#### 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, 2017

[ ] 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: 001-36833

## **VOLITIONRX LIMITED**



(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

91-1949078 (I.R.S. Employer Identification No.)

1 Scotts Road #24-05 Shaw Centre Singapore 228208 (Address of principal executive offices)

+1 (646) 650-1351

(Registrant's telephone number, including area code)

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. [X] Yes [] 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). [X] Yes [ ] No

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

Large accelerated filer	[]	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 7(a)(2)(B) of the Securities Act. []

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

As of November 8, 2017, there were 26,518,700 shares of the registrant's \$0.001 par value common stock issued and outstanding.

### VOLITIONRX LIMITED QUARTERLY REPORT ON FORM 10-Q FOR THE THREE MONTHS AND NINE MONTHS ENDED SEPTEMBER 30, 2017

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Except as otherwise indicated by the context, references in this report to "Company," "VolitionRx," "Volition," "we," "us" and "our" are references to VolitionRx Limited and its wholly-owned subsidiaries, Singapore Volition Pte. Ltd, Belgian Volition SPRL, Hypergenomics Pte. Ltd, Volition America, Inc. and Volition Diagnostics UK Limited. Additionally, unless otherwise specified, all references to "United States Dollars" or "\$" refer to the legal currency of the United States of America.

Nucleosomics<sup>®</sup>, Nu.Q<sup>TM</sup> and HyperGenomics<sup>®</sup> and their respective logos are trademarks and/or service marks of VolitionRx. All other trademarks, service marks and trade names referred to in this report are the property of their respective owners.

## PART I - FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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Condensed Consolidated Balance Sheets (Unaudited) (Expressed in United States Dollars, except share numbers)

	September 30, 2017 \$	December 31, 2016 \$
ASSETS	(UNAUDITED)	
Cash and cash equivalents	13,840,930	21,678,734
Prepaid expenses	244,667	165,927
Other current assets	170,883	166,887
Total Current Assets	14,256,480	22,011,548
Property and equipment, net	3,510,355	2,119,027
Intangible assets, net	592,876	602,193
Total Assets	18,359,711	24,732,768
LIABILITIES		
Accounts payable	431,734	281,179
Accrued liabilities	1,759,161	1,439,275
Management and directors' fees payable	54,994	81,057
Current portion of long-term debt	408,307	30,655
Current portion of capital lease liabilities	136,307	119,016
Deferred grant income	-	45,510
Current portion of grant repayable	41,356	36,804
Total Current Liabilities	2,831,859	2,033,496
Long-term debt	1,050,536	432,027
Capital lease liabilities	897,303	889,810
Grant repayable	185,991	202,325
Total Liabilities	4,965,689	3,557,658
STOCKHOLDERS' EQUITY		
Common Stock		
Authorized: 100,000,000 shares of common stock, at \$0.001 par value		
Issued and outstanding: 26,518,700 shares and 26,126,049 shares, respectively	26,519	26,126
Additional paid-in capital	65,151,681	62,287,252
Accumulated other comprehensive loss	(132,882)	(193,297)
Accumulated deficit	(51,651,296)	(40,944,971)
Total Stockholders' Equity	13,394,022	21,175,110
Total Liabilities and Stockholders' Equity	18,359,711	24,732,768

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

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited) (Expressed in United States Dollars, except share numbers)

	For the three months ended September 30, 2017 \$	For the three months ended September 30, 2016 \$	For the nine months ended September 30, 2017 \$	For the nine months ended September 30, 2016 \$
Revenue	-	_	-	_
Expenses				
General and administrative	226,606	163,870	729,449	558,120
Sales and marketing	134,737	88,989	435,971	249,591
Professional fees	520,372	400,698	1,182,837	1,272,638
Salaries and office administrative fees	943,510	857,093	2,720,620	1,686,210
Research and development	2,203,985	1,968,490	5,774,004	5,180,466
Total Operating Expenses	4,029,210	3,479,140	10,842,881	8,947,025
Net Operating Loss	(4,029,210)	(3,479,140)	(10,842,881)	(8,947,025)
Other Income				
Grants received	136,556		136,556	25,891
Total Other Income	136,556		136,556	25,891
Income tax expense				
Net Loss	(3,892,654)	(3,479,140)	(10,706,325)	(8,921,134)
Other Comprehensive Income/(Loss)				
Foreign currency translation adjustments	(32,399)	15,462	60,415	(33,583)
Total Other Comprehensive Income/(Loss)	(32,399)	15,462	60,415	(33,583)
Net Comprehensive Loss	(3,925,053)	(3,463,678)	(10,645,910)	(8,954,717)
Net Loss per Share – Basic and Diluted	(0.15)	(0.15)	(0.41)	(0.40)
Weighted Average Shares Outstanding – Basic and Diluted	26,512,195	23,524,982	26,343,101	22,075,538

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

## Condensed Consolidated Statements of Cash Flows (Unaudited) (Expressed in United States Dollars)

	For the nine months ended September 30, 2017	For the nine months ended September 30, 2016 \$
	\$	\$
Operating Activities:		
Net loss	(10,706,325)	(8,921,134)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	371,362	230,606
Loss on disposal of property and equipment	11,262	3,668
Stock based compensation	1,827,604	1,106,623
Warrants issued for services	38,806	105,995
Changes in operating assets and liabilities:		
Accounts receivable	(12,356)	_
Deferred grant income	(50,855)	(335)
Prepaid expenses	(75,723)	(35,283)
Other current assets	25,105	(36,456)
Accounts payable and accrued liabilities	264,266	872,934
Net Cash Used In Operating Activities	(8,306,854)	(6,673,382)
Investing Activities:		
Purchases of property and equipment	(1,340,230)	(89,433)
Net Cash Used in Investing Activities	(1,340,230)	(89,433)
Financing Activities:		
Net proceeds from issuance of common shares	998,412	13,506,295
Proceeds from debt payable	908,075	-
Debt repaid	(29,807)	-
Grants repaid	(38,487)	(36,135)
Payments on capital lease obligations	(94,227)	(62,225)
Net Cash Provided By Financing Activities	1,743,966	13,407,935
Effect of foreign exchange on cash	65,314	(33,343)
(Decrease)/Increase in Cash	(7,837,804)	6,611,777
Cash and cash equivalents – Beginning of Period	21,678,734	5,916,006
Cash and cash equivalents - End of Period	13,840,930	12,527,783
Supplemental Disclosures of Cash Elastic Cash		
Supplemental Disclosures of Cash Flow Information:	50.004	0.150
Interest paid Income tax paid	50,234	9,159
income tax paid		
Non Cash Investing and Financing Activities:		
Common stock issued on cashless exercises of stock options	-	21
Capital lease obligation for equipment purchases		329,334
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(The accompanying notes are an integral part of these condensed consolidated financial statements)

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

## (\$ expressed in United States Dollars)

### Note 1 - Condensed Financial Statements

The accompanying financial statements have been prepared by VolitionRx without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at September 30, 2017, and for all periods presented herein, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted. It is suggested that these unaudited condensed consolidated financial statements be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 2016 as filed with the Securities and Exchange Commission on March 10, 2017. The results of operations for the periods ended September 30, 2017 and 2016 are not necessarily indicative of the operating results for the full years.

#### Note 2 - Going Concern

The Company's financial statements are prepared using U.S. GAAP applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has incurred losses since inception of \$51,651,296, has negative cash flows from operations, and currently has no revenues, which creates substantial doubt about its ability to continue as a going concern.

The future of the Company as an operating business will depend on its ability to obtain sufficient capital contributions, financing and/or generate revenues as may be required to sustain its operations. Management plans to address the above as needed by, (a) securing additional grant funds, (b) obtaining additional financing through debt or equity financing, (c) up front sales of licensing rights and (d) developing and commercializing its products on an accelerated timeline. Management continues to exercise tight cost controls to conserve cash.

The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish the plans described in the preceding paragraph and eventually secure other sources of financing and attain profitable operations. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. If the Company is unable to obtain adequate capital, it could be forced to cease operations.

#### Note 3 - Summary of Significant Accounting Policies

#### Basis of Presentation

The financial statements of the Company have been prepared in accordance with U.S. GAAP and are expressed in United States Dollars. The Company's fiscal year end is December 31.

#### Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company also regularly evaluates estimates and assumptions related to deferred income tax asset valuation allowances.

The Company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.



Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

## Note 3 - Summary of Significant Accounting Policies (continued)

#### Principles of Consolidation

The accompanying condensed consolidated financial statements for the period ended September 30, 2017 include the accounts of the Company and its wholly-owned subsidiaries, Singapore Volition Pte. Ltd, Belgian Volition SPRL ("Belgian Volition"), Hypergenomics Pte. Ltd, Volition America, Inc., which was formed on February 3, 2017 ("Volition America"), and Volition Diagnostics UK Limited ("Volition Diagnostics"). All significant intercompany balances and transactions have been eliminated in consolidation.

#### Basic and Diluted Net Loss Per Share

The Company computes net loss per share in accordance with Accounting Standards Codification ("ASC") 260, "Earnings Per Share," which requires presentation of both basic and diluted earnings per share ("EPS") on the face of the income statement. Basic EPS is computed by dividing net loss available to common shareholders (numerator) by the weighted average number of shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method and convertible preferred stock using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. As of September 30, 2017, 850,151 dilutive warrants and options and 2,283,582 potentially dilutive warrants and options were excluded from the diluted EPS calculation as their effect is anti-dilutive.

#### Reclassification

Certain balances in previously issued financial statements have been reclassified to be consistent with the current period presentation.

#### Recent Accounting Pronouncements

Management has considered all recent accounting pronouncements issued since the last audit of our consolidated financial statements. The Company's management believes that these recent pronouncements will not have a material effect on the Company's consolidated financial statements. However, the following pronouncement has been adopted by the Company:

In March 2016, the FASB Issued ASU No. 2016-09, "Compensation – Stock Compensation (Topic 718)". The amendments in this update simplify aspects of accounting for share-based payment transactions. An entity can now make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest (current GAAP) or account for forfeitures when they occur. The amendments in this update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2016.

## Note 4 - Property and Equipment

The Company's property and equipment consist of the following amounts as of September 30, 2017 and December 31, 2016:

	Useful Life	Cost \$	Accumulated Depreciation \$	September 30, 2017 Net Carrying Value \$
Computer hardware and software	3 years	267,773	110,888	156,885
Laboratory equipment	5 years	817,851	262,517	555,334
Equipment held under capital lease	5 years	675,293	307,562	367,731
Office furniture and equipment	5 years	186,508	27,643	158,865
Buildings	30 years	1,549,446	30,096	1,519,350
Building improvements	5 -15 years	683,820	26,158	657,662
Land	Not amortized	94,528	-	94,528
		4,275,219	764,864	3,510,355

	Useful Life	Cost \$	Accumulated Depreciation \$	December 31, 2016 Net Carrying Value \$
Computer hardware and software	3 years	155,870	67,097	88,773
Laboratory equipment	5 years	313,655	151,541	162,114
Equipment held under capital lease	5 years	578,830	183,296	395,534
Office furniture and equipment	5 years	32,932	23,361	9,571
Buildings	30 years	1,378,911	-	1,378,911
Building improvements	5 -15 years	-	-	-
Land	Not amortized	84,124	-	84,124
		2,544,322	425,295	2,119,027

During the nine-month period ended September 30, 2017 and the nine-month period ended September 30, 2016, the Company recognized \$306,180 and \$165,293 respectively, in depreciation expense.

#### Notes to the Condensed Consolidated Financial Statements (Unaudited) (\$ expressed in United States Dollars)

## Note 5 - Intangible Assets

The Company's intangible assets consist of intellectual property and patents, mainly acquired in the acquisition of Belgian Volition (formerly ValiBio SA). The patents and intellectual property are being amortized over the assets' estimated useful lives, which range from 8 to 20 years.

	Cost \$	Accumulated Amortization \$	September 30, 2017 Net Carrying Value \$
Patents	1,198,930	606,054	592,876
	1,198,930	606,054	592,876
	Cost \$	Accumulated Amortization \$	December 31, 2016 Net Carrying Value \$
Patents	1,085,133	482,940	602,193
	1,085,133	482,940	602,193

During the nine-month period ended September 30, 2017, and the nine-month period ended September 30, 2016, the Company recognized \$65,182 and \$65,313, respectively, in amortization expense.

The Company amortizes the long-lived assets on a straight-line basis with terms ranging from 8 to 20 years. The annual estimated amortization schedule over the next five years is as follows:

2017 - remaining	\$26,321
2018	\$91,504
2019	\$91,504
2020	\$91,504
2021	\$91,504

The Company reviews its long-lived assets on an annual basis, to ensure that their carrying value does not exceed their fair market value. The Company carried out such a review in accordance with ASC 360 as of December 31, 2016. The result of this review confirmed that the fair value of the patents exceeded their carrying value as of December 31, 2016.

