

RenovaCare, Inc.  
Form 10-Q  
November 19, 2018

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

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

For the quarterly period ended **September 30, 2018**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number **000-30156**

**RENOVACARE, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction of incorporation)

**98-0384030**  
(I.R.S. Employer Identification No.)

**9375 E. Shea Blvd., Suite 107-A**

Edgar Filing: RenovaCare, Inc. - Form 10-Q

**Scottsdale, AZ 85260**

(Address of principal executive offices)

**888-398-0202**

(Registrant's telephone number, including area code)

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

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer	..	Accelerated filer	..
Non-accelerated filer	..	(Do not check if a smaller reporting company)	
Smaller reporting company	x	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 pursuant to Section 13(a) of the Exchange Act. "

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

As of November 16, 2018, the registrant had 76,840,522 shares of its common stock, par value \$0.00001 per share, issued and outstanding.

**RENOVACARE, INC.**

**FORM 10-Q**

**For The Quarter Ended September 30, 2018**

**TABLE OF CONTENTS**

	<b>Page #</b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements</u></b>	<b>3</b>
<u>Condensed Consolidated Balance Sheets as at September 30, 2018 (Unaudited) and December 31, 2017</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017 (Unaudited)</u>	4
<u>Condensed Consolidated Statements of Stockholders' Equity for the Nine Months Ended September 30, 2018 (Unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017 (Unaudited)</u>	6
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	7
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>18</b>
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	<b>27</b>
<b><u>Item 4. Controls and Procedures</u></b>	<b>27</b>
<b><u>PART II - OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	<b>28</b>
<b><u>Item 1A. Risk Factors</u></b>	<b>28</b>
<b><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	<b>28</b>
<b><u>Item 6. Exhibits</u></b>	<b>29</b>
<b><u>Signatures</u></b>	<b>32</b>

Table of Contents

## PART I

## Item 1. Financial Statements

**RENOVACARE, INC**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**AS OF SEPTEMBER 30, 2018 (UNAUDITED) AND DECEMBER 31,**  
**2017**

	<b>September 30,</b> <b>2018</b> (Unaudited)	<b>December 31,</b> <b>2017</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash	\$ 1,651,875	\$ 2,906,237
Prepaid expenses	17,933	750
<b>Total current assets</b>	<b>1,669,808</b>	<b>2,906,987</b>
Equipment, net of accumulated depreciation of \$608 and \$370, respectively	344	581
Intangible assets	152,854	152,854
<b>Total assets</b>	<b>\$ 1,823,006</b>	<b>\$ 3,060,422</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 172,154	\$ 107,336
Accounts payable - related parties	19,833	61,333
Contract payable	-	100,000
<b>Total current liabilities</b>	<b>191,987</b>	<b>268,669</b>
Interest payable to related parties	153,846	90,678
Convertible promissory notes payable to related party, net of discount of \$0 and \$58,438, respectively	1,095,000	1,036,562
<b>Total liabilities</b>	<b>1,440,833</b>	<b>1,395,909</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity (deficit)</b>		
Preferred stock: \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock: \$0.00001 par value; 500,000,000 shares authorized, 76,840,522 and 76,145,418 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	769	762
Additional paid-in capital	16,685,183	16,404,673
Retained deficit	(16,303,779)	(14,740,922)

<b>Total stockholders' equity</b>		382,173		1,664,513
<b>Total liabilities and stockholders' equity</b>	\$	1,823,006	\$	3,060,422

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

Table of Contents

**RENOVACARE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
<b>Revenue</b>	\$ -	\$ -	\$ -	\$ -
<b>Operating expenses</b>				
Research and development	45,683	139,819	279,000	363,785
General and administrative	386,809	434,923	1,176,242	1,599,338
<b>Total operating expenses</b>	<b>432,492</b>	<b>574,742</b>	<b>1,455,242</b>	<b>1,963,123</b>
<b>Loss from operations</b>	<b>(432,492)</b>	<b>(574,742)</b>	<b>(1,455,242)</b>	<b>(1,963,123)</b>
<b>Other income (expenses)</b>				
Interest income	4,564	738	13,990	1,195
Interest expense	(21,652)	(20,775)	(63,167)	(56,641)
Accretion of debt discount	-	(256,667)	(58,438)	(675,077)
<b>Total other income (expenses)</b>	<b>(17,088)</b>	<b>(276,704)</b>	<b>(107,615)</b>	<b>(730,523)</b>
<b>Net loss</b>	<b>\$ (449,580)</b>	<b>\$ (851,446)</b>	<b>\$ (1,562,857)</b>	<b>\$ (2,693,646)</b>
<b>Basic and Diluted Loss per Common Share</b>	<b>\$ (0.01)</b>	<b>\$ (0.01)</b>	<b>\$ (0.02)</b>	<b>\$ (0.04)</b>
<b>Weighted average number of common shares outstanding - basic and diluted</b>	<b>76,840,522</b>	<b>75,123,280</b>	<b>76,727,802</b>	<b>73,837,107</b>

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

Table of Contents

**RENOVACARE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS**  
**OF STOCKHOLDERS' EQUITY**  
**FOR THE NINE MONTHS ENDED**  
**SEPTEMBER 30, 2018**  
**(UNAUDITED)**

	<b>Common Stock</b>		<b>Additional</b>	<b>Retained</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-in</b>	<b>Deficit</b>	<b>Stockholders'</b>
			<b>Capital</b>		<b>Equity</b>
Balance, January 1, 2018	76,145,418	762	16,404,673	(14,740,922)	1,664,513
Issuance of common stock from the exercise of warrants	569,797	6	109,994	-	110,000
Issuance of common stock from the exercise of stock options	125,307	1	(1)	-	-
Stock based compensation due to common stock purchase options	-	-	170,517	-	170,517
Net loss for the nine months ended September 30, 2018	-	-	-	(1,562,857)	(1,562,857)
Balance, September 30, 2018	76,840,522	\$ 769	\$ 16,685,183	\$ (16,303,779)	\$ 362,173

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



Table of Contents

**RENOVACARE, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**

	<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (1,562,857)	\$ (2,693,646)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation	238	237
Stock based compensation expense	170,517	748,350
Accretion of debt discount	58,438	675,077
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses	(17,184)	19,735
Increase (decrease) in accounts payable	64,818	101,911
Increase (decrease) in accounts payable - related parties	(41,500)	(13,290)
Increase (decrease) in interest payable - related parties	63,168	55,965
Increase (decrease) in contract payable	(100,000)	(50,000)
Net cash flows used in operating activities	(1,364,362)	(1,155,661)
<b>Cash flows from financing activities</b>		
Proceeds from exercise of warrants and issuance of common stock	110,000	1,467,234
Payments of convertible promissory notes	-	(25,000)
Proceeds from the issuance of convertible promissory notes	-	445,000
Net cash flows provided by financing activities	110,000	1,887,234
<b>Increase (decrease) in cash and cash equivalents</b>	<b>(1,254,362)</b>	<b>731,573</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>2,906,237</b>	<b>418,031</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,651,875</b>	<b>\$ 1,149,604</b>
<b>Supplemental disclosure of cash flow information:</b>		
Interest paid in cash	\$ -	\$ 676
Income taxes paid in cash	\$ -	\$ -
<b>Supplemental disclosure of non-cash transactions:</b>		
Discount on convertible promissory note due to detachable warrants and beneficial conversion feature	\$ -	\$ 443,286

