VOLITIONRX LTD Form 10-Q November 04, 2015

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, 2015

. 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)

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Accelerated Filer

Large Accelerated Filer

reporting company" in Rule 12b-2 of the Exchange Act.

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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).

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller

X.Yes .No

Non-Accelerated Filer

Smaller Reporting Company

Χ.

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(Do not check if smaller reporting company)

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 4, 2015, there were 18,472,215 shares of the registrant s \$0.001 par value common stock issued and outstanding.

QUARTERLY REPORT ON FORM 10-Q

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2015

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Please note that throughout this Quarterly Report, and unless otherwise noted, the words "we," "our," "us," the "Company," or "VNRX" refers to VolitionRx Limited.

PART I - FINANCIAL INFORMATION

ITEM 1.

FINANCIAL STATEMENTS

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Condensed Consolidated Balance Sheets (Unaudited)

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

Condensed Consolidated Statements of Cash Flows (Unaudited)

Notes to the Condensed Consolidated Financial Statements (Unaudited)

Condensed Consolidated Balance Sheets

(Expressed in US dollars, except share numbers)

	September 30,	December 31,
	2015	2014
ASSETS	\$ (UNAUDITED)	\$
		2 120 0 4
Cash	6,851,526	2,138,964
Prepaid expenses Other current assets	259,459	144,095
Other current assets	151,650	52,659
Total Current Assets	7,262,635	2,335,718
Property and equipment, net	853,590	288,585
Intangible assets, net	744,930	808,726
Total Assets	8,861,155	3,433,029
LIABILITIES		
Accounts payable and accrued liabilities	694,524	797,909
Management and directors fees payable	94,402	146,016
Derivative liability		1,577,640
Current portion of capital lease liability	83,326	
Deferred grant income	177,480	191,512
Current portion of grant repayable	35,978	
Total Current Liabilities	1,085,710	2,713,077
Capital lease liability, net of current portion	330,290	
Deferred grant income, net of current portion	48,658	
Grant repayable, net of current portion	255,673	351,773
Total Liabilities	1,720,331	3,064,850

STOCKHOLDERS EQUITY

Preferred Stock

Authorized: 1,000,000 shares of preferred stock, at \$0.001 par value		
Issued and outstanding: Nil shares and Nil shares, respectively		
Common Stock		
Authorized: 100,000,000 shares of common stock, at \$0.001 par value		
Issued and outstanding: 18,072,215 shares and 14,691,332 shares, respectively	18,072	14,691
Additional paid-in capital	33,540,971	19,966,771
Accumulated other comprehensive loss	(65,249)	(103,832)
Accumulated Deficit	(26,352,970)	(19,509,451)
Total Stockholders Equity	7,140,824	368,179
Total Liabilities and Stockholders Equity	8,861,155	3,433,029

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

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Expressed in US dollars, except share numbers)

(unaudited)

	For the three months ended	For the three months ended	For the nine months ended	For the nine months ended
	September 30,	September 30,	September 30,	September 30,
	2015	2014	2015	2014
	\$	\$	\$	\$
Revenue		14,785		14,785
Expenses				
General and administrative Professional fees Salaries and office administrative fees Research and development	141,354 352,599 611,162 1,862,115	119,510 457,355	511,558 1,141,129 1,252,105 4,429,887	412,532 670,518
Total Operating Expenses	2,967,230	1,778,167	7,334,679	4,066,778
Net Operating Loss	(2,967,230)	(1,763,382)	(7,334,679)	(4,051,993)
Other Income / (Expenses) Grants received Gain / (loss) on derivative re-measurement		(4,130,562)	146,812 339,744	
Total Other Income / (Net Other Expenses)		(4,130,562)	486,556	(3,219,574)
Provision for income taxes	4,604		4,604	
Net Loss	(2,962,626)	(5,893,944)	(6,843,519)	(7,271,567)
Other Comprehensive Income / (Loss) Foreign currency translation adjustments Total Other Comprehensive Income / (Loss) Net Comprehensive Loss	14,463 14,463 (2,948,163) (0.16)	(19,893) (5,913,837)	38,583 38,583 (6,804,936) (0.39)	(33,731) (7,305,298)

Net Loss per Share Basic Diluted	(0.16)	(0.44)	(0.39)	(0.56)
Weighted Average Shares Outstanding Basic Diluted	18,042,087 18,042,087	13,524,998 13,524,998	17,504,026 17,504,026	13,057,866 13,057,866

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

Condensed Consolidated Statements of Cash Flows

(Expressed in US dollars)

(unaudited)