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Notes to the Condensed Consolidated Financial Statements (Unaudited) (\$ expressed in United States Dollars)

### Note 6 - Related Party Transactions

The Company has agreements with related parties for consultancy services, stock options and warrants. See Notes 8 (a), 8(b) and 9(b), for further details concerning these agreements.

#### Note 7 - Common Stock

#### **Issuances Upon Warrant Exercises**

On January 26, 2017, 2,000 warrants were exercised at a price of \$2.40 per share, for net cash proceeds to the Company of \$4,800. As a result, a total of 2,000 shares of common stock were issued.

From March 13, 2017 through April 3, 2017, 27,500 warrants were exercised at a price of \$2.20 per share, for net cash proceeds to the Company of \$60,500. As a result, a total of 27,500 shares of common stock were issued.

From April 3, 2017 through May 9, 2017, 313,151 warrants were exercised at a price of \$2.60 per share, for net cash proceeds to the Company of \$814,193. As a result, a total of 313,151 shares of common stock were issued. Of this issuance, 163,499 shares of common stock were issued to related parties, for net cash proceeds to the Company of \$425,097.

On July 7, 2017, 5,000 warrants were exercised at a price of \$2.20 per share, for net cash proceeds to the Company of \$11,000. As a result, a total of 5,000 shares of common stock were issued.

From July 9, 2017 through July 19, 2017, 45,000 warrants were exercised at a price of \$2.40 per share for net cash proceeds to the Company of \$108,000. As a result, a total of 45,000 shares of common stock were issued.

#### Note 8 - Warrants and Options

### a) Warrants

See Note 7.

The following table summarizes the changes in warrants outstanding of the Company during the nine-month period ended September 30, 2017:

	Number of Warrants	Weighted Average Exercise Price (\$)
Outstanding at December 31, 2016	2,162,638	2.40
Granted	-	-
Exercised	(392,651)	(2.38)
Expired	(38,307)	(2.40)
Outstanding at September 30, 2017	1,731,680	2.36
Exercisable at September 30, 2017	1,606,680	2.35

On February 14, 2017, the Company modified the performance criteria for a vesting milestone on an employee warrant agreement and as a result the Company re-measured warrants held by an employee, to purchase 25,000 shares of common stock at an exercise price of \$2.47 per share. These warrants vest on achievement of certain business objectives and expire 3 years from the date of vesting. The Company has calculated the estimated fair market value of these warrants using the Black-Scholes model and the following assumptions: term: 0.5 years, stock price: \$4.52, exercise price: \$2.47, 55.65% volatility, 0.66% risk free rate.

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

### Note 8 – Warrants and Options (continued)

On May 10, 2017, 28,307 warrants expired and on September 5, 2017, 10,000 warrants expired.

Effective August 22, 2017, the Company amended the expiry period of 24,000 warrants, originally granted on September 26, 2014. The expiration period was extended from three to four years for all 24,000 warrants, with their new expiration date being September 26, 2018. The Company recalculated the estimated fair market value of these warrants using the Black-Scholes model, but the result was deemed to be immaterially different to the original calculation and the financial statements were not adjusted.

Effective August 22, 2017, the Company amended the expiry period of 19,000 warrants, originally granted on November 17, 2014. The expiration period was extended from three to four years for all 19,000 warrants, with their new expiration date being November 17, 2018. The Company recalculated the estimated fair market value of these warrants using the Black-Scholes model, but the result was deemed to be immaterially different to the original calculation and the financial statements were not adjusted.

Below is a table summarizing the warrants issued and outstanding as of September 30, 2017, which have a weighted average exercise price of \$2.36 per share and an aggregate weighted average remaining contractual life of 1.55 years.

					Weighted Average Remaining		
					Contractual		
		Number			Life		
Date Issued	Number Outstanding	Exercisable	Exercise Price (\$)	Contractual Life (Years)	(Years)	Expiration Date	Proceeds to Company if Exercised (\$)
03/20/13	125,000	-	2.47	8.0 to 9.0	0.26	06/30/20 to 12/31/21	308,750
03/20/13	25,000	25,000	2.47	7.5	0.06	09/18/20	61,750
06/10/13	29,750	29,750	2.00	5.0	0.01	06/10/18	59,500
11/25/13	456,063	456,063	2.40	5.0	0.30	11/25/18	1,094,551
12/31/13	64,392	64,392	2.40	5.0	0.05	12/31/18	154,541
02/26/14	948,475	948,475	2.20	5.0	0.77	02/26/19	2,086,645
09/26/14	24,000	24,000	3.00	3.0	0.01	09/26/18	72,000
11/17/14	19,000	19,000	3.75	3.0	0.01	11/17/18	71,250
11/14/16	40,000	40,000	4.53	4.0	0.07	11/14/20	181,200
	1,731,680	1,606,680			1.55		4,090,187

Total remaining unrecognized compensation cost related to non-vested warrants is approximately \$41,324 and is expected to be recognized over a period of 1.3 years. As of September 30, 2017, the total intrinsic value of warrants was \$570,291.

Notes to the Condensed Consolidated Financial Statements (Unaudited) (\$ expressed in United States Dollars)

#### Note 8 - Warrants and Options (continued)

#### b) Options

The following table summarizes the changes in options outstanding of the Company during the nine-month period ended September 30, 2017:

	Number of Options	Weighted Average Exercise Price (\$)
Outstanding at December 31, 2016	2,384,300	3.75
Granted	871,000	4.99
Exercised	-	-
Expired	(211,000)	(4.05)
Outstanding at September 30, 2017	3,044,300	4.08
Exercisable at September 30, 2017	2,173,300	3.72

Effective January 1, 2017, the Company granted stock options to purchase 50,000 shares of common stock. These options vest on January 1, 2018 and expire 5 years after the vesting date, with an exercise price of \$4.80 per share. The Company has calculated the estimated fair market value of these options at \$157,890, using the Black-Scholes model and the following assumptions: term 6 years, stock price \$4.57, exercise price \$4.80, 80.70% volatility, 2.26% risk free rate.

Effective February 13, 2017, the Company granted stock options to purchase 25,000 shares of common stock. These options vest on February 13, 2018 and expire 5 years after the vesting date, with an exercise price of \$5.00 per share. The Company has calculated the estimated fair market value of these options at \$76,773, using the Black-Scholes model and the following assumptions: term 6 years, stock price \$4.52, exercise price \$5.00, 80.17% volatility, 2.24% risk free rate.

On March 1, 2017, stock options to purchase 5,000 shares of common stock expired unexercised.

On March 30, 2017, the Company granted stock options to purchase 686,000 shares of common stock. These options vest on March 30, 2018 and expire five years after their vesting date, with an exercise price of \$5.00 per share. The Company has calculated the estimated fair market value of these options at \$1,898,322, using the Black-Scholes model and the following assumptions: term 6 years, stock price \$4.18, exercise price \$5.00, 79.41% volatility, 2.25% risk free rate.

Effective April 10, 2017, the Company granted stock options to purchase 100,000 shares of common stock. These options vest on April 10, 2018 and expire 5 years after the vesting date, with an exercise price of \$5.00 per share. The Company has calculated the estimated fair market value of these options at \$258,077, using the Black-Scholes model and the following assumptions: term 6 years, stock price \$3.96, exercise price \$5.00, 79.33% volatility, 2.18% risk free rate.

On May 25, 2017, stock options to purchase 101,000 shares of common stock expired unexercised.

On May 31, 2017, stock options to purchase 25,000 shares of common stock expired unexercised.

Effective July 13, 2017, the Company granted stock options to purchase 10,000 shares of common stock. These options vest on July 13, 2018 and expire 5 years after the vesting date, with an exercise price of \$5.00 per share. The Company has calculated the estimated fair market value of these options at \$19,068, using the Black-Scholes model and the following assumptions: term 6 years, stock price \$3.15, exercise price \$5.00, 78.41% volatility, 2.16% risk free rate.

Effective August 14, 2017, the Company amended the expiry period of stock options to purchase 37,000 shares of common stock, which options were originally granted on March 20, 2013 and amended on June 27, 2016. The expiration period was extended from four to six years, with the outside expiration date of March 20, 2022, after vesting for all 37,000 stock options. The Company recalculated the estimated fair market value of these options using the Black-Scholes model, but the result was deemed to be immaterially different to the original calculation and the financial statements were not adjusted.

## Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

### Note 8 - Warrants and Options (continued)

Effective August 14, 2017, the Company amended the expiry period of stock options to purchase 16,300 shares of common stock, which options were originally granted on September 2, 2013 and amended on June 27, 2016. The expiration period was extended from four to six years, with the outside expiration date of September 2, 2022, after vesting for all 16,300 stock options. The Company recalculated the estimated fair market value of these options using the Black-Scholes model, but the result was deemed to be immaterially different to the original calculation and the financial statements were not adjusted.

On August 31, 2017, stock options to purchase 75,000 shares of common stock expired unexercised.

On September 1, 2017, stock options to purchase 5,000 shares of common stock expired unexercised.

On September 8, 2017, an amendment to the 2015 Stock Incentive Plan (the "2015 Plan") was approved by stockholders at the annual meeting to increase the number of shares of common stock available for issuance under the 2015 Plan by 750,000 shares to an aggregate maximum of 2,500,000 shares.

Below is a table summarizing the options issued and outstanding as of September 30, 2017, all of which were issued pursuant to the 2011 Equity Incentive Plan (for option issuances prior to 2016) or the 2015 Plan (for option issuances commencing in 2016) and which have a weighted average exercise price of \$4.08 per share and an aggregate weighted average remaining contractual life of 3.56 years.

Date Issued 11/25/11 09/01/12 03/20/13 09/02/13 05/16/14 08/18/14 05/18/15 07/23/15 04/15/16 06/23/16	Number Outstanding 303,000 10,000 37,000 16,300 25,000 645,000 20,000 317,000 775,000 15,000	Number Exercisable 303,000 10,000 37,000 16,300 25,000 645,000 20,000 317,000 775,000 15,000	Exercise Price (\$) 4.00-5.00 6.31 2.35-4.35 2.35-4.35 3.00-5.00 2.50 and 3.00 3.80 4.00 4.00 4.00	Contractual Life (Years) 6.0-7.0 6.5-9.0 6.5-9.0 3.5-6.0 4.5 and 5.5 4.5 4.5 6.0 6.0	Weighted Average Remaining Contractual Life (Years) 0.06 0.00 0.04 0.02 0.01 0.40 0.01 0.25 1.16 0.02	Expiration Date 11/25/17-11/25/18 03/01/18-09/01/18 09/20/19-03/20/22 03/02/20-09/02/22 11/16/17-05/16/20 02/18/19-02/18/20 11/18/19 01/23/20 04/15/22 06/23/22	Proceeds to Company if Exercised (\$) 1,414,000 63,100 123,950 54,605 100,000 1,773,750 76,000 1,268,000 3,100,000 60,000
06/23/16	15,000	15,000	4.00	6.0	0.02	06/23/22	60,000
11/11/16	10,000	10,000	5.00	6.0	0.02	11/11/22	50,000
01/01/17	50,000	-	4.80	6.0	0.09	01/01/23	240,000
02/13/17	25,000	-	5.00	6.0	0.04	02/13/23	125,000
03/30/17	686,000	-	5.00	6.0	1.24	03/30/23	3,430,000
04/10/17	100,000	-	5.00	6.0	0.18	04/10/23	500,000
07/13/17	10,000	-	5.00	6.0	0.02	07/13/23	50,000
	3,044,300	2,173,300			3.56		12,428,405

Total remaining unrecognized compensation cost related to non-vested stock options is approximately \$1,160,892 and is expected to be recognized over a period of 1.0 years. As of September 30, 2017, the total intrinsic value of stock options was \$46,900.

## Note 9 - Commitments and Contingencies

### a) Walloon Region Grant

On March 16, 2010, the Company entered into an agreement with the Walloon Region government in Belgium wherein the Walloon Region would fund up to a maximum of 1,238,340 ((1,048,020)) to help the research endeavors of the Company in the area of colorectal cancer ("CRC"). The Company had received the entirety of these funds in respect of approved expenditures as of June 30, 2014. Under the terms of the agreement, the Company is due to repay 371,502 ((314,406)) of this amount by installments over the period from June 30, 2014 to June 30, 2023. The Company has recorded the balance of 886,838 ((733,614)) to other income in previous years as there is no obligation to repay this amount. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 6% royalty on such revenue to the Walloon Region. The maximum amount payable to the Walloon Region, in respect of the aggregate of the amount repayable of 3371,502 ((314,406)) and the 6% royalty on revenue, is twice the amount of funding received. As at September 30, 2017, \$227,347 ((192,406)) was outstanding to be repaid to the Walloon Region under this agreement.