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



Table of Contents

**RENOVACARE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Basis of Presentation, Organization, Nature and Continuance of Operations, Going Concern, Recent Accounting Standards and Earnings (Loss) Per Share**

**Organization**

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

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

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

**Going Concern**

The Company has recently incurred net operating losses and operating cash flow deficits. As of September 30, 2018, the Company’s accumulated deficit is \$16,303,779. The Company does not currently generate revenues and will continue to incur losses from operations and operating cash flow deficits in the future. The Company’s activities are subject to significant risks and uncertainties due to the stage of the development of the Company’s cellular therapies. The future of the Company will depend on its ability to successfully raise capital from external sources to fund operations. If the Company is unable to obtain adequate funds, or if such funds are not available to it on acceptable

terms, the Company's ability to continue its business to develop its cellular therapies will be significantly impaired and it may cause the Company to curtail operations.

The matters described above raise substantial doubt about the Company's ability to continue as a going concern within one year after the date these condensed consolidated financial statements were issued. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

### **Basis of Presentation**

The unaudited financial statements of RenovaCare, Inc. as of September 30, 2018, and for the three and nine months ended September 30, 2018 and 2017, have been prepared in accordance with generally accepted accounting principles ("GAAP") in the United States for interim financial reporting and include the Company's wholly-owned subsidiary, RenovaCare Sciences Corp. ("**RenovaCare Sciences**"). Accordingly, they do not include all of the disclosures required by accounting principles generally accepted in the United States for complete financial statements and should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2017, as filed with the Securities and Exchange Commission as part of the Company's Form 10-K on March 13, 2018. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the interim financial information have been included. The results of operations for any interim period are not necessarily indicative of the results of operations for the entire year.

Table of Contents

**Nature and Continuance of Operations**

The Company does not have any commercialized products. The Company's activities have consisted principally of performing research and development activities and raising capital. These development activities are subject to significant risks and uncertainties, including possible failure of preclinical testing. The Company has not generated any revenue since inception and has sustained recurring losses and negative cash flows from operations since inception. The Company expects to incur losses as it continues development of its products and technologies and expects that it will need to raise additional capital through the sale of its securities to accomplish its business plan and failing to secure such additional funding before achieving sustainable revenue and profit from operations poses a significant risk. The Company's ability to fund the development of its cellular therapies will depend on the amount and timing of cash receipts from future financing activities. There can be no assurance as to the availability or terms upon which such financing and capital might be available.

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

**Recent Accounting Standards**

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

In July 2018, the FASB issued ASU No. 2018-10, "Codification Improvements to Topic 842, Leases", which amends narrow aspects of the guidance issued in the amendments in ASU 2016-02. ASU 2019-10 is effective for the Company beginning January 1, 2019. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2018-10 will have on its consolidated financial statements.

In July 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-11, *Earnings Per Share (Topic 260)*, *Distinguishing Liabilities from Equity (Topic 480)*, *Derivatives and Hedging (Topic 815)*. The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative

liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company has determined that the adoption of ASU 2017-11 will currently have no impact on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for public business entities for reporting periods for which financial statements have not yet been issued. The Company adopted the guidance under ASU 2017-09 with no material impact on its consolidated financial statements.

Table of Contents

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

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606)”, to clarify the principles used to recognize revenue for all entities. In March 2016, the FASB issued ASU 2016-08 to further clarify the implementation guidance on principal versus agent considerations. The guidance is effective for annual and interim periods beginning after December 15, 2017, and early adoption is permitted. The Company has determined that the adoption of ASU 2014-09 did not have an impact on the consolidated financial statements.

In January 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in this ASU modify how entities measure equity investments and present changes in the fair value of financial liabilities. Under the new guidance, entities will have to measure equity investments that do not result in consolidation and are not accounted under the equity method at fair value and recognize any changes in fair value in net income unless the investments qualify for the practical expedient exception. An entity may elect to measure an equity security without a readily determinable fair value that does not qualify for the practical expedient to estimate fair value under ASC 820, Fair Value Measurements, and as such these investments may be measured at cost. This ASU is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company has adopted this ASU on a prospective basis in the first quarter of 2018 and has determined that investments within the scope of the standard will be recorded at fair value with changes in fair value recognized in earnings which may lead to increased volatility in other expense.

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

**Earnings (Loss) Per Share**

The Company presents both basic and diluted earnings per share (“EPS”) amounts. Basic EPS is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period presented. Diluted EPS amounts are based upon the weighted average number of common and common equivalent shares outstanding

during the period presented. The Company has not included the effects of warrants, stock options and convertible debt on net loss per share because to do so would be antidilutive.



Table of Contents

Following is the computation of basic and diluted net loss per share for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Basic and Diluted EPS Computation</b>				
Numerator:				
Loss available to common stockholders'	\$ (449,580)	\$ (851,446)	\$ (1,562,857)	\$ (2,693,646)
Denominator:				
Weighted average number of common shares outstanding	76,840,522	75,123,280	76,727,802	73,837,107
Basic and diluted EPS	\$ (0.01)	\$ (0.01)	\$ (0.02)	\$ (0.04)

The shares listed below were not included in the computation of diluted losses

per share because to do so would have been antidilutive for the periods presented:

Stock options	357,500	545,000	357,500	545,000
Warrants	3,011,912	2,689,158	3,011,912	2,689,158
Convertible debt	682,591	647,813	682,591	647,813
Total shares not included in the computation of diluted losses per share	4,052,003	3,881,971	4,052,003	3,881,971

**Note 2. Assets – Intellectual Property**

On July 12, 2013, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an asset purchase agreement (“APA”) with Dr. Jörg Gerlach, MD, PhD, pursuant to which RenovaCare Sciences purchased all of Dr. Gerlach’s rights, title and interest in the CellMisT<sup>TM</sup> System. Acquisition related costs amounted to \$52,852 and were capitalized together with the cash payment upon the closing of the transaction in July 2013 of \$100,002. Intangible assets amounted to \$152,854 at September 30, 2018 and December 31, 2017.

