renovacareinc.com. Information contained on our web site (or any other website) does not constitute part of this prospectus.

Risk Factors

Our business operations are subject to numerous risks, including the risk of delays in, or discontinuation of, our research and development due to lack of financing, poor results, inability to commercialize our technologies or to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider, you are urged to carefully review and consider the section titled "**Risk Factors**" beginning on page 8 of this prospectus.

Table of Contents

THE OFFERING

Securities Being Offered:	4,404,136 shares of common stock, consisting of:
	(a) 2,223,886 shares of common stock that were purchased by the Selling Stockholder in private placements with us pursuant to exemptions from the registration requirements of the Securities Act;
	(c) 810,000 shares of common stock issuable upon exercise of a Series D Warrants allowing the holder to purchase shares of common stock at an exercise price of $1.10 per share through June 5, 2020; the Series D Warrants contain cashless exercise provisions.
	(b) 460,250 shares of common stock issuable upon exercise of a Series G Warrants that vested on July 12, 2014 allowing the holder to purchase shares of common stock at an exercise price of $2.68 per share through July 21, 2022; the Series D Warrants contain cashless exercise provisions.
	(d) 910,000 shares of common stock issuable upon exercise of a Series H Warrants allowing the holder to purchase shares of common stock at an exercise price of $2.75 per share through October 16, 2022; the Series D Warrants contain cashless exercise provisions.
	The Series D, G, and H Warrants are referred to collectively as the "**Warrants**."
Offering Price:	The Selling Stockholders will determine at what price they may sell the offered shares, and such sales may be made at prevailing market prices, or at privately negotiated prices.
Selling Stockholders:	The Selling Stockholders are existing stockholders who purchased shares of our common stock and warrants to purchase shares of our common stock, from us in a private transaction pursuant to exemptions from the registration requirements of the Securities Act. Please refer to the section titled "**Selling Stockholders**" of this prospectus.
Shares Outstanding Prior to Commencement of the Offering:	On April 3, 2018 there were 77,536,626 issued and outstanding.
Authorized Capital Stock:	Our authorized capital stock consists of stock of 500,000,000 shares of common stock, par value of $0.00001, and 10,000,000 shares of preferred stock, par value of $0.0001. No preferred shares are issued and outstanding.

Shares Outstanding upon Closing of the Offering:	Assuming all of the Warrants are exercised on a cash basis upon completion of this offering there will be 79,716,876 shares issued and outstanding.
OTC Pink Market Symbol:	RCAR
Transfer Agent:	Worldwide Stock Transfer, LLC, One University Plaza, Suite 505, Hackensack, NJ 07601.

Table of Contents

Risk Factors:	Our business operations are subject to numerous risks, including the risk of delays in, or discontinuation of, our research and development due to lack of financing, poor results, inability to commercialize our technologies or to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products.
	Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider, you are urged to carefully review and consider the section titled "**Risk Factors**" beginning on page 8 of this prospectus.
Use of Proceeds:	Although we will pay substantially all the expenses incident to the registration of the Shares, we will not receive any proceeds from the sales by the Selling Stockholders. We may, however, receive proceeds from the exercise of the Warrants; if such proceeds are received by us, they will be used to fund the research and development of the CellMist™ System and for working capital and general corporate purposes. See "**Use of Proceeds**."
Duration of Offering:	Pursuant to the terms of Registration Rights Agreements (collectively, the "**Registration Rights Agreement**") we entered into with the Selling Stockholders, we agreed to keep the registration statement, of which this prospectus is a part of, effective until the earlier of:
	(a) the date the investor's securities have been sold in accordance with Rule 144, as promulgated under the Securities Act ("**Rule 144**") or this prospectus as the same may be amended, modified or supplemented from time to time;
	(b) such securities become eligible for resale without volume or manner-of-sale restrictions and without current public information pursuant to Rule 144 as set forth in a written opinion letter to such effect, addressed, delivered and acceptable to our transfer agent as reasonably determined by us, upon the advice of our counsel; or,
	(c) such securities have otherwise been disposed of by the investor pursuant to an exemption from the registration requirements of the Securities Act.

Table of Contents

Selected Financial Data

The following tables set forth a summary of certain selected consolidated financial for the fiscal years ended December 31, 2017 and 2016. Historical results are not necessarily indicative of the results that may be expected for any future period. The consolidated financial data below should be read in conjunction with "**Management's Discussion and Analysis of Financial Condition and Results of Operations**" and the consolidated financial statements and notes included elsewhere in this prospectus.

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

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

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.

Table of Contents

Risks Related To Our Business

We have experienced significant losses, have not generated any revenues, expect losses to continue for the foreseeable future and may never achieve or maintain profitability.

We are a development-stage company. We do not have any commercialized products and have not generated any revenue since inception and do not expect to generate any revenue for the foreseeable future. We had a loss from operations of 2,695,823and $1,898,222 for our fiscal years ended December 31, 2017 and 2016, respectively. We have incurred a cumulative deficit of $14,740,922 through December 31, 2017. We anticipate incurring losses through at least December 31, 2018. We may not be able to successfully achieve or sustain profitability. Successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure.

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

As of December 31, 2017, we had cash and cash equivalents of $2,906,237. We anticipate that we will remain engaged in research and product development activities through at least December 31, 2018. Based upon our current level of operations and expenditures, we believe that absent any modification or expansion of our existing research, development and testing activities, cash on hand should be sufficient to enable us to continue operations through at least December 31 2018. The Company expects to incur losses as it continues development of its products and technologies and expects that it will need to raise additional capital through the sale of its securities to accomplish its business plan and failing to secure such additional funding before achieving sustainable revenue and profit from operations poses a significant risk. The Company's ability to fund the development of its cellular therapies will depend on the amount and timing of cash receipts from future financing activities. There can be no assurance as to the availability or terms upon which such financing and capital might be available.

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

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

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

Table of Contents

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

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

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

Commercialization of our CellMist™ System will require significant further research, development and testing as we must ascertain whether the CellMist™ System can form the basis for a commercially viable technology or product. If our research and development fails to prove commercial viability of the CellMist™ System, we may need to abandon our business model and/or cease doing business, in which case our shares may have no value and you may lose your investment. We anticipate we will remain engaged in research and development, through at least December 31, 2018.

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

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

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

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

Table of Contents

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

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

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

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

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

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

The development of medical device products, such as our CellMist™ System, involves an inherent risk of product liability claims and associated adverse publicity. Any products we may develop may be found to be harmful or to contain harmful substances. This exposes us to substantial risk of litigation and liability or may force us to discontinue production of certain products. There can be no assurance that we will be able to obtain or maintain insurance on reasonable terms or to otherwise protect ourselves against potential product liability claims that could impede or

prevent commercialization of any products we may develop and commercialize. Furthermore, a product liability claim could damage our reputation, whether or not such claims are covered by insurance or are with or without merit. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect on our business or financial condition. Furthermore, product liability lawsuits, regardless of their success, would likely be time consuming and expensive to resolve and would divert management's time and attention, which could seriously harm our business.

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

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

Filing, prosecuting and defending patents on all of our products in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to

develop their own products. These products may compete with our products, and may not be covered by any patent claims or other intellectual property rights.

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

Table of Contents

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

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

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

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

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

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

- patent infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not the claims have merit, and which could delay a product and divert management's attention from our business;