#### b) Consulting Agreement

On May 11, 2016, Singapore Volition, upon the review and approval by the Company's Compensation Committee, entered into a consultancy agreement with PB Commodities Pte. Ltd ("PB Commodities"), for the services of Cameron Reynolds (the "2016 Reynolds Consulting Agreement"). Under the terms of the 2016 Reynolds Consulting Agreement, PB Commodities received \$25,925 per month for the services provided to Singapore Volition by Mr. Reynolds on its behalf. The 2016 Reynolds Consulting Agreement replaced and terminated the existing consultancy agreement for the provision of office space, office support staff, and consultancy services between Singapore Volition and PB Commodities dated August 6, 2010, as amended. The 2016 Reynolds Consulting Agreement was terminated on March 31, 2017 in connection with Mr. Reynolds entering into an Employment Agreement with Volition Diagnostics, effective April 1, 2017.

#### c) Lease Obligations Payable

The Company leases three Tecan machines (automated liquid handling robots) under a lease classified as a capital lease. The total cost of this leased laboratory equipment is 650,416 (€550,454). The leased equipment is depreciated on a straight-line basis over five years. Total depreciation charged to the income statement, related to the leased equipment is 97,307 (€82,568) for the nine months ended September 30, 2017 and 92,139 (€82,568) for the nine months ended September 30, 2016.

On October 4, 2016, and effective on October 25, 2016, Belgian Volition entered into a Real Estate Capital Lease Agreement (the "Capital Lease Agreement") with ING Asset Finance Belgium S.A. ("ING"). The Capital Lease Agreement became a contractual obligation of Belgian Volition upon the execution of the Deed of Sale to acquire the Company's new research and development facility described below. Pursuant to the Capital Lease Agreement, ING paid \$1.32 million (€1.12 million) in return for Belgian Volition granting to ING a right of emphyteusis (a form of leasehold) on the property located in the Belgian Créalys zoning at 5032 Isnes-Spy, Rue Phocas Lejeune 22, Gembloux cadastre, 8th division, Section B, n 55 (the "Property") for a period of 27 years, extendable to the authorized maximum legal term of 99 years. In addition, the Capital Lease Agreement provides that ING shall grant Belgian Volition a 15-year lease over the Property with an option for Belgian Volition to purchase the Property outright upon payment of \$39,702 (€33,600) at the end of the lease. The Capital Lease Agreement provides that Belgian Volition make the first lease payment of \$519,904 (€440,000) following the execution of the Capital Lease Agreement, and then quarterly lease payments of approximately \$15,889 (€13,447), based on a fixed rate of 2.62% for the term of the lease. On October 25, 2016, Belgian Volition acquired the Property by entering into a Deed of Sale to the Sale Agreement with Gerard Dekoninck S.A. The purchase price for the Property consisted of \$1.42 million (€1.2 million), exclusive of any closing costs (the "Purchase Price"). The Purchase Price was funded by Belgian Volition with cash on hand and the monies received under the Capital Lease Agreement. Occupation of the Property occurred in March 2017. Total depreciation charged to the income statement, related to the leased building is \$30,096 (€25,471) for the nine months ended September 30, 2017 and \$nil (€nil) for the nine months ended September 30, 2016.

#### Note 9 - Commitments and Contingencies (continued)

The following is a schedule showing the future minimum lease payments under capital leases by years and the present value of the minimum payments as of September 30, 2017.

Present value of minimum lease payments	\$ 1,033,610
Long term portion	\$ 897,303
Current portion	\$ 136,307
Made up of:	
Present value of minimum lease payments	\$ 1,033,610
Less: Amount representing interest	\$ (161,843)
Total minimum lease payments	\$ 1,195,453
Thereafter	\$ 659,357
2021	\$ 63,555
2020	\$ 110,603
2019	\$ 160,862
2018	\$ 160,860
2017	\$ 40,216

The Company also leases premises and facilities under operating leases with terms ranging from 12 months to 60 months. The annual non-cancelable operating lease payments on these leases are as follows:

2017	\$ 204,965
2018	\$ 221,240
2019	\$ 85,088
2020	\$ 50,333
2021	\$ 13,803
Total	\$ 575,429

## d) Hvidovre Hospital, Denmark Agreement

On November 2, 2016, the Company entered into a clinical research agreement with Hvidovre Hospital, University of Copenhagen in Denmark, relating to a program of samples testing associated with CRC and other diseases. The first phase of the agreement will expire on September 30, 2018 and the Company may participate in additional phases upon its election (and payment of required amounts). Total payments (inclusive of local taxes) to be made by the Company under the agreement for the first phase are \$2,382,995 (DKR 15,000,000).

### Note 9 - Commitments and Contingencies (continued)

### e) Long Term Debt: Preface S.A. Loan Agreements

On September 16, 2016, Belgian Volition entered into an unsecured loan agreement with Namur Invest or Preface S.A. for the amount of \$519,904 (€440,000) (the "Loan Agreement"). The proceeds from the Loan Agreement were received by Belgian Volition on October 20, 2016. The Loan Agreement provides for an approximate 7-year term, a fixed interest rate at 4.85%, and interest only payments between the receipt of proceeds and June 30, 2017. Thereafter, monthly repayments of \$7,785 (€6,588) will be made. See Note 9(c) for the use of the proceeds from the Loan Agreement.

On May 2, 2017, Belgian Volition entered into an additional unsecured loan agreement with Namur Invest or Preface S.A. for the amount of \$413,560 ( $\in$ 350,000) (the "May 2017 Loan Agreement"). The May 2017 Loan Agreement provides for an approximate 3.5-year repayment term, a fixed interest rate at 4.00% and interest only payments between the receipt of proceeds and December 31, 2017. Thereafter, monthly repayments of \$10,568 ( $\in$ 8,944) will be made. The proceeds from the May 2017 Loan Agreement will be used to fund a pathway study for our product – the Nu.Q<sup>TM</sup> Colorectal Cancer Screening Triage Test.

#### f) Long Term Debt: ING Loan Agreement

On October 25, 2016, Belgian Volition entered into a secured loan agreement with ING for an amount up to \$319,032 ( $\notin$ 270,000) (the "Supplemental Loan"). The Supplemental Loan provides for a 15-year term commencing on March 31, 2017, a fixed interest rate at 2.96%, and quarterly repayments of \$6,542 ( $\notin$ 5,536), commencing on April 28, 2017. The maximum amount of the loan facility had been drawn down by Belgian Volition by the loan commencement date of March 31, 2017 and interest only payments were made from the initial draw down of the loan until September 30, 2017. The proceeds of the Supplemental Loan were used to finance the construction of a laboratory in the new research and development facility (see Note 9(c)).

#### g) Clinical Study Agreement with the University of Michigan

On July 17, 2017, Volition America entered into a Clinical Study Agreement with the Regents of the University of Michigan (the "University of Michigan"), with regards to Volition America's participation with the University of Michigan and the National Cancer Institute Early Detection Research Network ("EDRN"), in a clinical study (the "University of Michigan Clinical Study Agreement") involving approximately 13,500 samples. The enrollment period and sample collection is anticipated to take up to 3 years to complete. The total maximum payment due by Volition America in accordance with the agreement is \$3 million spread over 12 equal quarterly installments of \$250,000. The foregoing description of the University of Michigan Clinical Study Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.1.

#### h) Straight Loan: ING Loan Agreement

On August 28, 2017, Belgian Volition received prefunding of  $236,320 \ (0.000)$  from ING, pursuant to a loan agreement (the "Straight Loan Agreement") entered into on December 13, 2016 and repayable upon receipt of grants for investment in Créalys business park from the Walloon Region. The term of the Straight Loan Agreement is until July 2018, on a rolling monthly basis at an interest rate of the Euribor rate + 2%. The proceeds of the Straight Loan Agreement were used to finance the investment in the Créalys business park.

#### i) Long Term Debt: SOFINEX Loan Agreement

On September 20, 2017, VolitionRx and Belgian Volition entered into an unsecured loan agreement with SOFINEX, a Belgian public organization focused on the internationalization of Walloon companies, for an amount of \$1,200,000 (€1,000,000) (the "SOFINEX Loan Agreement"). The SOFINEX Loan Agreement provides for a 7-year repayment term, with a grace period for principal payments until December 31, 2019, and a fixed interest rate of 4.5%. As of September 30, 2017, no cash has been drawn down under this agreement.

## j) Legal Proceedings

There are no legal proceedings which the Company believes will have a material adverse effect on its financial position.



Notes to the Condensed Consolidated Financial Statements (Unaudited) (\$ expressed in United States Dollars)

## Note 10 – Subsequent Events

None.

## END NOTES TO FINANCIALS

# **WIENAIGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

#### **Cautionary Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 or the Report, contains forwardlooking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact included in this Report or incorporated by reference into this Report are forward-looking statements. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items; plans or expectations with respect to our development activities or business strategy; statements concerning clinical studies and results, statements concerning industry trends; statements regarding anticipated demand for our products, or the products of our competitors, statements relating to manufacturing forecasts, and the potential impact of our relationship with contract manufacturers and original equipment manufacturers on our business; statements relating to the commercialization of our products, assumptions regarding the future cost and potential benefits of our research and development efforts; forecasts of our liquidity position or available cash resources; statements relating to the impact of pending litigation; and statements relating to the assumptions underlying any of the foregoing. Throughout this Report, we have attempted to identify forward-looking statements by using words such as "may," "believe," "will," "could," "project," "anticipate," "expect," "estimate," "should," "continue," "potential," "plan," "forecasts," "goal," "seek," "intend," other forms of these words or similar words or expressions or the negative thereof (although not all forward-looking statements contain these words).

We have based our forward-looking statements on our current expectations and projections about trends affecting our business and industry and other future events. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Forward-looking statements are subject to substantial risks and uncertainties that could cause our future business, financial condition, results of operations or performance, to differ materially from our historical results or those expressed or implied in any forward-looking statement contained in this Report. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. Other risks and uncertainties include our failure to obtain necessary regulatory clearances or approvals to distribute and market future products in the clinical in-vitro diagnostics, or IVD market; a failure by the marketplace to accept the products in our development pipeline or any other diagnostic products we might develop; we will face fierce competition and our intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; and other risks identified elsewhere in this Report, as well as in our other filings with the Securities and Exchange Commission, or the SEC. In addition, actual results may differ as a result of additional risks and uncertainties of which we are currently unaware or which we do not currently view as material to our business. For these reasons, readers are cautioned not to place undue reliance on any forward-looking statements.

You should read this Report in its entirety, together with our Annual Report on Form 10-K filed with the SEC on March 10, 2017, or Annual Report, the documents that we file as exhibits to this Report and the documents that we incorporate by reference into this Report, with the understanding that our future results may be materially different from what we currently expect. The forward-looking statements we make speak only as of the date on which they are made. We expressly disclaim any intent or obligation to update any forward-looking statements after the date hereof to conform such statements to actual results or to changes in our opinions or expectations. If we do update or correct any forward-looking statements, readers should not conclude that we will make additional updates or corrections.

#### **Company Overview**

Volition is a multi-national life sciences company developing simple, easy to use, blood-based cancer tests to accurately diagnose a range of cancers. The tests are based on the science of Nucleosomics<sup>®</sup>, which is the practice of identifying and measuring nucleosomes in the bloodstream - an indication that disease is present.

As cancer screening programs become more widespread, our products aim to help in diagnosing a range of cancers quickly, simply, accurately, cost effectively and with much higher population compliance. Early diagnosis through widespread screening has the potential to not only prolong the life of patients, but also to improve their quality of life.

We are developing blood-based diagnostics for the most prevalent cancers, beginning with Colorectal Cancer, or CRC. Following CRC, we anticipate focusing on lung cancer, prostate and pancreatic cancer, using our Nucleosomics<sup>®</sup> biomarker discovery platform. Our development pipeline includes assays to be used for symptomatic patients or asymptomatic (screening) populations. The platform employs a range of simple Nu.Q<sup>TM</sup> immunoassays on an industry standard ELISA format, which allows rapid quantification of epigenetic changes in biofluids (whole blood, plasma, serum, sputum, urine, etc.) compared to other more complicated and expensive approaches such as bisulfite conversion and polymerase chain reaction. Our Nu.Q<sup>TM</sup> biomarkers can be used alone, or in combination to generate profiles related to specific conditions.

We have developed thirty-nine Nu.Q<sup>TM</sup> blood-based assays to date to detect specific biomarkers that can be used individually or in combination to generate a profile which forms the basis of a product for a particular cancer or disease. We are also looking at a range of additional low cost orthogonal ELISA markers that may add to the test accuracy while maintaining our aim of providing a low-cost test that requires only a small amount of blood.

We anticipate that because of their ease of use and cost efficiency, our tests have the potential to become the first method of choice for cancer diagnostics, allowing detection of a range of cancers at an earlier stage. We anticipate the initial use will be for the testing of individuals who, for reasons such as time, cost, or aversion to current methods, are not currently screened, or are not up to date with their screening.