**Note 3. Contract Payable**

On June 9, 2014, the Company, together with its wholly owned subsidiary, RenovaCare Sciences, entered into an amended asset purchase agreement (the “Amended APA”) with Dr. Jörg Gerlach, MD, PhD, pursuant to which

RenovaCare Sciences purchased all of Dr. Gerlach’s rights, title and interest in the CellMist™ System. The Amended APA provided for cash payments of \$300,000 as partial consideration for the purchase with the final payment due of \$100,000 paid on January 24, 2018.

See also “Note 8. Related Party Transactions.”

**Note 4. Debt**

As of September 30, 2018 and December 31, 2017, the Company had the following outstanding debt balances:

	<b>Issue Date</b>	<b>Maturity Date</b>	<b>Principal</b>	<b>Debt Discount</b>	<b>Balance</b>	<b>Interest Payable</b>
<b>As of September 30, 2018:</b>						
February 2017 Note as amended	2/23/2017	12/31/2019	\$ 395,000	\$ -	\$ 395,000	\$ 46,400
September 2016 Note as amended	9/9/2016	12/31/2019	700,000	-	700,000	107,446
			\$ 1,095,000	\$ -	\$ 1,095,000	\$ 153,846
<b>As of December 31, 2017:</b>						
February 2017 Note as amended	2/23/2017	12/31/2019	\$ 395,000	\$ (58,438)	\$ 336,562	\$ 24,074
September 2016 Note as amended	9/9/2016	12/31/2019	700,000	-	700,000	66,604
			\$ 1,095,000	\$ (58,438)	\$ 1,036,562	\$ 90,678

Table of Contents

**February 2017 Convertible Promissory Notes**

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

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

The Company calculated the fair value of the Series F Warrants and intrinsic value of the beneficial conversion feature which resulted in a \$443,286 discount to the February 2017 Notes which was fully accreted on March 31, 2018.

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

During 2017, the Company repaid the Investor and Sierchio in full, including total note principal of \$50,000 and total accrued interest of \$1,825.

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

During the three months ended September 30, 2018 and 2017, the Company recognized \$7,653 and \$7,724, respectively, of interest expense. During the nine months ended September 30, 2018 and 2017, the Company recognized \$22,326 and \$18,548, respectively, of interest expense. During the three months ended September 30, 2018 and 2017, the Company recognized \$0 and \$121,939, respectively, of accretion related to the debt discount. During the nine months ended September 30, 2018 and 2017, the Company recognized \$58,438 and \$275,286, respectively, of accretion related to the debt discount.

#### *September 9, 2016 Convertible Promissory Note*

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

Table of Contents

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

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

The Company calculated the fair value of the Series E Warrant and intrinsic value of the beneficial conversion feature which resulted in a \$700,000 discount to the Note which was fully accreted on December 31, 2017.

During the three months ended September 30, 2018 and 2017, the Company recognized \$13,999 and \$13,051, respectively, of interest expense. During the nine months ended September 30, 2018 and 2017, the Company recognized \$40,841 and \$38,093, respectively, of interest expense. During the three months ended September 30, 2018 and 2017, the Company recognized \$0 and \$134,728, respectively, of accretion related to the debt discount. During the nine months ended September 30, 2018 and 2017, the Company recognized \$0 and \$399,791, respectively, of accretion related to the debt discount.

**Note 5. Common Stock and Warrants**

***Common Stock***

At September 30, 2018, the Company had 500,000,000 authorized shares of common stock with a par value of \$0.00001 per share, 76,840,522 shares of common stock outstanding and 19,400,765 shares reserved for issuance under the Company’s 2013 Long-Term Incentive Plan (the “2013 Plan”) as adopted and approved by the Company’s Board of Directors (the “Board”) on June 20, 2013 that provides for the grant of stock options to employees, directors, officers and consultants. See “Note 6. Stock Options” for further discussion.

During the nine months ended September 30, 2018, the Company had the following common stock related transactions:

- On February 3, 2018, Thomas Bold, the Company's President, CEO and Interim Chief Financial Officer exercised options to purchase up to 60,000 shares, on a cashless basis, resulting in the issuance of 44,083 shares of common stock.
- On February 11, 2018, a consultant exercised options to purchase up to 40,000 shares, on a cashless basis, resulting in the issuance of 17,480 shares of common stock.

Table of Contents**Warrants**

The following table summarizes information about warrants outstanding at September 30, 2018 and December 31, 2017:

Description	Shares of Common Stock Issuable from Warrants		Weighted Average Exercise Price	Expiration
	Outstanding as of September 30, 2018	December 31, 2017		
Series A	240,000	720,000	\$ 0.35	July 12, 2019
Series D	810,000	910,000	\$ 1.10	June 5, 2020
Series E	584,416	584,416	\$ 1.54	September 8, 2021
Series F				February 23, 2022
	7,246	14,492	\$ 3.45	& March 9, 2022
Series G	460,250	460,250	\$ 2.68	July 21, 2022
Series H	910,000	920,000	\$ 2.75	October 16, 2022
Total	3,011,912	3,609,158		

**Note 6. Stock Options**

On June 20, 2013, the Company's Board adopted the 2013 Long-Term Incentive Plan and on November 15, 2013, a stockholder owning a majority of the Company's issued and outstanding stock approved adoption to the 2013 Plan. Pursuant to the terms of the 2013 Plan, an aggregate of 20,000,000 shares of the Company's common stock are reserved for issuance to the Company's officers, directors, employees and consultants in order to attract and hire key technical personnel and management. Options granted to employees under the 2013 Plan, including directors and

officers who are employees, may be incentive stock options or non-qualified stock options; options granted to others under the 2013 Plan are limited to non-qualified stock options. As of September 30, 2018, there were 19,400,765 shares available for grant.

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

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



Table of Contents**Stock Option Activity**

The following table summarizes stock option activity for the nine month period ended September 30, 2018 and year ended December 31, 2017:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price (\$)</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value (\$)</b>
Outstanding at December 31, 2016	385,000	1.42		
Grants	310,000	4.20		
Exercises	(150,000)	1.12		
Outstanding at December 31, 2017	545,000	3.09		
Exercises	(187,500)	2.86		
Outstanding at September 30, 2018	357,500	3.21	7.82 years	42,825
Exercisable at September 30, 2018	347,500	3.27	7.89 years	37,325

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. There were no stock options granted during the nine months ended September 30, 2018. There were 310,000 stock options granted during the nine months ended September 30, 2017 with a weighted-average grant date fair value of \$3.38. During the nine months ended September 30, 2018, there were 187,500 options exercised on a cashless basis resulting in the issuance of 125,307 shares of common stock, with an aggregate intrinsic value of \$1,126,675. During the nine months ended September 30, 2017, there were 150,000 options exercised on a cashless basis resulting in the issuance of 102,582 shares of common stock, with an aggregate intrinsic value of \$397,100.