	For the nine months ended September 30,	For the nine months ended September 30,
	2015	2014
	\$	\$
Operating Activities		
Net loss	(6,843,519)	(7,271,567)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	164,330	99,904
Stock based compensation	980,399	311,907
Common stock and warrants issued for services	23,364	403,483
Non-operating income grants received	(146,812)	(143,987)
(Gain) / Loss on derivative re-measurement	(339,744)	3,363,561
Changes in operating assets and liabilities:		
Prepaid expenses	(121,004)	(61,483)
Other current assets	(96,421)	(88,422)
Accounts payable and accrued liabilities	(304,369)	238,446
Net Cash Used In Operating Activities	(6,683,776)	(3,148,158)
Investing Activities		
Purchases of patents	(55,000)	
Purchases of property and equipment	(270,939)	(297,607)
Net Cash Used in Investing Activities	(325,939)	(297,607)
Financing Activities		
Net proceeds from issuance of common shares	11,335,921	4,893,529
Grants received	146,812	143,987
Grants repaid	(33,174)	(33,166)
Deferred grant income	48,191	(00,200)
Capital lease funding	203,051	
	. ,	

Net Cash Provided By Financing Activities	11,700,801	5,004,350
Effect of foreign exchange on cash	21,476	(27,622)
Increase in Cash	4,712,562	1,530,963
Cash Beginning of Period	2,138,964	888,704
Cash End of Period	6,851,526	2,419,667
Supplemental Disclosures of Cash Flow Information: Interest paid Income tax paid	4,863	10,274
Non Cash Investing and Financing Activities: Reduction in derivative liability Capital lease obligation for equipment purchases	1,237,896 413,616	

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

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 1 - Condensed Financial Statements

The accompanying unaudited financial statements have been prepared by VolitionRx Limited (the Company) 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, 2015, 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 have been condensed or omitted. It is suggested that these condensed unaudited financial statements be read in conjunction with the financial statements and notes thereto included in the Company's December 31, 2014 audited financial statements. The results of operations for the periods ended September 30, 2015 and 2014 are not necessarily indicative of the operating results for the full years.

Note 2 - Going Concern

The Company's financial statements are prepared using generally accepted accounting principles in the United States of America 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 \$26,352,970 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 and/or financing as may be required to sustain its operations. Management's plan to address this need includes, (a) continued exercise of tight cost controls to conserve cash, (b) receiving additional grant funds, and (c) obtaining additional financing through debt or equity financing.

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

Use of Estimates

The preparation of financial statements in conformity with US generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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.

Principles of Consolidation

The accompanying condensed consolidated financial statements for the period ended September 30, 2015 include the accounts of the Company and its wholly-owned subsidiaries, Singapore Volition Pte. Ltd, Belgian Volition S.A. and Hypergenomics Pte. Ltd. All significant intercompany balances and transactions have been eliminated in consolidation.

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 3 - Summary of Significant Accounting Policies (continued)

Cash and Cash Equivalents

The Company considers all highly liquid instruments with a maturity of three months or less at the time of issuance to be cash equivalents. As at September 30, 2015 and December 31, 2014, the Company had \$6,851,526 and \$2,138,964 respectively in cash and cash equivalents. At September 30, 2015 and December 31, 2014 the Company had approximately \$nil and \$nil in its domestic accounts in excess of Federal Deposit Insurance Corporation insured limits, respectively. At September 30, 2015 and December 31, 2014 the Company had approximately \$398,855 and \$233,727 in its foreign accounts in excess of the Belgian Deposit Guarantee insured limits, respectively. At September 31, 2014 the Company had approximately \$6,181,206 and \$1,879,840 in its foreign accounts in excess of the Singapore Deposit Insurance Scheme, respectively.

Basic and Diluted Net Loss Per Share

The Company computes net loss per share in accordance with 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 at September 30, 2015, 1,996,681 dilutive warrants and 601,685 potentially dilutive options were excluded from the Diluted EPS calculation as their effect is anti-dilutive.

Foreign Currency Translation

The Company s functional currency is the Euro and its reporting currency is the United States dollar. Management has adopted ASC 830-20, Foreign Currency Matters Foreign Currency Transactions . All assets and liabilities

denominated in foreign currencies are translated using the exchange rate prevailing at the balance sheet date. For revenues and expenses, the weighted average exchange rate for the period is used. Gains and losses arising on translation or settlement of foreign currency denominated transactions or balances are included in other comprehensive loss.

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.

Property and Equipment

Property and equipment is stated at cost and is amortized on a straight-line basis, at the following rates:

Computer Hardware	3 years
Laboratory Equipment	5 years
Equipment held under Capital Lease	5 years
Office Furniture and Equipment	5 years

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 4 - Property and Equipment

The Company s property and equipment consist of the following amounts as of September 30, 2015 and December 31, 2014:

		Accumulated	September 30, 2015 Net Carrying
	Cost	Depreciation	Value
	\$	\$	\$
Computer hardware	68,185	44,206	23,979
Laboratory equipment	329,073	95,656	233,417
Equipment held under capital			
lease	618,875	41,258	577,617
Office furniture and equipment	35,210	16,633	18,577
	1,051,343	197,753	853,590

		Accumulated	December 31, 2014 Net Carrying
	Cost	Depreciation	Value
	\$	\$	\$
Computer hardware	48,331	39,293	9,038
Laboratory equipment	313,285	53,080	260,205
Equipment held under capital			
lease	-	-	-
Office furniture and equipment	31,745	12,403	19,342
	393,361	104,776	288,585

On April 8, 2015 the Company entered into a five year capital lease to purchase three Tecan machines (automated liquid handling robots) for a total sum of \$618,875 (€550,454).