We intend to commercialize our products in the future through various channels within the European Union, the United States and throughout the rest of the world, beginning with Asia. Patient compliance is critical for asymptomatic CRC population screening programs; however, current CRC screening programs have poor compliance. For example, in the United States there are several recommended CRC screening test options, including: colonoscopy, fecal tests and computed tomography colonoscopy; however, the participation rate as of 2014 was just 65.7% of the eligible patient population. The UK, like many European countries, employs a front-line fecal test for screening that also has a low compliance rate of between 59% and 67%. These figures indicate that about one-third of the populations of the United States and the UK are unscreened. The unscreened populations of many other countries are much higher. This low level of screening participation is a serious issue as it often leads to the late diagnosis of cancer when it is much harder to treat.

We believe that the only viable option to achieve high levels of compliance will come from affordable blood tests that use a small amount of blood taken as part of the patient's normal health check procedure. We aim to launch such a front-line CRC population screening test for asymptomatic people who are non-compliant with current screening methods in Europe in 2018 and in Asia soon after. This product will require a small amount of blood and will use the same established, robust, low-cost ELISA methodology employed in the PSA test for prostate cancer.

We are also very serious about meeting this urgent need for a highly compliant asymptomatic CRC screening test in the United States. To this end, in July 2017 we signed a contract to participate in a large 13,500 screening subject trial in the United States in conjunction with the National Cancer Institute's Early Detection Research Network. Over 4,500 samples have already been collected and up to 9,000 samples will now be collected prospectively over the coming two to three years. The aim of this study is to validate a panel of biomarkers including our Nu.Q<sup>TM</sup> Colorectal Cancer Screening Test in a large asymptomatic population to support U.S. regulatory approval.

Our first product – the Nu.Q<sup>TM</sup> Colorectal Cancer Screening Triage Test, which we refer to as the Triage Test, achieved the CE Mark in December 2016, allowing us to start commercialization in the European Union. This test is undergoing continuing development. In addition, in conjunction with our collaborators in Denmark, we are undertaking a pathway design study.

We are also taking our first regulatory steps in Asia as we prepare the submission of our tests to numerous Asian regulatory authorities. We aim to announce several trials in Asia for our various potential CRC products in the coming quarters.



#### **Overview of Plan of Operations**

Management has identified the specific processes and resources required to achieve the near and medium-term objectives of our business plan, including personnel, facilities, equipment, research and testing materials including antibodies and clinical samples, and the protection of intellectual property. To date, operations have proceeded satisfactorily in relation to the business plan. However, it is possible that some resources will not readily become available in a suitable form or on a timely basis or at an acceptable cost. It is also possible that the results of some processes may not be as expected, and that modifications of procedures and materials may be required. Such events could result in delays to the achievement of the near and medium-term objectives of the business plan regarding the progression of clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market.

We do not anticipate earning significant revenues in 2017 and until such time as we are able to fully market our intended products on the IVD market. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our plan of operations described herein, obtain financing and eventually attain profitable operations.

#### Liquidity and Capital Resources

As of September 30, 2017, the Company had cash and cash equivalents of \$13,840,930, prepayments of \$244,667, other current assets of \$170,883 and current liabilities of \$2,831,859. This represents a working capital surplus of \$11,424,621.

The Company used \$8,306,854 in net cash for operating activities for the nine months ended September 30, 2017, compared to \$6,673,382 for the nine months ended September 30, 2016. The increase in cash used year-over-year is, to a large extent, due to increased expenditures on research and development activities in the current period. The increase in salaries and office administrative fees is mainly a result of non-cash adjusting, stock and warrant amortization. See "*Results of Operations*" for more detail.

The Company used \$1,340,230 in net cash for investing activities for the nine months ended September 30, 2017, compared to \$89,433 for the nine months ended September 30, 2016. This increase in cash used year-over-year is primarily a result of the purchase of equipment and building improvements for the new research and development facility in Belgium.

Net cash provided by financing activities amounted to \$1,743,966 for the nine months ended September 30, 2017, compared to \$13,407,935 for the nine months ended September 30, 2016. Primarily the Company received combined proceeds of \$908,075 from an ING bank loan and a Preface S.A. loan in the nine months ended September 30, 2017 along with approximately \$998,412 in net cash proceeds from the exercise of warrants. During the comparable 2016 period, the Company raised \$13,107,030 in net cash proceeds in March 2016 through the sale and issuance of approximately 4.3 million shares of common stock in a public offering and raised \$399,265 in net cash proceeds from the exercise of warrants.

We intend to use our cash reserves to predominantly fund further research and development activities. We do not currently have any substantial source of revenues and expect to rely on additional future financing, through the sale of additional equity securities or raising of debt or sale of licensing rights, but there is no assurance that we will be successful in raising further funds.

In the event that additional financing is delayed, we will prioritize the maintenance of our research and development personnel and facilities, primarily in Belgium and the maintenance of our patent rights. However, the completion of clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market would be delayed. In the event of an ongoing lack of financing, it may be necessary to discontinue operations, which will adversely affect the value of our common stock.

#### **Going Concern**

We have not attained profitable operations and are dependent upon obtaining financing to pursue any extensive activities. For these reasons, our auditors stated in their report on our audited financial statements for the fiscal year ended December 31, 2016 that they have substantial doubt that we will be able to continue as a going concern without further financing.

#### **Results of Operations**

## Three Months Ended September 30, 2017 and September 30, 2016

The following table sets forth the Company's results of operations for the three months ended on September 30, 2017 and the comparative period for the three months ended September 30, 2016.

	Three months Ended September 30, 2017 (\$)	Three months Ended September 30, 2016 (\$)	Increase/ (Decrease) (\$)	Percentage Increase/ (Decrease) (%)
Revenues	-		-	-
General and administrative expenses	226,606	163,870	62,736	38%
Sales and marketing expenses	134,737	88,989	45,748	51%
Professional fees	520,372	400,698	119,674	30%
Salaries and office administrative fees	943,510	857,093	86,417	10%
Research and development expenses	2,203,985	1,968,490	235,495	12%
Total Operating Expenses	(4,029,210)	(3,479,140)	550,070	16%
Other Income	136,556		136,556	100%
Income Taxes				
Net Loss	(3,892,654)	(3,479,140)	413,514	12%
Basic and Diluted Loss Per Common Share	(0.15)	(0.15)		
Weighted Average Basic and Diluted Common Shares Outstanding	26,512,195	23,524,982	2,987,213	13%
Common Shares Outstanding	20,512,195	25,527,762	2,767,213	1370

### Revenues

The Company had not generated revenues from operations in either the three months ended September 30, 2017 or the three months ended September 30, 2016. The Company's operations are still predominantly in the development stage.

#### **Total Operating Expenses**

For the three months ended September 30, 2017, the Company's total operating expenses increased by \$550,070, or 16%, compared to the same period in 2016. Total operating expenses are comprised of general and administrative expenses, sales and marketing expenses, professional fees, salaries and office administrative fees, and research and development expenses described below.

#### General and Administrative Expenses

General and administrative expenses increased by \$62,736, or 38%, in the three-month period ended September 30, 2017 compared to the prior year period. The increase in the 2017 period was in part due to additional costs from operating a larger UK office, incurring costs of \$18,775, an increased level of insurance coverage, incurring costs of \$19,456, and increased IT costs of \$13,911. The incremental IT costs mainly related to investments associated with increased IT security and controls.

#### Sales and Marketing Expenses

Sales and marketing expenses increased by \$45,748, or 51%, in the three-month period ended September 30, 2017 compared to the prior year period. The increase was primarily a result of the recruitment of additional sales and marketing personnel, incurring new costs of \$67,806 in 2017. These increased costs were offset against decreases in marketing fees across certain areas.

#### **Professional Fees**

Professional fees increased by \$119,674, or 30%, in the three-month period ended September 30, 2017 compared to the prior year period. The increase was mainly due to higher consultancy fees of \$88,234 for preparation of Sarbanes-Oxley compliance and conference costs of \$22,848.

#### Salaries and Office Administrative Fees

Salaries and office administrative fees increased by \$86,417, or 10%, in the three-month period ended September 30, 2017 compared to the prior year period. The increase was mainly the result of increased stock option and warrant amortization costs of \$53,441, with increased employee headcount and staff salaries also contributing to the total change.

#### **Research and Development Expenses**

Research and development expenses increased by \$235,495, or 12%, in the three-month period ended September 30, 2017 compared to the prior year period. The increase was predominantly due to the first-time payment required for the EDRN study in the United States of \$250,000.

#### **Other Income**

Other income amounted to \$136,556 for the three months ended September 30, 2017 of grant funds from public bodies for approved expenditure with no obligation to repay. For the comparable period in 2016, no grant income was received.

#### Net Loss

For the three months ended September 30, 2017, the Company's net loss was \$3,892,654, an increase of \$413,514, or 12%, in comparison to a net loss of \$3,479,140 for the three months ended September 30, 2016. The change was a result of the factors described above.

#### Nine Months Ended September 30, 2017 and September 30, 2016

The following table sets forth the Company's results of operations for the nine months ended on September 30, 2017 and the comparative period for the nine months ended September 30, 2016.

	Nine months Ended September 30, 2017 (\$)	Nine months Ended September 30, 2016 (\$)	Increase/ (Decrease) (\$)	Percentage Increase/ (Decrease) (%)
Revenues	-	-	-	-
General and administrative expenses	729,449	558,120	171,329	31%
Sales and marketing expenses	435,971	249,591	186,380	75%
Professional fees	1,182,837	1,272,638	(89,801)	(7%)
Salaries and office administrative fees	2,720,620	1,686,210	1,034,410	61%
Research and development expenses	5,774,004	5,180,466	593,538	11%
Total Operating Expenses	(10,842,881)	(8,947,025)	1,895,856	21%
Other Income	136,556	25,891	110,665	427%
Income Taxes				
Net Loss	(10,706,325)	(8,921,134)	1,785,191	20%
Basic and Diluted Loss Per Common Share	(0.41)	(0.40)	0.01	3%
Weighted Average Basic and Diluted Common Shares Outstanding	26,343,101	22,075,538	4,267,563	19%

#### Revenues

The Company had not generated revenues from operations in either the nine months ended September 30, 2017 or the nine months ended September 30, 2016. The Company's operations are still predominantly in the development stage.

#### **Total Operating Expenses**

For the nine months ended September 30, 2017, the Company's total operating expenses increased by \$1,895,856, or 21%, compared to the same period in 2016. Total operating expenses are comprised of general and administrative expenses, sales and marketing expenses, professional fees, salaries and office administrative fees and research and development expenses.

#### General and Administrative Expenses

General and administrative expenses increased by \$171,329, or 31%, in the nine-month period ended September 30, 2017 compared to the prior year period. The increase was primarily the result of the Company's insurance costs, which rose by \$52,393, additional costs of \$52,450 due to the move to a larger UK office, along with an increase in IT costs of \$50,121 associated with investments in IT security and controls.

#### Sales and Marketing Expenses

Sales and marketing expenses increased by \$186,380, or 75%, in the nine-month period ended September 30, 2017 compared to the prior year period. The increase was primarily a result of the recruitment of additional marketing personnel, incurring new costs of \$182,399.

#### **Professional Fees**

Professional fees decreased by \$89,801, or 7%, in the nine-month period ended September 30, 2017 compared to the prior year period. The decrease in professional fees was mainly as a result of reduced legal fees in respect of capital raises in 2016.

#### Salaries and Office Administrative Fees

Salaries and office administrative fees increased by \$1,034,410, or 61%, in the nine-month period ended September 30, 2017 compared to the prior year period. The increase was the result of an increase in the cost of stock option and warrant amortization expense of \$604,950 year-over-year, as well as some headcount and remuneration increases.

#### **Research and Development Expenses**

Research and development expenses increased by \$593,538, or 11%, in the nine-month period ended September 30, 2017 compared to the prior year period. Increases in costs on a year-over-year basis include the first payment for the EDRN study in the United States of \$250,000, increase in employment costs due to headcount and remuneration of \$235,063, and an increase in the cost of stock option amortization expense of \$59,150. Depreciation expense also increased by \$81,255 year-over-year due to the new research and development facility in March 2017.

#### Other Income

Other income increased to \$136,556 for the nine months ended September 30, 2017 compared to the comparable figure in 2016 of \$25,891, relating to grant funds received from public bodies in respect of approved expenditure with no obligation to repay.

#### Net Loss

For the nine months ended September 30, 2017, the Company's net loss was \$10,706,325, an increase of \$1,785,191, or 20%, in comparison to a net loss of \$8,921,134 for the nine months ended September 30, 2016. The change was a result of the factors described above.

#### **Off-Balance Sheet Arrangements**

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a 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 are material to stockholders.