The share-based compensation cost resulting from stock option grants, including those previously granted and vesting over time is expensed ratably over the respective vesting periods. During the three months ended September 30, 2018 and 2017, the Company recognized \$371 and \$127,478, respectively, in share-based compensation related to stock options. During the nine months ended September 30, 2018 and 2017, the Company recognized \$170,517 and \$748,350, respectively, in share-based compensation related to stock options.

As of September 30, 2018, the Company had approximately \$877 of unrecognized compensation cost related to unvested stock options which is expected to be recognized over a period of 0.50 years. Stock-based compensation has been included in the Consolidated Statement of Operations as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Research and development	\$ -	\$ 10,725	\$ 27,966	\$ 75,515
General and administrative	371	116,753	142,551	672,835
<b>Total</b>	<b>\$ 371</b>	<b>\$ 127,478</b>	<b>\$ 170,517</b>	<b>\$ 748,350</b>

Table of Contents

The following table summarizes information about stock options outstanding and exercisable at September 30, 2018:

Range of Exercise Prices	Stock Options Outstanding			Stock Options Exercisable			
	Number of Shares Subject to Outstanding Options	Weighted Average Contractual Life (years)	Weighted Average Exercise Price	Number of Shares Subject To Exercise	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	
0.80	10,000	5.87	0.80	10,000	5.87	0.80	
1.05	55,000	5.50	1.05	45,000	5.50	1.05	
1.25	7,500	6.71	1.25	7,500	6.71	1.25	
1.34	7,500	6.75	1.34	7,500	6.75	1.34	
1.65	10,000	7.09	1.65	10,000	7.09	1.65	
1.70	7,500	7.04	1.70	7,500	7.04	1.70	
1.91	20,000	7.46	1.91	20,000	7.46	1.91	
2.28	7,500	7.81	2.28	7,500	7.81	2.28	
4.20	232,500	8.62	4.20	232,500	8.62	4.20	
Total	357,500	7.82	\$ 3.21	347,500	7.89	\$ 3.27	

**Note 7. Commitments**

Effective March 1, 2015, the Company entered into a lease agreement (the “Lease”) in the Pittsburgh Life Sciences Greenhouse at a monthly rate of \$750. The Lease was renewed effective March 1, 2016 at a monthly rate of \$800 through August 30, 2018. Rent expense for the three months ended September 30, 2018 and 2017 was \$1,600 and \$2,400, respectively. Rent expense for the nine months ended September 30, 2018 and 2017 was \$6,400 and \$7,200, respectively.

In connection with the Company’s anticipated regulatory filings, the Company has engaged StemCell Systems GmbH (“StemCell Systems”) to provide it with prototypes and related documents under various agreements. Pursuant to these engagements the Company incurred expenses of \$14,315 and \$39,708 during the three months ended September 30, 2018 and 2017, respectively, and \$39,499 and \$146,538 during the nine months ended September 30, 2018 and 2017, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

Edgar Filing: RenovaCare, Inc. - Form 10-Q

On August 1, 2017, the Company and the University of Pittsburgh entered into a Corporate Research Agreement whereby the University of Pittsburgh will perform academic research related to the Company's technologies in exchange for \$171,595. During the three and nine months ended September 30, 2018, the Company expensed \$nil and \$85,798, respectively, pursuant to the Corporate Research Agreement. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a professor at the University.

See also "Note 8. Related Party Transactions."

Table of Contents

**Note 8. Related Party Transactions**

As compensation for their service on the Board, Dr. Kirkland and Mr. Sierchio receive an annual retainer of \$6,000, payable in equal quarterly installments in arrears. The Chairman of the Board receives \$1 per year.

Effective July 1, 2018, Joseph Sierchio resigned his position as a Company director. The law firm of Satterlee Stephens LLP (“Satterlee”), of which Joseph Sierchio is a partner, provides counsel to the Company. Mr. Sierchio will continue to be the Company’s primary attorney. During the three months ended September 30, 2018 and 2017, the Company recognized \$67,813 and \$15,115 of fees for legal services billed by Satterlee. During the nine months ended September 30, 2018 and 2017, the Company recognized \$227,175 and \$195,783 of fees for legal services billed by Satterlee. At September 30, 2018 and December 31, 2017, accounts payable to Satterlee amounted to \$148,715 and \$30,000, respectively.

In connection with the Company’s anticipated FDA and other regulatory filings, the Company engaged StemCell Systems to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$14,315 and \$39,708 during the three months ended September 30, 2018 and 2017, respectively, and \$39,499 and \$146,538 during the nine months ended September 30, 2018 and 2017, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

Dr. Gerlach is entitled to payments for consulting services. During the three months ended September 30, 2018 and 2017, the Company recognized expenses related to Dr. Gerlach services of \$Nil and \$10,000, respectively. During the nine months ended September 30, 2018 and 2017, the Company recognized expenses related to Dr. Gerlach services of \$7,020 and \$28,540, respectively. Accounts payable to Dr. Gerlach amounted to \$nil and \$17,640 at September 30, 2018 and December 31, 2017, respectively.

On August 1, 2013, the Company entered into a consulting agreement, as amended on May 1, 2016, with Jatinder Bhogal, an individual owning in excess of 5% of our issued and outstanding shares of common stock, to provide consulting services to the Company through his wholly owned company, Vector Asset Management, Inc. (“VAM”). Pursuant to the consulting agreement Vector assisted the Company with identifying subject matter experts in the medical device and biotechnology industries and assisted the Company with its ongoing research, development and eventual commercialization of its Regeneration Technology. Pursuant to the amendment the monthly consulting fee was increased to \$6,800 from \$5,000. On June 22, 2018, the Company and VAM entered into an Executive Consulting Agreement (“ECA”) whereby Mr. Bhogal will serve as the Company’s Chief Operating Officer. The ECA supersedes the prior consulting agreement. Pursuant to the ECA, VAM will receive compensation of \$120,000 per year. During the three months ended September 30, 2018 and 2017, the Company recognized \$30,000 and \$20,400, respectively for consulting services provided by VAM. During the nine months ended September 30, 2018 and 2017, the Company recognized \$73,467 and \$61,200, respectively for consulting services provided by VAM.



Table of Contents

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

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

On February 22, 2018, Mr. Sierchio, a member of the Company's board of directors until his resignation effective July 1, 2018, 1) exercised options to purchase up to 37,500 shares, on a cashless basis, resulting in the issuance of 22,711 shares of common stock; 2) exercised a Series F Warrant to purchase up to 7,246 shares, on a cashless basis, resulting in the issuance of 4,899 shares of common stock; and 3) exercised a Series H Warrant to purchase up to 10,000 shares, on a cashless basis, resulting in the issuance of 7,418 shares of common stock.

On February 3, 2018, Thomas Bold, the Company's President, exercised options to purchase up to 60,000 shares, on a cashless basis, resulting in the issuance of 44,086 shares of common stock.