#### **Future Financings**

We may seek to obtain additional capital through the sale of debt or equity securities, if we deem it desirable or necessary. However, we may be unable to obtain such additional capital when needed, or on terms favorable to us or our stockholders, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our stockholders will be reduced, stockholders may experience additional dilution, or such equity securities may provide for rights, preferences or privileges senior to those of the holders of our common stock. If additional funds are raised through the issuance of debt securities, the terms of such securities may place restrictions on our ability to operate our business.

#### **Critical Accounting Policies**

Our financial statements and accompanying notes have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP, applied on a consistent basis. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods.

We regularly evaluate the accounting policies and estimates that we use to prepare our financial statements. A complete summary of these policies is included in the notes to our financial statements. In general, management's estimates are based on historical experience, on information from third party professionals, and on various other assumptions that are believed to be reasonable under the facts and circumstances. Actual results could differ from those estimates made by management.



#### **Recently Issued Accounting Pronouncements**

The Company has implemented all applicable new accounting pronouncements that are in effect. The Company does not believe that there are any other applicable new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information under this item.

## ITEM 4. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

Disclosure controls and procedures are controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by our company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our Principal Executive and Principal Financial Officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management carried out an evaluation under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer have concluded, as they previously concluded as of December 31, 2016, that our disclosure controls and procedures continue to not be effective as of September 30, 2017, because of material weaknesses in our internal control over financial reporting, as described below and in detail in our Annual Report.

#### Changes in Internal Control over Financial Reporting

The Audit Committee of the Board of Directors meets regularly with our financial management, and with the independent registered public accounting firm engaged by us. Internal accounting controls and the quality of financial reporting are discussed during these meetings. The Audit Committee has discussed with the independent registered public accounting firm matters required to be discussed by the auditing standards adopted or established by the Public Company Accounting Oversight Board ("PCAOB"). In addition, the Audit Committee and the independent registered public accounting firm have discussed the independent registered public accounting firm's independence from the Company and its management, including the matters in the written disclosures required by PCAOB Rule 3526 "Communicating with Audit Committees Concerning Independence."

As of September 30, 2017, we did not maintain sufficient internal controls over financial reporting:

due to a lack of adequate segregation of duties in some areas of Finance; and

the to a lack of sufficient oversight in the area of IT, where certain processes may affect the internal controls over financial reporting.

We have developed, and are currently implementing, a remediation plan for such weaknesses. Specifically, we have identified and selected a system for financial reporting that will allow further automation of the reporting process, thereby strengthening the control environment over financial reporting.

As we continue to evaluate and work to enhance our internal controls over financial reporting, we may determine that additional measures should be taken to address these or other control deficiencies, and/or that we should modify our remediation plan.

There have been no changes in our internal controls over financial reporting that occurred during the fiscal quarter ended September 30, 2017, other than those described above, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.



#### Limitations of the Effectiveness of Disclosure Controls and Internal Controls

Our management, including our Principal Executive Officer and Principal Financial Officer, does not expect that our disclosure controls and internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control.

The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions; over time, a control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

### PART II - OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we may be subject to claims, counter claims, suits and other litigation of the type that generally arise from the conduct of our business. We know of no material, existing or pending legal proceedings against our company, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which our directors, officers or any affiliates, or any registered or beneficial shareholders, are an adverse party or have a material interest adverse to our interest.

## ITEM 1A. RISK FACTORS

There have been no material changes in our assessment of risk factors affecting our business since those presented in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 as filed with the Securities and Exchange Commission on March 10, 2017, as amended by those presented in our Quarterly Report on Form 10-Q, Item 1A., for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on May 11, 2017.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the quarter ended September 30, 2017, the Company issued the shares described below in private placements pursuant to Section 4(a)(2) of the Securities Act, and Rule 506 of Regulation D, in each case on the basis that the shares were offered and sold in a non-public offering to an "accredited investor" as defined in Rule 501 of Regulation D. Additionally, at the time of the issuances, unless registered for resale, the shares were deemed to be restricted securities under the Securities Act and the certificates evidencing such shares bear a legend to that effect.

On July 7, 2017, 5,000 warrants were exercised at a price of \$2.20 per share, for net cash proceeds to the Company of \$11,000. As a result, a total of 5,000 shares of common stock were issued to one U.S. accredited investor. The shares were registered for resale on Form S-3 (Registration No. 333-195213).

From July 9, 2017 through July 19, 2017, 45,000 warrants were exercised at a price of \$2.40 per share for net cash proceeds to the Company of \$108,000. As a result, a total of 15,000 shares of common stock were issued to one (1) U.S. accredited investor and 30,000 shares of common stock were issued to two (2) non - U.S. accredited investors.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

#### ITEM 5. OTHER INFORMATION

None.

			Incorporate	d by Referei	ice	
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
<u>10.1</u>	Clinical Study Agreement, dated July 17, 2017, by and between Volition America, Inc. and the Regents of the University of Michigan.					Х
<u>10.2</u>	Unsecured Credit Agreement, dated September 20, 2017, by and among VolitionRx Limited, Belgian Volition SPRL and SOFINEX (English translation of French original).	8-K	001-36833	10.1	09/21/17	
<u>31.1</u>	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.					Х
<u>31.2</u>	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.					Х
<u>32.1*</u>	Certifications of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					Х
101.INS	XBRL Instance Document.					Х
101.SCH	XBRL Taxonomy Extension Schema Document.					Х
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					Х
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					Х
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					Х
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					Х

The certifications attached as Exhibit 32.1 accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the registrant for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any of the registrant's filings under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in any such filing.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## VOLITIONRX LIMITED

Dated: November 9, 2017

Dated: November 9, 2017

By: /s/ Cameron Reynolds

Cameron Reynolds President and Chief Executive Officer (Authorized Signatory and Principal Executive Officer)

By: /s/ David Vanston

David Vanston Chief Financial Officer and Treasurer (Authorized Signatory and Principal Financial and Accounting Officer)

### CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (the "Agreement") is entered into on July 17, 2017 (the "Effective Date") by and among the Regents of the University of Michigan with its principal office and place of business at 3003 South State Street, Ann Arbor, MI 48109-1274 ("Lead Institution"), and Volition America, Inc., a Delaware corporation, with its principal office and place of business at 100 Congress Avenue, Suite 2000, Austin TX 78701 (together "Laboratory").

#### BACKGROUND

Laboratory has expressed an interest in participating with the National Cancer Institute ("NCI") Early Detection Research Network ("EDRN") (the "Clinical Study") Great Lakes New England Clinical Validation Center ("GLNE CVC") clinical study as set forth in the grant proposal submitted by the Regents of the University of Michigan ("Lead Institution") to the National Cancer Institute titled "the Great Lakes New England Clinical Validation Center," which Lead Institution has established with those research institutions listed on Exhibit A attached hereto (each, a "Research Institution") with funding provided by NCI. Together the Lead Institution and other Research Institutions are referred to as the "Institutions" under this Agreement. Each Research Institution has agreed to enroll patients in accordance with the protocol attached hereto as Exhibit A (as may be amended in accordance with this Agreement, the "Protocol"). The Institutions together will enroll approximately 9,000 adults age 60 or older who have not undergone a prior screening or diagnostic colonoscopy falling within the catchment areas defined by the Protocol (the "Study Subjects," as more specifically defined in Section 1.5 below). Samples obtained from Study Subjects in accordance with the Protocol (the "Samples," as more specifically defined in Section 4.1 below) will be tested for blood-based, cell-free circulating biomarkers on the Laboratory's proprietary Nu.Q<sup>TM</sup> platform ("Services" as more specifically defined in Section 2.1) at the laboratory facilities in Belgium and other places owned or contracted by Laboratory or its affiliates at no charge to the Lead Institution or the Research Institution, and Laboratory will provide a copy of all test results for the Clinical Study (the "Test Results") to Lead Institution's designated Data Management Coordinating Center (the "DMCC") following the completion of the performance of the Services by the Laboratory on the Samples. The DMCC will collect and store all such Test Results, and shall share Test Results with the Institutions for collaborative analysis.

## RECITALS

Whereas, the Laboratory is engaged in the business of diagnostic testing, including without limitation for clinical trials, development of new kits and assays and reference laboratory services;

Whereas, the Lead Institution has the qualified personnel, experience, facilities and resources to undertake and competently manage the Clinical Study, and has engaged and subcontracted with the Research Institutions to participate in the Clinical Study; and

Whereas, Laboratory and Lead Institution wish to perform the activities described and in adherence to the Protocol (the "Activities") as part of the Clinical Study, subject to the terms and conditions set forth herein.

NOW, THEREFORE, the parties hereto agree as follows:

### LEAD INSTITUTION RESPONSIBILITIES

1.1 Lead Investigator. Lead Institution's principal investigator is named on the signature page hereto and shall be designated as the Lead Investigator under this Agreement, and Lead Institution, including the Lead Investigator, shall be responsible for administrative activities in the conduct of the Clinical Study, as specified in the Protocol, including without limitation engaging and subcontracting with the Research Institutions and the principal investigators assigned by each Research Institution to the Clinical Study (each, a "Principal Investigator") and administering all payments to the Research Institutions from the consideration paid to Lead Institution in accordance with Section 3.

1.2 <u>IRB Approval</u>. The Lead Investigator shall obtain all requisite approvals from the Institutional Review Board ("IRB") of the Protocol, the Investigational Plan (as such term is defined in 21 C.F.R. Section 812.25), and the informed consent form to be used for Study Subjects ("Informed Consent"). Lead Institution will allow Laboratory to review and comment on-the Informed Consent used in the conduct of the Clinical Study. The Lead Investigator shall provide Laboratory with written confirmation of the IRB approval prior to Laboratory performing Services on any Study Subject Samples (as defined below). If the IRB withdraws approval of the Clinical Study at any time, the Lead Investigator shall immediately notify Laboratory and the Research Institutions in writing and concurrently provide a written explanation of the circumstances leading to such withdrawal. In such event, Laboratory, in its absolute discretion, may terminate this Agreement by written notice to the Lead Institution effective immediately upon delivery. Lead Investigator shall be responsible for notifying all of the Research Institutions and Principal Investigators of such termination.

1.3 <u>Protection of Human Subjects.</u> To the extent required by Applicable Law, each party shall promptly notify the other party of information discovered through the course of performing the Clinical Study that could affect the safety or medical care of participants, affect the willingness of participants to continue participation, influence the conduct of the study, or alter the IRB approval to continue the study. Lead Institution shall take reasonable measures to ensure that all Research Institutions and Principal Investigators shall (a) comply with the ethical standards used in human research; and (b) comply with the Protocol, applicable law, and its ethical standards to protect Study Subjects.

1.4 Commencement and Completion. It is anticipated that the Clinical Study will commence on the Effective Date and that Study Subject enrollment will be completed approximately three (3) years from initiation of enrollment on the study, unless this Agreement is otherwise terminated pursuant to its terms (the "Enrollment Period"). The parties anticipate that the Clinical Study will be completed within twelve (12) months thereafter (together with the Enrollment Period, the "Study Term"). The parties agree that time is a critical element of this Clinical Study, and the Lead Institution, including the Lead Investigator, agrees to use diligent efforts to complete the Clinical Study by the expiration of the Study Term.

1.5 <u>Study Subject Accrual</u>. The Clinical Study will involve a total of approximately 9,000 new Study Subjects (within the Enrollment Period) ("New Study Subjects") and 4677 previous Study Subjects ("Previous Study Subjects). New Study Subjects and Previous Study Subjects are collectively referred to as "Study Subjects". New Study Subjects shall be enrolled by Institutions pursuant to Protocol eligibility criteria and before the expiration of the Enrollment Period. Samples from each New Study Subject shall be obtained and forwarded to GLNE CVC.

1.6 <u>Study Subject Sample Access.</u> Laboratory will perform Services on Samples obtained from New Study Subjects (the "New Study Subject Samples") and from Previous Study Subjects (the "Previous Study Subject Samples"), which Lead Institution will coordinate with NCI to provide to Laboratory, as per the following schedule, in accordance with Section 4.2:

(i) Subject to available NCI funding and EDRN approval, a serum aliquot from each of the 4,677 Previous Study Subject Samples will be delivered to Laboratory. The time table to delivery of these samples rests with NCI resources as these samples are under control of the NCI at their Frederick MD repository. The Lead Institution will make very effort to obtain release of these samples from the Previous Study Subject Samples within one hundred eighty (180) days of the first quarterly payment by Laboratory as per Section 3.1 below, however, the parties acknowledge and agree that such releases, including the time required to identify and pull these samples, are subject to NCI priorities and resources; and

(ii) all New Study Subject Samples collected in a calendar quarter will be delivered on a schedule mutually agreed upon but at a maximum interval of ninety (90) days (quarterly) allowing at least ninety (90) days required to pull and ship the samples after completion of a given quarter; provided, that Laboratory will be supplied at least four hundred (400) New Study Subject Samples in each calendar quarter commencing January 1, 2018.