On August 1, 2017, the Company and the University of Pittsburgh entered into a Corporate Research Agreement whereby the University of Pittsburgh will perform academic research related to the Company's technologies in exchange for \$171,595. During the three and nine months ended September 30, 2018, the Company paid the University of Pittsburgh \$nil and \$85,798, respectively, pursuant to the Corporate Research Agreement. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a professor at the University.

During the quarter ended September 30, 2018, the Company was offered executive office space located at 9375 E. Shea Blvd., Suite 107-A, Scottsdale, AZ 85260 for consideration of \$1 per year. The executive office space is owned indirectly by Harmel S. Rayat, the Company's majority shareholder and Chairman and CEO.

**Note 9. Subsequent Event**

Management has reviewed material events subsequent of the period ended September 30, 2018 and prior to the filing of financial statements in accordance with FASB ASC 855 "Subsequent Events".





Table of Contents

**Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

**Forward-Looking Statements**

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Quarterly Report filed on Form 10-Q. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors.*

This discussion and analysis should be read in conjunction with the accompanying unaudited interim consolidated financial statements and related notes. The discussion and analysis of the financial condition and results of operations are based upon the unaudited interim consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an on-going basis we review our estimates and assumptions. The estimates were based on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Critical accounting policies, the policies we believe are most important to the presentation of its financial statements and require the most difficult, subjective and complex judgments, are outlined below in “Critical Accounting Policies,” and have not changed significantly.

**Cautionary Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains certain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, as well as information relating to RenovaCare, Inc. and its subsidiaries that is based on management’s exercise of business judgment and assumptions made by and information currently available to management. Although forward-looking statements in this Quarterly Report on Form 10-Q reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. When used in this document and other documents, releases and reports released by us, the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “the facts suggest” and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view

of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. Actual events, transactions and results may materially differ from the anticipated events, transactions or results described in such statements. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Many factors could cause actual results to differ materially from our forward looking statements and unknown, unidentified or unpredictable factors could materially and adversely impact our future results. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to our forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events. Several of these factors include, without limitation:

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

Table of Contents

The safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, apply to forward-looking statements made by us. The reader is cautioned that no statements contained in this Form 10-Q should be construed as a guarantee or assurance of future performance or results. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks described in this report and matters described in this report generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur.

**Overview**

RenovaCare, Inc. (formerly Janus Resources, Inc.) (together with its wholly owned subsidiary, “**RenovaCare**” the “**Company**” “**we**” “**us**” and “**our**”) was incorporated under the laws of the State of Nevada and has an authorized capital of 500,000,000 shares of \$0.00001 par value common stock, of which 76,840,522 shares are outstanding as of September 30, 2018, and 10,000,000 shares of \$0.0001 par value preferred stock, of which none are outstanding.

Our principal executive offices are located at 9375 E. Shea Blvd., Suite 107-A, Scottsdale, AZ 85260. Our telephone number is (888) 398-0202.

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

**Description of Business**

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

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

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

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

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

Table of Contents

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

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

**Our Market Opportunity**

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

***Burn Wounds***

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

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

Morbidity, and Mortality” available at: <http://ccforum.com/content/14/5/R188>).

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

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

## Table of Contents

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

## ***Our Technology***

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

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

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

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

## ***Domestic Regulation***

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

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

### **Premarket Approval**

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

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



Table of Contents

**Investigational Device Exemption (“IDE”)**

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

*HIPAA Requirements*

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

*Other U.S. Regulatory Requirements*

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

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

### *International Regulation*

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

### **Competition**

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

Table of Contents

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

**Intellectual Property**

*General*

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

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

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

**Strategy**

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

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

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

Table of Contents**Results of Operations**

*Three and nine months Ended September 30, 2018 compared with the three and nine months Ended September 30, 2017*

**Operating Expenses**

A summary of our operating expense for the three and nine months ended September 30, 2018 and 2017 follows:

**Three Months Ended**

	<b>September 30,</b>		<b>Increase /</b>	<b>Percentage</b>
	<b>2018</b>	<b>2017</b>	<b>(Decrease)</b>	<b>Change</b>
Operating expenses				
Research and development	\$ 45,683	\$ 129,094	\$ (83,411)	-65%
General and administrative	386,438	318,170	68,268	21%
Stock compensation	371	127,478	(127,107)	-100%
Total operating expenses	\$ 432,492	\$ 574,742	\$ (142,250)	-25%

**Nine Months Ended**

	<b>September 30,</b>		<b>Increase /</b>	<b>Percentage</b>
	<b>2018</b>	<b>2017</b>	<b>(Decrease)</b>	<b>Change</b>
Operating expenses				
Research and development	\$ 251,034	\$ 288,270	\$ (37,236)	-13%
General and administrative	1,033,691	926,503	107,188	12%
Stock compensation	170,517	748,350	(577,833)	-77%
Total operating expenses	\$ 1,455,242	\$ 1,963,123	\$ (507,881)	-26%

**Research and Development**

Research and development (“**R&D**”) costs represent costs incurred to develop our CellIM™ System and are incurred pursuant to agreements with third party providers and certain internal R&D cost allocations. Payments under these agreements include salaries and benefits for R&D personnel, allocated overhead, contract services and other costs. R&D costs are expensed when incurred. R&D costs, excluding stock based compensation, decreased \$83,411 and

\$37,236 during the three and nine months ended September 30, 2018 compared to 2017 respectively, as a result of the timing of our R&D expenses.

### *General and Administrative*

General and administrative costs include all expenditures incurred other than research and development related costs, including costs related to personnel, professional fees, travel and entertainment, public company costs, insurance and other office related costs. Costs increased \$68,268 during the three months ended September 30, 2018 compared to 2017 due primarily to an increase in legal fees offset by decreased investor communications related fees and IP related fees. Costs increased \$107,188 during the nine months ended September 30, 2018 compared to 2017 due primarily to an increase in investor communications related fees and legal fees offset by decreased IP related costs.

### *Stock Compensation*

Expense associated with equity based transactions is calculated and expensed in our financial statements as required pursuant to various accounting rules and is non-cash in nature. Stock compensation represents the expense associated with the amortization of our stock options. Stock compensation expense decreased during the three and nine months ended September 30, 2018 compared to 2017 due to the May 11, 2017 grant of 310,000 stock options with a weighted average grant date fair value of \$3.38 per share of which 160,000 vested on the date of grant and expense associated with the remaining options was amortized ratably through the one year vesting period through May 11, 2018.

Table of Contents

**Other Income (Expense)**

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

**Liquidity and Capital Resources**

The Company expects to incur losses as it continues development of its products and technologies. To date, the Company has been funded through the sale of equity securities and proceeds from convertible promissory notes. As of September 30, 2018, the Company had \$1,651,875 of cash. Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America and applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. As discussed in Note 1 to the condensed consolidated financial statements, we have incurred recurring operating losses since inception of \$16,303,779 and there is substantial doubt about the Company's ability to continue as a going concern within one year after the date these condensed consolidated financial statements were issued. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern. We require additional funds to meet our obligations and maintain our operations. We do not currently have cash flow from operations as we have no commercialized products; without cash flow from operations, we will need to obtain additional funds (presumably through equity offerings, debt borrowing or through the exercise of outstanding warrants, which, if exercised in total for cash would result in proceeds of \$5,551,969; all of our outstanding warrants currently include a "cashless exercise" feature) in order to implement our current research and development programs for the CellMist™ System. If we are unable to obtain adequate funds, or if such funds are not available to us on acceptable terms, our ability to continue our business as planned will be significantly impaired and it may cause us to curtail operations.

Net cash used in operating activities was \$1,364,362 during the nine months ended September 30, 2018, compared to net cash used in operating activities of \$1,155,661 during the nine months ended September 30, 2017. The increase in cash used in operating activities during the nine months ended September 30, 2018 compared to the same period in 2017 is primarily due to an increase in general and administrative and research and development costs, a contractual, \$100,000 payment to Dr. Gerlach compared to \$50,000 in the prior year and payments against payables in the current year that exceeded similar payments in the prior year.

Net cash provided by financing activities was \$110,000 during the nine months ended September 30, 2018, compared to \$1,887,234 during the nine months ended September 30, 2017. During the nine months ended September 30, 2018,

the Company received \$110,000 from the exercise of 100,000 Series D Warrants at an exercise price of \$1.10 compared to \$1,122,610 received pursuant to the July 2017 Private Placement, \$445,000 received pursuant to the February 2017 Notes and \$344,624 from the exercise of 114,493 Series F Warrants at an exercise price of \$3.01 during the nine months ended September 30, 2017.

### **Fair Value of Financial Instruments and Risks**

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

### **Off-balance Sheet Arrangements and Contractual Obligations**

We do not have any off-balance sheet arrangements or contractual obligations at September 30, 2018, and the subsequent period to through the date of this report, that are likely to have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that have not been disclosed in our consolidated financial statements.



Table of Contents

**Recently Issued Accounting Pronouncements**

See Note 1 to our Consolidated Financial Statements for more information regarding recent accounting standards and their impact to our consolidated results of operations and financial position.

**Related Party Transactions**

Our proposed business raises potential conflicts of interests between certain of our officers and directors and us. Certain of our directors are employees or consultants to other companies in the healthcare industry and, to the extent that such other companies may participate in ventures in which we may participate, our directors may have a conflict of interest in negotiating and concluding terms regarding the extent of such participation. In the event that such a conflict of interest arises at a meeting of our directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. Other than as indicated, we have no other procedures or mechanisms to deal with conflicts of interest. We are not aware of the existence of any conflict of interest as described herein.

The Board is responsible for review, approval, or ratification of “related-person transactions” involving RenovaCare, Inc. or its subsidiaries and related persons. Under SEC rules (Section 404 (d) of Regulation S-K), a related person is a director, officer, nominee for director, or 5% stockholder of the company since the beginning of the previous fiscal year, and their immediate family members. RenovaCare, Inc. is required to report any transaction or series of transactions in which the company or a subsidiary is a participant, and a related person has a direct or indirect material interest where the amount involved exceeds the lesser of \$120,000 or one percent of the average of the smaller reporting company’s total assets at year end for the last two completed fiscal years.

Other than as disclosed below, during the nine months ended September 30, 2018, none of our current directors, officers or principal shareholders, nor any family member of the foregoing, nor, to the best of our information and belief, any of our former directors, senior officers or principal shareholders, nor any family member of such former directors, officers or principal shareholders, has or had any material interest, direct or indirect, in any transaction, or in any proposed transaction which has materially affected or will materially affect us.

As compensation for their service on the Board, Dr. Kirkland and Mr. Sierchio receive an annual retainer of \$6,000, payable in equal quarterly installments in arrears. The Chairman of the Board received compensation of \$1 per year.

Effective July 1, 2018, Joseph Sierchio resigned his position as a Company director. The law firm of Satterlee Stephens LLP (“Satterlee”), of which Joseph Sierchio is a partner, provides counsel to the Company. Mr. Sierchio will continue to be the Company’s primary attorney. During the three months ended September 30, 2018 and 2017, the Company recognized \$67,813 and \$15,115 of fees for legal services billed by Satterlee. During the nine months ended September 30, 2018 and 2017, the Company recognized \$227,175 and \$195,783 of fees for legal services billed by Satterlee. At September 30, 2018 and December 31, 2017, the Company’s balance sheet contained a payable to Satterlee in the amount of \$148,715 and \$30,000, respectively.

In connection with the Company’s anticipated FDA and other regulatory filings, the Company engaged StemCell Systems to provide it with prototypes and related documents. Pursuant to this engagement the Company incurred expenses of \$14,315 and \$39,708 during the three months ended September 30, 2018 and 2017, respectively, and \$39,499 and \$146,538 during the nine months ended September 30, 2018 and 2017, respectively. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a principal of StemCell Systems.

Dr. Gerlach is entitled to payments for consulting services. During the three months ended September 30, 2018 and 2017, the Company recognized expenses related to Dr. Gerlach services of \$nil and \$8,460, respectively. During the nine months ended September 30, 2018 and 2017, the Company recognized expenses related to Dr. Gerlach services of \$7,020 and \$28,540, respectively. Accounts payable to Dr. Gerlach amounted to \$nil and \$17,640 at September 30, 2018 and December 31, 2017, respectively.

Table of Contents

On August 1, 2013, the Company entered into a consulting agreement, as amended on May 1, 2016, with Jatinder Bhogal, an individual owning in excess of 5% of our issued and outstanding shares of common stock, to provide consulting services to the Company through his wholly owned company, Vector Asset Management, Inc. (“VAM”). Pursuant to the consulting agreement Vector assisted the Company with identifying subject matter experts in the medical device and biotechnology industries and assisted the Company with its ongoing research, development and eventual commercialization of its Regeneration Technology. Pursuant to the amendment the monthly consulting fee was increased to \$6,800 from \$5,000. On June 22, 2018, the Company and VAM entered into an Executive Consulting Agreement (“ECA”) whereby Mr. Bhogal will serve as the Company’s Chief Operating Officer. The ECA supersedes the prior consulting agreement. Pursuant to the ECA, VAM will receive compensation of \$120,000 per year. During the three months ended September 30, 2018 and 2017, the Company recognized \$30,000 and \$20,400, respectively for consulting services provided by VAM. During the nine months ended September 30, 2018 and 2017, the Company recognized \$73,467 and \$61,200, respectively for consulting services provided by VAM.