Laboratory shall not be obligated to perform Services on all New Subject Study Samples and Previous Study Subject Samples.

1.7 <u>Use of Samples</u>. To the extent permitted under applicable law and regulations and any relevant informed consent document, Laboratory shall have a perpetual, non-terminable and fully paid-up right to use all the Samples provided under this Agreement in connection with blood-based, cell-free circulating biomarkers on the Laboratory's proprietary Nu.Q<sup>TM</sup> platform including as part of the Services and for additional indications.

1.8 <u>Key Personnel.</u> The parties agree that the participation of the Principal Investigators are important to the successful performance and completion of the Clinical Study. If a Principal Investigator is unable to complete his or her responsibilities in connection with the Clinical Study for any reason, or withdraws from participation in the Clinical Study, the Lead Institution shall coordinate with the applicable Research Institution to appoint a successor, and the Lead Institution shall immediately notify Laboratory in writing of such successor.

1.9 <u>Laboratory Visits.</u> Lead Investigator shall ensure Laboratory's representatives may conduct periodic visits of Lead Insitution, at mutually acceptable times during normal business hours, and at Laboratory's sole reasonable expense, as applicable, to review the progress of the Clinical Study. Lead Institution shall cooperate with Laboratory and use reasonable efforts to provide all information requested. 1.10 <u>Changes to the Protocol</u>. In the event that modifications to the Protocol as it pertains to Laboratory Services provided hereunder appear desirable or necessary, such changes may be made through prior written agreement between the Laboratory and the Lead Institution, provided, however, any requisite IRB approval of such changes is obtained prior to implementing such changes to the Protocol. If in the course of performing this Agreement, however, generally accepted standards of clinical study and medical practice relating to the safety of Study Subjects require a deviation from the Protocol, such standards will be followed. In such case, the party aware of the need for a deviation will promptly inform the other party in writing of the facts causing such deviation as soon as the facts are known to that party. Lead Institution shall be responsible for notifying all of the Research Institutions and Principal Investigators of any such changes as they may pertain to Research Institution activities.

1.11 <u>Medical Records; HIPAA Privacy Rule ; and Genetic Testing Laws</u>. Lead Institution, including Lead Investigator, shall comply with all applicable Laws governing the privacy and security of Clinical Study participant information, including without limitation HIPAA, as well as applicable U.S. Federal and State genetic testing laws, and shall use reasonable measures to ensure that all Research Institutions and Principal Investigators do the same, including without limitation all applicable genetic testing laws of each Research Institution's jurisdiction.

1.12 <u>Advertising</u>. In the event Lead Institution elects to advertise to recruit patients for enrollment in the Clinical Study and such advertisements include reference to Laboratory, Lead Institution will provide a copy of any such advertisement to Laboratory for prior written approval. The Lead Institution will be responsible for obtaining IRB approval of all advertisements prior to use.

1.13 <u>Compliance with Law – Financial Disclosure</u>. The Lead Institution shall provide Laboratory with sufficient and accurate financial information, including without limitation facilitation of the acquisition of such information from Research Institutions, to allow the Laboratory to prepare and submit complete and accurate certification or disclosure statements as required under 21 C.F.R. Part 54, as amended. The Lead Institution shall also promptly update this information if any relevant changes occur during the course of the Clinical Study and for one (1) year following the completion of the Clinical Study.

## 2 LABORATORY RESPONSIBILITIES

2.1 <u>Laboratory Services.</u> "Laboratory Services" shall mean any clinical testing activities that shall be performed by Laboratory in the performance of the Clinical Study as set forth in the Protocol. Laboratory agrees to perform the Laboratory Services at no charge to NCI, the Lead Institution, the Research Institutions or Principal Investigators. Laboratory shall use commercially reasonable efforts to perform the Laboratory Services in compliance with (i) the terms and conditions of this Agreement, including without limitation, and to the extent applicable, the terms, specifications and limitations in the Protocol and any amendments thereto; (ii) Laboratory's standard operating procedures for the applicable tests to be provided; (iii) any applicable laws, regulations or rulings governing its performance, including without limitation all applicable health, medical privacy and safety laws and regulations, and all applicable laws and regulations with respect to the handling and disposal of infectious or hazardous waste.

2.2 <u>Laboratory Limitations</u>. Laboratory will not: (i) use Study Subject information except for the purposes of the Clinical Study and as authorized by the Study Subject in the Informed Consent Form; (ii) disclose Study Subject-identifying information or disclose Study Subject private information to any third party (other than as permitted by Research Institutions, NCI and Lead Institution or the Repository) unless required to do so by Applicable Law or government order or pursuant to a written request of the Study Subject; (iii) remove de-identified Study Subject information from Samples; or (iv) attempt to contact any Study Subject not previously known to Laboratory, as applicable, unless required to protect the Study Subject's welfare.

## 3 CONSIDERATION

3.1 In consideration of its participation in the Clinical Study on the terms and conditions of this Agreement, Laboratory shall provide direct and indirect funding in the amount of up to Three Million United State Dollars (US\$3,000,000). Direct payments by the Laboratory for the Clinical Study will be as follows:

Starting one (1) month from the date of Institutional Review Board approval from the Calgary, Canada Institution and 50% of participating United States Institutions, Laboratory will make up to twelve (12) quarterly installment payments to Lead Institution of Two Hundred Fifty Thousand United States Dollars (US\$250,000) each not to exceed three million United States Dollars (US\$3,000,000) in total payments under Section 3 during the term of this Agreement.

3.2 The funding amounts detailed in Section 3.1 are the sole consideration for Laboratory's participation in the Clinical Study, and are inclusive of all rights provided to Laboratory herein, including without limitation pursuant to Sections 1.5, 1.6, 1.7, 7 and 8. All of the funding amounts provided hereunder shall be used for costs and expenses of the Clinical Study.

3.3 The funding amounts detailed in Section 3.1 will be provided to the GLNE Operations Office at the University of Michigan pursuant to the issuance of an invoice to Laboratory by Lead Institution.

## 4 CLINICAL STUDY SAMPLES

4.1 <u>Study Samples</u>. The term "Samples" shall be understood to include biological materials derived from New Study Subjects enrolled in the Clinical Study, including but not limited to: blood plasma, serum, feces, DNA extracts and other biological materials as may be agreed between the Parties. The term "Samples" shall also include biological materials extracted prior to the Enrollment Period from Previous Study Subjects meeting the eligibility criteria set forth in the Protocol and banked for future use, solely to the extent any such Samples may be used for such purpose, in accordance with all the requirements of this Agreement, including without limitation Study Subject approvals and waivers, as necessary. Without limiting the foregoing, Laboratory will receive 4 ml of serum from each of the New Study Subject Samples and at least 2 ml of serum from each of the Previous Study Subject Samples. To the extent that more than 2 ml of serum from Previous Study Subject Samples is available, up to a maximum of 4 ml will be provided to Laboratory.

4.2 <u>Transfer of Study Samples</u>. The Samples will be stored by either GLNE CVC or NCI. Where Samples are stored by GLNE CVC, Lead Institution shall be solely responsible for the proper delivery and transport of the Samples to Laboratory under the terms of this Agreement in compliance with all applicable international, federal, state and local laws, regulations, and standards for the shipment and transportation of biological specimens from their point of origin to Laboratory's facility located in Belgium. Lead Institution and Laboratory shall agree on the day and time for delivery of the Samples to Laboratory. All Samples are considered biohazardous and should be handled, stored, and transported according to appropriate laws, regulations, and government guidelines, including those issued by the Occupational Safety and Health Administration, the Centers for Disease Control and Prevention, and the Department of Transportation. Where Samples are stored by NCI, the Samples will be provided to Laboratory pursuant to the NCI Materials Transfer Agreement set forth in Exhibit B and executed by Latoratory and NCI.

## 5 STUDY RECORDS, REPORTS AND DATA

5.1 <u>Study Records.</u> Lead Institution, including Lead Investigator, shall maintain, and Lead Institution shall cause all Research Institutions and Principal Investigators to maintain, complete, accurate and current Clinical Study records for its Study Subjects as set forth in the Protocol ("Study Records"). Lead Investigator shall retain the right to audit all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data and summaries of financial records. All Study Records shall be retained by each Institution for a period of two (2) years after the later of completion of the Clinical Study or termination of this Agreement, whichever is later, or such longer period as specified in the Protocol or as required by law.

5.2 <u>Case Report Forms.</u> Lead Institution shall obligate each Research Institution to promptly complete full clinical evaluations and original or electronic case report forms ("CRFs"), as appropriate, on each Study Subject in accordance with the Protocol.

5.3 <u>Annual Reports</u>. During the term of this Agreement, Lead Institution shall provide Laboratory with annual written reports, detailing the progress of the Clinical Study. Such reports shall include the number of Study Subjects, the number of Samples obtained, a summary of any adverse events, and a general description of the Clinical Study's progress. Lead Institution shall provide such reports to the Laboratory within ninety (90) days after each anniversary of the Effective Date. Lead Institution shall also provide Laboratory with quarterly reports commencing the second quarter after the Effective Date. These quarterly reports are only required to provide the number of Study Subjects enrolled, on trial, completed trial, ineligible, eligible and numbers of endpoint events for analysis and will be provided together with the invoices issued by Lead Institution in respect of the quarterly payments detailed in Section 3.1(c).

5.4 <u>Final Report</u>. Within ninety (90) days after completion or termination of the Clinical Study, the Lead Institution shall provide to the Research Institutions, Laboratory, and to the IRB a final Clinical Study report similar in content to the annual report specified in Section 5.3.

## **CONFIDENTIALITY**

6.1 <u>Confidential Information</u>. "Confidential Information" shall mean any information, data or material that is identified as confidential at the time of disclosure and is disclosed by a party ("Disclosing Party") to the other party ("Receiving Party") in connection with the Clinical Study or any other activities in connection with this Agreement and, if disclosed in non-tangible form, is confirmed as confidential in writing within twenty (20) working days of disclosure. Confidential Information shall not include information that: (i) was generally known and available in the public domain at the time it was disclosed, or becomes generally known and available in the public domain through no breach of this Agreement by the Receiving Party; (ii) was known by Receiving Party prior to disclosure, as demonstrated by written records; (iii) was developed by the Receiving Party independently of and without reference to the Confidential Information, or (iv) is received by Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party.

6.2 <u>Nondisclosure/Nonuse</u>. Except as otherwise expressly provided herein, for the term of this Agreement and for a period of five (5) years thereafter, no Receiving Party shall disclose to any third party Confidential Information disclosed hereunder, and shall not use for any purpose other than as expressly provided herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, Receiving Party shall disclose Confidential Information only to those employees or contractors of Receiving Party who require such Confidential Information to any employee or contractors, Receiving Party shall advise such employee or contractor of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event Receiving Party is required to disclose Confidential Information pursuant to law or the order or requirement of a court, administrative agency, or other governmental body, Receiving Party may disclose such Confidential Information to the minimum extent necessary provided that the Receiving Party provides the Disclosing Party with reasonable advance written notice thereof to enable Disclosing Party to seek a protective order or otherwise prevent such disclosure.

6.3 <u>Protection</u>. Each Receiving Party shall maintain reasonable procedures to prevent accidental or other loss or disclosure of any Confidential Information of Disclosing Party, and shall use at least the same procedures and degree of care that it uses to protect its own proprietary information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party or other party aware of such breach of this Section 6 shall immediately notify Disclosing Party in writing, specifying all details of the circumstances.

6.4 <u>Return of Confidential Information</u>. Except as otherwise provided herein, upon termination, cancellation or expiration of this Agreement for any reason, all documents and other tangible items containing Confidential Information, together with all copies or summaries, abstracts or synopsis thereof shall be promptly returned to the applicable Disclosing Party, provided however, that one (1) copy of Confidential Information may be retained for archival purposes. If Disclosing Party requests, each Receiving Party shall provide written confirmation that they have returned all such materials to Disclosing Party.

## **PUBLICATION**

7.1 The parties recognize the value of disseminating research results. It is understood that publication of results of the Clinical Study is expected. The Lead Investigator will collaborate with the Laboratory and the Research Institutions and Principal Investigators to publish the results of the Clinical Study, subject to the obligations of Section 6 above and this Section 7. Drafting of documents for publication and co-authorship shall follow the guidelines of the International Committee of Medical Journal Editors' "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (updated October 2008). Lead Institution will register and update the Study listing on ClinicalTrials.gov.