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

On February 22, 2018, Mr. Sierchio, a member of the Company’s board of directors until his resignation effective July 1, 2018, 1) exercised options to purchase up to 37,500 shares, on a cashless basis, resulting in the issuance of 22,711 shares of common stock; 2) exercised a Series F Warrant to purchase up to 7,246 shares, on a cashless basis, resulting in the issuance of 4,899 shares of common stock; and 3) exercised a Series H Warrant to purchase up to 10,000 shares, on a cashless basis, resulting in the issuance of 7,418 shares of common stock.

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

On February 3, 2018, Thomas Bold, the Company’s President, exercised options to purchase up to 60,000 shares, on a cashless basis, resulting in the issuance of 44,086 shares of common stock.

On August 1, 2017, the Company and the University of Pittsburgh entered into a Corporate Research Agreement whereby the University of Pittsburgh will perform academic research related to the Company’s technologies in exchange for \$171,595. During the three and nine months ended September 30, 2018, the Company expensed \$42,899 and \$85,798, respectively, pursuant to the Corporate Research Agreement. Dr. Gerlach, from whom the Company purchased the CellMist™ System technologies, is a professor at the University.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

#### **Item 4. Controls and Procedures**

##### **Disclosure Controls and Procedures**

At the end of the period covered by this Quarterly Report on Form 10-Q for the three month period ended September 30, 2018, an evaluation was carried out under the supervision of and with the participation of our management, including the Chief Executive Officer (“**CEO**”) of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act). Based on that evaluation the CEO has concluded that as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that: (i) information required to be disclosed by us in reports that we file or submit to the SEC under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms and (ii) material information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our management, including our CEO, as appropriate, to allow for accurate and timely decisions regarding required disclosure.

##### **Changes in Internal Control over Financial Reporting**

During the period covered by this report, there were no changes to internal control over financial reporting that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Table of Contents

**PART II – OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

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

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

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

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

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

On February 13, 2018, the Company issued 100,000 shares of common stock, upon the exercise of a Series D Warrant at an exercise price of \$1.10 per share resulting in \$110,000 of proceeds to the Company.

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

On February 22, 2018, Mr. Sierchio, a member of the Company's board of directors until his resignation effective July 1, 2018, 1) exercised options to purchase up to 37,500 shares, on a cashless basis, resulting in the issuance of 22,711 shares of common stock; 2) exercised a Series F Warrant to purchase up to 7,246 shares, on a cashless basis, resulting in the issuance of 4,899 shares of common stock; and 3) exercised a Series H Warrant to purchase up to 10,000 shares, on a cashless basis, resulting in the issuance of 7,418 shares of common stock.

The issuance of common stock was completed pursuant to the exemptions from registration provided by, among others, Section 4(a)(2) of the Securities Act of 1933, as amended (the "**Securities Act**") and the provisions of Regulation D and Regulation S as promulgated under the Securities Act. The Company intends to use the proceeds from the Series D Warrant exercise for working capital and general corporate purposes.

Table of Contents**Item 6. Exhibits**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
<u>3.1</u>	<u>Articles of Incorporation, as amended, of the Company, incorporated by reference and included in the Company's Registration Statement on Form 10-SB 12g filed on May 11, 1999, SEC file number 000-30156-99616992.</u>
<u>3.2</u>	<u>Articles of Incorporation, as amended, of the Company incorporated by reference and included in the Company's Form 8-K filed on January 10, 2011, SEC file number 000-30156-11520181.</u>
<u>3.3</u>	<u>Articles of Incorporation, as amended, of the Company incorporated by reference and included in the Company's Form 8-K filed on January 10, 2014, SEC file number 000-30156-14521612.</u>
<u>3.4</u>	<u>By-laws of the Company incorporated by reference and included in the Company's Registration Statement on Form 10-SB 12g filed on May 11, 1999, SEC file number 000-30156-99616992.</u>
<u>4.1†</u>	<u>Form of Series A Common Stock Purchase Warrant dated July 12, 2013, incorporated by reference and included in the Company's Form 8-K filed on July 18, 2013, as amended on November 21, 2013 and December 27, 2013, SEC file number 000-30156-131300357.</u>
<u>4.2</u>	<u>Form of Stock Purchase Warrant, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657.</u>
<u>4.3</u>	<u>Registration Rights Agreement dated November 29, 2013, between Kalen Capital Corporation and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657.</u>
<u>4.4</u>	<u>Form of Series D Common Stock Purchase Warrant, incorporated by reference and included in the Company's Form 8-K filed on June 10, 2015, SEC file number 000-30156-15981571.</u>
<u>4.5</u>	<u>Convertible Promissory Note dated September 9, 2016, between Kalen Capital Corporation and the Company; incorporated by reference and included in the Company's Form 8-K filed on September 16, 2016, SEC file number 000-30156-161888353</u>

<u>4.6</u>	<u>Series E Stock Purchase Warrant dated September 9, 2016; incorporated by reference and included in the Company's Form 8-K filed on September 16, 2016, SEC file number 000-30156-161888353</u>
<u>4.7</u>	<u>Form of Convertible Promissory Note dated February 23, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 1, 2017, SEC file number 000-30156-17654590</u>
<u>4.8</u>	<u>Form of Series F Stock Purchase Warrant dated February 23, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 1, 2017, SEC file number 000-30156-17654590</u>
<u>4.9</u>	<u>Convertible Promissory Note dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968</u>
<u>4.10</u>	<u>Form of Series G Stock Purchase Warrant dated July 21, 2017; incorporated by reference and included in the Company's Form 8-K filed on July 24, 2017, SEC file number 000-30156-17978114</u>
<u>4.11</u>	<u>Form of Series H Stock Purchase Warrant dated October 16, 2017; incorporated by reference and included in the Company's Form 8-K filed on October 18, 2017, SEC file number 000-30156-171141509</u>
<u>4.12</u>	<u>Form of Subscription Agreement dated July 21, 2017; incorporated by reference and included in the Company's Form 8-K filed on July 24, 2017, SEC file number 000-30156-17978114</u>
<u>4.13</u>	<u>Form of Securities Purchase Agreement dated October 16, 2017; incorporated by reference and included in the Company's Form 8-K filed on October 18, 2017, SEC file number 000-30156-171141509</u>
<u>10.1</u>	<u>Employment Agreement dated June 20, 2013, between Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156-131259657</u>
<u>10.2</u>	<u>Asset Purchase Agreement dated as of June 21, 2013, between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on July 18, 2013, as amended on November 21, 2013 and December 27, 2013, SEC file number 000-30156-131300357</u>
<u>10.3§</u>	<u>Form of Stock Option Agreement, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156-131259657.</u>