7.2 The Lead Institution, including Lead Investigator shall furnish Laboratory with a written copy of any proposed publication or disclosure, including without limitation, disclosures at research seminars, lectures and professional meetings and the submission of papers for publication that include Laboratory submitted results at least sixty (60) days prior to submission for publication or disclosure so that Laboratory may have a reasonable opportunity to review the accuracy of the information related to the results generated by Laboratory under this Agreement and protect its proprietary rights to information, inventions, or products developed under the Clinical Study. Lead Institution, including Lead Investigator shall consider Laboratory's comments in good faith. Further, if Laboratory indicates that such publication or disclosure contains Confidential Information provided by Laboratory, the Lead Institution, including Lead Investigator, when applicable may release the draft document for publication or disclosure. Lead Institution, including Lead Investigator, when applicable may release the draft document for publication or presentation after the aforementioned 60-day term has elapsed; provided that if, during the 60-day review period, Laboratory indicates that additional time is required to apply for patents to protect proprietary rights to inventions or products developed under the Clinical Study that are disclosed in the proposed publication, Lead Institution, including Lead Investigator, when applicable may release the draft document for publication or presentation after the aforementioned 60-day term has elapsed; provided that if, during the 60-day review period, Laboratory indicates that additional time is required to apply for patents to protect proprietary rights to inventions or products developed under the Clinical Study that are disclosed in the proposed publication, Lead Institution, including Lead Investigator, when applicable, will delay such publication for a period of up to ninety (90) days to

7.3 Except as set forth in this Agreement or the Protocol, Laboratory will not use the Institutions' name(s) in any advertising, marketing, or sales promotional material without the Institutions prior written approval, or in any material that implies or suggests endorsement of a product or service of Laboratory; <u>provided</u>, that, as soon as practicable following the date hereof, Laboratory may issue a press release approved by Lead Institution announcing the existence of this Agreement and Laboratory's participation in the Clinical Study. Additionally, Laboratory may make public statements in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by Lead Institution pursuant to this Section 7.3 and which do not reveal non-public information about the Institutions.

## 8 **OWNERSHIP RIGHTS**

8.1 Data. Each Institution shall retain ownership of Study Records, which shall be the Confidential Information of the applicable Institution. Subject to the publication rights set forth in Section 7.2 above, any Test Results or other data resulting from the Laboratory Services performed on samples from the Study Subjects and provided by Laboratory ("Results"), shall be jointly owned by Laboratory and the applicable Institution enrolling such Study Subjects. Lead Institution acknowledges that (i) Laboratory, in accordance with such joint ownership shall have the royalty-free right to use the Results for any purpose, including, without limitation, incorporating some or all of the Results in its own patient database and forwarding such Results to the DMCC as requested by Lead Investigator, and (ii) the Institution enrolling Study Subjects, in accordance with such joint ownership shall have the royalty-free right to use the Results use the Results solely for research purposes and not commercialization.

8.2 <u>Inventions.</u> Inventorship of patentable inventions shall be determined by U.S. Patent Law and ownership shall follow inventorship.

8.3 <u>Rights of U.S. Government.</u> All rights granted herein are subject to the applicable rights and regulations of the U.S. Government.

## **REPRESENTATIONS AND WARRANTIES**

9.1 Lead Institution. Lead Institution represents and warrants that: (i) it has the legal authority and right to enter into this Agreement; (ii) it has no obligation to any other party which materially impairs its ability to fulfill its obligations under this Agreement; (iii) it will conduct its activities in connection with the Clinical Study in accordance with the Protocol and in full compliance with all applicable local, state and federal laws and regulations for the protection of the rights, safety and welfare of human subjects in clinical trials, and the conditions of the IRB; and (iv) the Clinical Study was approved by the IRB. Lead Institution represents that it is not aware of any circumstance, including but not limited to any restrictions placed on the use of the Study Samples by the IRB that would prevent it from freely transferring the Study Samples to Laboratory for the purposes described in this Agreement.

Lead Institution represents to Laboratory that it will use reasonable measures to assure that:

(a) each Research Institution, the Clinical Study will be conducted under the supervision of the applicable Principal Investigator, and Lead Institution shall provide Laboratory with the curriculum vitae of any Principal Investigator upon request.

(a) the Research Institution and Principal Investigator shall perform the Clinical Study as set forth in the Protocol in compliance with: (a) generally accepted standards of good clinical practice, (b) the Protocol, (c) written instructions provided by the Lead Investigator, and (d) all applicable local, state and federal laws and regulations governing the performance of clinical investigations including but not limited to (i) the Investigational Device Exemptions regulations (21 C.F.R. Section 812, Subpart E, et seq.); (ii) those relating to the rights, safety and welfare of human subjects in clinical trials; (iii) those relating to kickbacks and physician, referrals including, without limitation, 42 U.S.C. Sec. 1320a-7b(b) et. Seq. and 42 U.S.C. Sec. 1395nn; and (iv) the Health Insurance Portability and Accountability Act ("HIPAA"), as set forth below ("Applicable Law").

(t)will obligate the Research Institutions to not deviate from the Protocol without the prior written consent of Lead Investigator, except as necessary to ensure Clinical Study participant safety, in which case the applicable Principal Investigator will immediately notify the Lead Investigator of such deviation in writing.

(d) h Research Institution shall provide adequate personnel to conduct the Clinical Study, and all such personnel shall have the necessary education, training, licensure and experience to perform their respective Clinical Study responsibilities, including without limitation, appropriate training on the enrollment of eligible Study Subjects, the Protocol and all other relevant activities requested by Lead Investigator or Laboratory in performance thereof.

(a)ch Principal Investigator shall obtain a written authorization, Informed Consent and IRB waiver for all Study Subjects enrolled through the applicable Research Institution prior to performance of any procedures in connection with the Clinical Study, which authorization, consent and waivers shall include the right for Lead Institution to disclose their information in connection with the Clinical Study, including genetic testing information if applicable, to the Repository and the Laboratory for their use in connection with the Clinical Study to the extent necessary to perform the activities contemplated by the Protocol and to comply with Applicable Laws relating to the Clinical Study.

9.2 <u>Laboratory</u>. The Laboratory represents and warrants that: (i) it has the legal authority and right to enter into this Agreement; (ii) it has no obligation to any other party that is in conflict with its obligations under this Agreement and (iii) the person executing this Agreement on its behalf has been authorized to do so.

9.3 <u>No Impairment; No Conflict</u>. During the term of this Agreement, Lead Institution represents that it will not enter into any agreement to provide services that would in any way materially impair its ability to complete the Clinical Study in accordance with the Protocol and the terms of this Agreement.

9.4 <u>No Action by FDA</u>. Lead Institution represents that it has not received any warnings or other adverse communications from the FDA relating to the conduct of a human clinical trial that would affect its participation in the Clinical Study or compliance with the terms of this Agreement with respect to itself, or any Research Institution or Principal Investigator.

9.5 <u>No Pending Litigation</u>. Lead Institution represents that it is not currently involved in, nor is it aware of, any pending claim, litigation or proceedings relating to its role in the conduct of a human clinical trial. Lead Institution represents that it is not aware of any such claim, litigation or proceeding with respect to Research Institutions or Principal Investigators.

9.6 <u>Full Disclosure</u>. Lead Institution has provided written notice to Laboratory of any (i) clinical study or trial in which the Lead Investigator or, to the best of its knowledge, any Principal Investigator was involved that was terminated for any reason prior to completion, (ii) receipt of Form 483 Notices of Observation from the FDA, Notice of Adverse Findings or any regulatory warning letter by Lead Institution or any Research Institution, and (iii) disqualifications of such Lead Investigator or any Principal Investigator from receiving investigational drugs or medical devices by the FDA or any comparable foreign regulatory entity.

9.7 <u>No Debarment</u>. Lead Institution, including Lead Investigator, hereby certifies that, to the best of its knowledge, all of the Research Institutions and their respective Principal Investigators, have not been debarred under the provisions of 21 U.S.C. §335a(a) or (b), as amended. In the event that the Lead Institution: (i) becomes debarred or learns that Lead Investigator, a Research Institution or Principal Investigator is debarred; or (ii) receives notice of action or threat of action with respect to such debarment, during the term of this Agreement, Lead Institution or Principal Investigator becomes debarred as set forth in clause (i) above, the Lead Institution shall immediately terminate its participation in this Agreement without any further action or notice by any party hereto. In the event that Lead Institution notifies Laboratory of action or threat of action as set forth in clause (ii) above, the Laboratory will have the right to terminate or suspend (in its sole discretion) provision of Laboratory Services immediately.

9.8 <u>No Services of Debarred Persons</u>. Each party hereby certifies that they have not and will not use in any capacity the services of any individual, corporation, partnership or association in connection with the Clinical Study which has been debarred under 21 U.S.C. §335a(a) or (b), as amended. In the event that a party becomes aware of the debarment or threatened debarment of any individual, corporation, partnership or association providing services to such party which directly or indirectly relates to such party's activities under this Agreement, such party will notify the other parties in writing immediately, and such party may immediately terminate its participation in this Agreement without any further action or notice by any party hereto.

9.9 No Other Warranties. EXCEPT FOR THE LIMITED WARRANTIES GIVEN IN THIS SECTION 9, THE PARTIES HERETO MAKE AND RECEIVE NO WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE WITH RESPECT TO THE SUBJECT MATTER CONTAINED HEREIN, AND EACH EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE.

9.10 <u>Healthcare Compliance Laws</u>. Each party agrees to comply with all applicable laws and regulations. Neither Laboratory nor Lead Institution shall engage in any activity prohibited by anti-kickback, anti self-referral, or any other federal, state or local law or regulation which relate to health care and/or the performance of services under this Agreement, as those regulations now exist or as subsequently amended, renumbered, revised or promulgated. Lead Institution shall use reasonable measures to ensure that all Research Institutions shall comply with all applicable laws. It is not the intent of either Laboratory or Lead Institution, including Lead Investigator, that any payments, gift, donation or other consideration made under this Agreement be in return for the referral of ongoing business, if any, or in return for the purchasing, leasing, or ordering of any services other than the specific services described in this Agreement. All payments or transfers of value specified in this Agreement are consistent with fair market value in an arms-length transaction for the goods or services provided.

## **INDEMNIFICATION AND INSURANCE**

10.1 <u>Laboratory Indemnification</u>. Laboratory shall hold harmless and indemnify Lead Institution, its trustees, officers, medical and professional staff (including its Lead Investigator), employees, agents, successors or assigns from and against third party claims for personal injury (including death) to any person or damage to property arising out of or in connection with Laboratory's or its employees' acts or omissions, except to the extent such claims arise from Lead Institution's breach of this Agreement including without limitation failure to follow the Protocol, negligence or willful misconduct.

10.2 Institution Indemnification. To the extent permitted by law, Lead Institution shall hold harmless and indemnify the Laboratory and its directors, officers, employees, agents, successors or assigns from and against third party claims for personal injury (including death) to any person or damage to property resulting from the acts or omissions of the Lead Investigator or Lead Institution including failure of such Lead Investigator to adhere to the Protocol, Laboratory's written instructions with respect to the Clinical Study, or applicable FDA or other governmental requirements except when such actions are necessary for patient safety, clinical care and treatment purposes in the reasonable medical judgment of the Lead Investigator.

10.3 <u>Procedure</u>. Any party entitled to indemnification under this Section 10 shall give the indemnifying party prompt notice of any covered claim, shall provide the indemnifying party with the opportunity to defend against the claim, and shall reasonably cooperate in such defense at the indemnifying party's expense; provided, however, failure of any party to do so shall not relieve the other party of its obligation(s) to indemnify, except to the extent that the indemnifying party can demonstrate it was actually prejudiced by such failure. Notwithstanding anything to the contrary in this Agreement, neither party shall enter into any settlement, consent judgment, or other voluntary final disposition of any claim that has a material adverse effect on the rights of the other party or admits any wrongdoing or fault by the other party or imposes on the other party any payment or other liability, without the prior written consent of the other party.

10.4 <u>Insurance</u>. Each party shall, at its own expense, maintain a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. During the term of this Agreement and upon one party's request, the other party shall provide such party with a certificate of insurance (or the self-insured equivalent) and shall provide to such party thirty (30) days' prior written notice of cancellation of such insurance.

## 11 TERM AND TERMINATION

11.1 Term. This Agreement shall begin on the Effective Date and remain in full force and effect for the Study Term or until the completion of the Clinical Study and submission of the final report pursuant to Section 5.4 above, unless earlier terminated in accordance with this Section 11.

11.2 <u>Termination at Will</u>. Either party may terminate this Agreement upon sixty (60) days prior written notice to the

11.3 <u>Partial Termination by Lead Investigator and/or Laboratory</u>. In the event that a Principal Investigator becomes unavailable or withdraws from the Clinical Study, and the Research Institution is unable to appoint a successor within thirty (30) days after Lead Investigator is so notified in writing, Laboratory may request that Lead Investigator terminate such Research Institution's participation in the Clinical Study.