10.4

Finder's Agreement dated August 13, 2013, between Vector Asset Management, Inc. and the Company, incorporated by reference and included in the Company's Form 10-Q filed on August 14, 2013, SEC file number 000-30156-13109753

29

Table of Contents

<u>10.5</u>	<u>At-Will Executive Services Agreement dated October 1, 2013, between Rhonda B. Rosen and the Company, incorporated by reference and included in the Company's Form 10-Q filed on November 14, 2013, SEC file number 000- 30156-13129717</u>
<u>10.6</u>	<u>Subscription Agreement for 3,500,000 units dated November 29, 2013, between Kalen Capital Corporation and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156-131259657</u>
<u>10.7</u>	<u>At-Will Consulting Agreement effective as of December 1, 2013, between Thomas Bold and the Company, incorporated by reference and included in the Company's Form 8-K filed on December 5, 2013, SEC file number 000-30156- 131259657</u>
<u>10.8</u>	<u>Stock Purchase Agreement dated December 31, 2013, between Duke Mountain Resources, Inc., Fostung Resources Ltd. and the Company, incorporated by reference and included in the Company's Form 8-K filed on January 7, 2014, SEC file number 000-30156-14513586</u>
<u>10.9</u>	<u>At-Will Consulting Agreement effective as of April 1, 2014, between Patsy Trisler and the Company, incorporated by reference and included in the Company's Form 8-K filed on April 7, 2014, SEC file number 000-30156- 14838542</u>
<u>10.10</u>	<u>Stock Option Agreement dated April 1, 2014, between Patsy Trisler and the Company, incorporated by reference and included in the Company's Form 8-K filed on April 7, 2014, SEC file number 000-30156-14838542</u>
<u>10.11</u>	<u>Post-Closing Amendment to Asset Purchase Agreement between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on September 15, 2014, SEC file number 000-30156-141102510</u>
<u>10.12</u>	<u>Option Agreement dated May 1, 2015 between Jörg Gerlach, MD, PhD and the Company, incorporated by reference and included in the Company's Form 8-K filed on May 5, 2015; SEC file number 000-30156-158333270.</u>
<u>10.13</u>	<u>Form of Subscription Agreement, incorporated by reference and included in the Company's Form 8-K filed on June 10, 2015, SEC file number 000-30156-15923671.</u>

<u>10.14</u>	<u>Loan Agreement between Kalen Capital Corporation and the Company; incorporated by reference and included in the Company's Form 8-K filed on September 16, 2016, SEC file number 000-30156-161888353</u>
<u>10.15</u>	<u>Form of Loan Agreement dated February 23, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 1, 2017, SEC file number 000-30156-17654590</u>
<u>10.16</u>	<u>Loan Agreement dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968</u>
<u>10.17</u>	<u>Amendment to Loan Agreement between Joseph Sierchio and the Company dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968</u>
<u>10.18</u>	<u>Amendment to Loan Agreement between Kalen Capital Corporation and the Company dated March 9, 2017; incorporated by reference and included in the Company's Form 8-K filed on March 14, 2017, SEC file number 000-30156-17686968</u>
<u>10.19</u>	<u>Form of Subscription Agreement dated July 21, 2017; incorporated by reference and included in the Company's Form 8-K filed on July 24, 2017, SEC file number 000-30156-17978114</u>
<u>10.20</u>	<u>Form of Securities Purchase Agreement dated October 16, 2017; incorporated by reference and included in the Company's Form 8-K filed on October 18, 2017, SEC file number 000-30156-171141509</u>
<u>10.21</u>	<u>January 29, 2018 Amendment to Convertible Promissory Note dated February 23, 2017; incorporated by reference and included in the Company's Form 10-K filed on March 13, 2018, SEC file number 000-30156-18686314</u>
<u>10.22</u>	<u>January 29, 2018 Amendment to Convertible Promissory Note dated September 9, 2016; incorporated by reference and included in the Company's Form 10-K filed on March 13, 2018, SEC file number 000-30156-18686314</u>
<u>10.23</u>	<u>Corporate Research Agreement dated August 1, 2017; incorporated by reference and included in the Company's Form 10-K filed on March 13, 2018, SEC file number 000-30156-18686314</u>
<u>10.24</u>	<u>Amendment to Consulting Agreement dated May 1, 2016 between Vector Asset Management, Inc. and the Company; incorporated by reference and included in the Company's Form 10-K filed on March 13, 2018, SEC file number</u>



Table of Contents

<u>10.25</u>	<u>January 29, 2018 First Amendment to Loan Agreement dated February 23, 2017; incorporated by reference and included in the Company's Form 10-K filed on March 13, 2018, SEC file number 000-30156-18686314</u>
<u>10.26</u>	<u>January 29, 2018 First Amendment to Loan Agreement dated September 9, 2016; incorporated by reference and included in the Company's Form 10-K filed on March 13, 2018, SEC file number 000-30156-18686314</u>
<u>10.27</u>	<u>Executive Consulting Agreement dated June 22, 2018; incorporated by reference and included in the Company's Form 8-K filed on June 25, 2018, SEC file number 000-30156-18916934</u>
<u>14.1</u>	<u>Code of Ethics, incorporated by reference and included in the Company's Form 10-K file on April 15, 2009, SEC file number 000-30156-09750383.</u>
<u>31.1</u>	<u>Certification of the Chief Executive Officer pursuant to Rule 13a-14(a).*</u>
<u>31.2</u>	<u>Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(a).*</u>
<u>32.1</u>	<u>Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*</u>
<u>32.2</u>	<u>Certification by the Interim Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*</u>
<u>99.1</u>	<u>2013 Long-Term Incentive Plan, incorporated by reference and included in the Company's Form 8-K filed on June 26, 2013, SEC file number 000-30156-13933444.</u>
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension - Schema Document**
101.CAL	XBRL Taxonomy Extension - Calculation Linkbase Document**
101.DEF	XBRL Taxonomy Extension - Definition Linkbase Document**
101.LAB	XBRL Taxonomy Extension - Label Linkbase Document**
101.PRE	XBRL Taxonomy Extension - Presentation Linkbase Document**

\* Filed herewith.

Edgar Filing: RenovaCare, Inc. - Form 10-Q

- † Portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and the omitted material has been separately filed with the Securities and Exchange Commission.
- § Indicates a management contract or compensatory plan or arrangement.
- \*\* Furnished herewith. XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of Sections 13 or 15 (d) of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**RenovaCare, Inc.**

(Registrant)

Date: November 19, 2018

By: */s/ Harmel S. Rayat*  
Name: Harmel Rayat  
Title: Chief Executive Officer and  
Principal Executive Officer

Date: November 19, 2018

By: */s/ Stephen Yan-Klassen*  
Name: Stephen Yan-Klassen  
Title: Chief Financial Officer and  
Principal Financial Officer