11.4 <u>Termination for Breach</u>. Any party to this Agreement may terminate participation in this Agreement upon thirty (30) days' prior written notice to the other party of such party's material breach of this Agreement if such breach is not cured within such thirty (30) day period.

11.5 Effect of Termination. In the event of termination of this Agreement, for any reason (including, without limitation, completion of the Clinical Study), the Lead Investigator shall cease providing Study Samples to Laboratory; provided, that, to the extent permitted by applicable law and regulations and any relevant informed consent document, Laboratory shall have the continued right to use the Study Samples in its possession in connection with blood-based, cell-free circulating biomarkers on the Laboratory's proprietary Nu.Q<sup>TM</sup> platform including for additional indications. Within one hundred eighty (180) days from the effective date of any termination (including, without limitation, completion of the Clinical Study), the Lead Investigator and Lead Institution shall obtain from the Research Institutions and Principal Investigators all available unblinded patient data collected in connection with the Clinical Study including without limitation Annual Reports and the final written report described in Section 5.4 above, and except as otherwise provided herein, any materials and Confidential Information provided by Laboratory or Lead Institution for the conduct of the Clinical Study; provided, however that one (1) copy of Confidential Information may be retained for archival purposes. If Lead Institution or Laboratory terminates this Agreement for any reason, Lead Institution will provide, and Laboratory will have the perpetual right to use, all available unblinded patient data for the Study Samples already paid for and received by Laboratory on the completion of the Clinical Study. If the Clinical Study is terminated for any reason, Lead Institution will provide, and Laboratory will have the perpetual right to use, all available unblinded patient data for the Study Samples already provided to Laboratory immediately upon termination and completion of the analysis by relevant EDRN components (e.g. Data Management and Coordinating Center) of the Clinical Study. For avoidance of doubt, the patient data included in the Case Report Forms to the Protocol shall be made available to Laboratory under this Section 11.5, which shall include, without limitation, (a) patient conditions (i.e. colorectal cancer, high risk adenoma), (b) age, (c) sex, (d) any other history, and (e) any other diseases. In addition, Lead Institution agrees to, and will ensure that all Research Institutions, hold unblinded patient data for at least three (3) months after the completion of the Clinical Study.

11.6 <u>Survival</u>. Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of such termination. The rights and duties under Sections 1.3, 6, 7, 8, 9, 10.1, 10.2, 10.3, 10.4, 12.1, 12.2, and 12.7, and the last sentence of Section 5.1 shall survive the expiration or termination of this Agreement for any reason.

## **MISCELLANEOUS**

12.1 <u>Use of Names.</u> Except as permitted in Section 7 above, no party to this Agreement shall use the name or other identifying marks of any other party in any advertising, promotional or sales literature or in any news release or other media publicity without the prior written consent of the party whose name or mark is to be used. Notwithstanding the foregoing, no party shall unreasonably withhold its consent to any use of its name, which accurately and appropriately describes the scope and nature of the parties' participation in the Clinical Study, and which does not imply directly or indirectly any endorsement of the other party or its products by the party whose name is to be used.

12.2 <u>Assignment</u>. The parties agree that their rights and obligations under this Agreement may not be delegated, transferred or assigned to a third party without prior written consent of the other parties hereto. Notwithstanding the foregoing, Laboratory may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets pertaining to the subject matter of this Agreement whether by sale, merger, operation of law or otherwise.

12.3 <u>Force Majeure</u>. No party hereto will be held liable or responsible to the other parties, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected party, including, without limitation, fire, floods, earthquakes, natural disasters, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God, or acts, omissions or delays in acting by any governmental authority or other party hereto.

12.4 <u>Notices</u>. Any notice required or permitted hereunder shall be in writing and shall be deemed to have been delivered (i) when delivered by hand; or (ii) when shipped by private express carrier (such as DHL), shipping charges prepaid, to the party to whom delivery shall be made at the respective addresses as set forth below, or such other address as the party may substitute by written notice; or (iii) when faxed to the number set forth below with confirming letter mailed thereafter under the conditions described in (ii).

If to Laboratory:	Volition American, Inc. Suite 2000 100 Congress Avenue Austin, TX 78701 Attn: Jason Terrell
If to Lead Institution:	Regents of the University of Michigan c/o Dean E. Brenner, Lead Investigator 2150 Cancer Center 1500 E Medical Center Drive Ann Arbor, MI 48109-5930
Lead Investigator:	Dean E. Brenner, M.D. 2150 Cancer Center 1500 E Medical Center Drive Ann Arbor, MI 48109-5930

12.5 <u>Governing Law</u>. This Agreement shall be governed and construed by the laws of Michigan, without reference to its conflict of laws principles.

12.6 Limitation of Liability. IN NO EVENT SHALL ANY PARTY BE LIABLE TO ANY OTHER PARTY FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE SUBJECT MATTER HEREOF, HOWEVER CAUSED AND WHETHER SUCH CLAIM IS BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF SUCH PARTY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THIS LIMITATION OF LIABILITY SHALL BE RESTRICTED TO THIS CLINICAL STUDY ONLY AND SHALL NOT EXTEND TO ANY OTHER CURRENT OR FUTURE STUDY CONTRACT AGREEMENTS BETWEEN ANY OF THE PARTIES.

12.7 <u>Modification; Waiver</u>. This Agreement may not be altered, amended or modified in any way except in writing signed by the parties. The failure of a party to enforce any provision of this Agreement shall not be construed to be a waiver of the right of such party to thereafter enforce that provision or any other provision or right.

12.8 <u>Severability</u>. In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the parties in entering this Agreement.

12.9 Independent Contractors. The parties agree that the relationship between the Laboratory, the Lead Institution and Lead Investigator created by this Agreement is that of independent contractors and that neither the Lead Investigator nor the Lead Institution may create or assume any obligations on behalf of the Laboratory.

12.10 <u>Entire Agreement</u>. This Agreement and the Exhibits attached hereto represent the entire understanding of the parties with respect to the subject matter of this Agreement, and supersede all prior discussions, agreements and writings in respect to such subject matter. In the event of any inconsistency between this Agreement and the Exhibits, the terms of this Agreement shall govern.

12.11 <u>Counterparts</u>. This Agreement may be executed in counterparts and delivered by fax, each of which shall be deemed an original, and all of which, together, shall constitute one and the same instrument.

12.12 <u>Headings</u>. Headings are provided solely for the benefit of the Parties and shall not be used to interpret or construe

## LABORATORY

## LEAD INSTITUTION

## THE RECKNUS KOPNIA MIRRICARE RESIDENCE OF MICHIGAN

By: /s/ Kevin P. Hegarty Name: Kevin P. Hegarty Title: Execitive Vice President & Chief Financial Officer

Date: 7.12.2017

## LEAD INVESTIGATOR

By: <u>/s/ Dean E. Brenner</u> Name: Dean E. Brenner Title: Professor of Internal Medicine

## By: /s/ Jason Terrell

Name: Jason Terrell MD Title: Executive Executive Officer Volition America, Inc

Date: 7.17.2017

EXHIBIT A

## STUDY PROTOCOL

GLNE 010, Version 5.0 March 6, 2017

[EDRN to insert]

### EXHIBIT B

## NCI MATERIAL TRANSFER AGREEMENT for

4.0 mLs of frozen human plasma from Study Subjects conforming to sample collection as described in the Early Detection Research Network ("EDRN") Study Protocol and at least 2 mLs but upto 4 mLs, if available, of previously banked frozen human serum samples from the same Study Subjects collected as described in GLNE 010. These Samples are transferred under the terms of the EDRN Clinical Study Agreement executed between the Regents of the University of Michigan and Volition America, Inc. (the "Clinical Study Agreement")

## RECIPIENT: SCIENTIST:

1. The NCI agrees to transfer to the RECIPIENT the following MATERIAL, which is the property of the original provider of the MATERIAL to the NCI:

(hereinafter referred to as "MATERIAL") and any clinical data, results and raw data relating to the MATERIAL that neither contains nor is associated with identifiable private information ("DATA").

2. THIS MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The MATERIAL will not be used for commercial purposes such as screening, production or sale, for which a commercialization license may be required. The RECIPIENT agrees to use the MATERIAL and DATA in compliance with all applicable statutes and regulations. The MATERIAL is to be used solely for the research specified in Exhibit A attached to the Clinical Study Agreement and only by the RECIPIENT SCIENTIST and those persons under his or her direct supervision. All requests for use for other persons should be forwarded to the EDRN Executive Committee.

3. The MATERIAL and DATA have been collected from human subjects in accordance with all applicable federal regulations for the protection of human subjects, including, as applicable, 45 CFR Part 46, "Protection of Human Subjects," and the *Standards for Privacy of Individually Identifiable Health Information* set forth in 45 C.F.R. Part 164, and appropriate Assurances and IRB approved protocols, which include all necessary informed consents and authorizations. NCI provides the MATERIAL pursuant to an exemption from IRB approval (NIH Office of Human Subjects Research Protections Exemption #\_\_\_\_). The DATA provided by NCI neither contains nor is associated with identifiable private information. RECIPIENT agrees to use the MATERIAL in compliance with all applicable laws, regulations, and policies of the National Institutes of Health relating to human subjects and human biospecimens. The RECIPIENT agrees not to attempt to obtain identifying information on, or otherwise seek to re-identify or contact the human subjects associated with the MATERIAL or DATA provided under this Agreement.

4. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE NCI MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL OR DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this Agreement, except that the NCI, as an agency of the United States Government, assumes liability only to the extent as provided under the Federal Tort Claims Act, 28 USC, chapter 171.

5. The MATERIAL is provided at no cost.

6. Inventorship of any inventions arising from the RECIPIENT's use of the MATERIAL shall be governed by U.S. patent law. Ownership of such inventions shall follow the laws and RECIPIENT's institutional rules governing assignment obligations of the inventors. No right, title or interest in any such invention is transferred by virtue of this Agreement.

7. The RECIPIENT agrees to acknowledge the contributions of the NCI's EDRN program in all publications resulting from the use of this MATERIAL. It is recommended that the following statement be included in the methods or acknowledgement section of such publications: *"Tissue samples were provided by the National Cancer Institute on behalf of the Early Detection Research Network (EDRN)."* By entering into this Agreement, the NCI does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to this Agreement.

8. The NCI shall have the right to terminate this Agreement if the RECIPIENT materially breaches any of its obligations or responsibilities under this Agreement, and such material breach is not cured within thirty (30) days of receipt of written notice from the NCI. Upon termination, the RECIPIENT will, at the NCI's discretion, either return or destroy any remaining MATERIAL and DATA in accordance with applicable laws and regulations.

9. The RECIPIENT and RECIPIENT SCIENTIST agree to deposit all primary data and processed data obtained using the MATERIAL with the EDRN Data Management and Coordinating Center (DMCC) within four (4) months after processing the MATERIAL in accordance with the Clinical Study Agreement. The DMCC will conduct the data analysis and results will be provided to the RECIPIENT SCIENTIST. The results will be posted on a secure domain of the EDRN website (eCAS) three (3) months after the results have been provided to the RECIPIENT SCIENTIST. The NCI EDRN reserves the right to post the results to its public website upon completion of the study.

10. This Agreement may be executed in one or more counterparts, each of which together shall be deemed original but all of which together shall constitute one and the same document. A facsimile or Portable Document Format (PDF) of the original signature of the representative of a party shall have the same validity as an original signature for the purpose of this Agreement.

The RECIPIENT and the NCI must both sign this agreement and then the NCI will send the MATERIAL.

FOR THE RECIPIENT:

RECIPIENT Scientist:\_\_\_\_\_\_\_RECIPIENT Organization:\_\_\_\_\_\_

 Name of Authorized Official:

 Title of Authorized Official:

 Address:

Signature of Authorized Official \_\_\_\_\_\_ Date: \_\_\_\_\_

FOR THE NCI:

Name of Authorized Official:Lisa D. Finkelstein, Ph.D.Title of Authorized Official:Technology Transfer Specialist<br/>Technology Transfer Center<br/>National Cancer Institute<br/>9609 Medical Center Drive, Rm 1E530<br/>Rockville, MD 20852

\_\_\_\_\_

Signature of Authorized Official: Date:\_\_\_\_\_

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Cameron Reynolds, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VolitionRx Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2017

/s/ Cameron Reynolds

Cameron Reynolds President and Chief Executive Officer

### CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Vanston, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VolitionRx Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2017

/s/ David Vanston

David Vanston Chief Financial Officer and Treasurer

## CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certifications are hereby made in connection with the Quarterly Report on Form 10-Q of VolitionRx Limited (the "Company") for the quarterly period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"):

I, Cameron Reynolds, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: November 9, 2017

/s/ Cameron Reynolds Cameron Reynolds President and Chief Executive Officer

I, David Vanston, Chief Financial Officer and Treasurer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: November 9, 2017

/s/ David Vanston

David Vanston Chief Financial Officer and Treasurer