During the nine month period ended September 30, 2015 and the year ended December 31, 2014, the Company recognized \$99,851 and \$47,095 in depreciation expense respectively.

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 5 - Intangible Assets

The Company s intangible assets consist of intellectual property, principally patents, mainly acquired in the acquisition of ValiBio SA. The patents are being amortized over their remaining lives, which range from 8 to 16 years.

	Cost \$	Accumulated Amortization \$	September 30, 2015 Net Carrying Value \$
Patents	1,148,791	403,861	744,930
	1,148,791	403,861	744,930
	Cost \$	Accumulated Amortization \$	December 31, 2014 Net Carrying Value \$
Patents	1,173,593 1,173,593	364,867 364,867	808,726 808,726

On February 20, 2015, the Company purchased the Nucleosomics® WO2005019826: Detection of Histone Modifications in Cell-Free Nucleosomes patent (i.e. the patent that underlies the NuQ®-M tests) from Chroma Therapeutics Limited for the sum of \$55,000. Prior to this date, the Company had held the exclusive licence for the patent.

During the nine month period ended September 30, 2015, and the year ended December 31, 2014, the Company recognized \$64,479 and \$95,037 in amortization expense, respectively.

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:

\$21,912
\$87,647
\$87,647
\$87,647
\$87,647

The Company periodically reviews its long lived assets 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, 2014. The result of this review confirmed that the fair value of the patents exceeded their carrying value as of December 31, 2014.

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 6 - Related Party Transactions

The Company has had agreements with a related party to rent office space, be provided with office support staff, and have consultancy services provided on behalf of the Company. See Note 11 for obligations under the agreements.

Note 7 - Common Stock

On February 6, 2015, the Company issued 2,475,000 shares of common stock at a price of \$3.75 per share, for net cash proceeds of approximately \$8.5 million.

On February 13, 2015, the Company issued 343,383 shares of common stock at a price of \$3.75 per share, for net cash proceeds of approximately \$1.2 million.

On February 23, 2015, 25,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$55,000. As a result, a total of 25,000 shares of common stock were issued.

On March 6, 2015, 400,000 shares of common stock were issued at a price of \$3.75 per share, for net cash proceeds to the Company of \$1.5 million.

On June 11, 2015, 100,000 warrants were exercised at a price of \$0.50 per share, giving cash proceeds to the Company of \$50,000. As a result, a total of 100,000 shares of common stock were issued.

On July 20, 2015, 25,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$55,000. As a result, a total of 25,000 shares of common stock were issued.

On September 16, 2015, 12,500 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$27,500. As a result, a total of 12,500 shares of common stock were issued.

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Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 8 Warrants and Options

a)

Warrants

On February 23, 2015, 25,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$55,000. As a result, a total of 25,000 shares of common stock were issued.

On May 10, 2015, 26,685 warrants with an exercise price of \$1.75 per share terminated by their terms.

On June 11, 2015, 100,000 warrants were exercised at a price of \$0.50 per share, giving cash proceeds to the Company of \$50,000. As a result, a total of 100,000 shares of common stock were issued.

On July 20, 2015, 25,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$55,000. As a result, a total of 25,000 shares of common stock were issued.

On September 16, 2015, 12,500 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$27,500. As a result, a total of 12,500 shares of common stock were issued.

Below is a table summarizing the warrants issued and outstanding as of September 30, 2015, which have a weighted average exercise price of \$2.01 per share and a weighted average remaining contractual life of 4.7 years.

					Proceeds to Company
Date	Number	Exercise	Contractual	Expiration	if
Issued	Outstanding	Price \$	Life (Years)	Date	Exercised \$
03/15/11	100,000	0.50	5	3/15/2016	50,000
03/24/11	100,000	0.50	5	3/24/2016	50,000
04/01/11	100,000	0.50	5	4/1/2016	50,000
06/21/11	100,000	0.50	5	6/21/2016	50,000
07/13/11	250,000	1.05	5	07/13/16	262,500
05/11/12	344,059	2.60	4	05/10/16	894,553
03/20/13	150,000	2.47	3	03/20/16	370,500
				to 12/20/19	
06/10/13	29,750	2.00	5	12/10/18	59,500
08/07/13	45,000	2.40	3	08/07/16	108,000
11/25/13	456,063	2.40	5	11/25/18	1,094,551
12/31/13	64,392	2.40	5	11/25/18	154,541
01/28/14	10,000	2.40	3	01/28/17	24,000
02/26/14	1,468,475	2.20	5	02/26/19	3,230,645
09/05/14	10,000	2.40	3	09/05/17	24,000
09/26/14	24,000	3.00	3	09/26/17	72,000
11/17/14	19,000	3.75	3	11/17/17	71,250
	3,270,739				6,566,040

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 8 Warrants and Options (continued)

b)

Options

On May 18, 2015, the Company granted options to purchase 20,000 shares. These options vest six months after the date of grant, and expire four years after the vesting date, with an exercise price of \$3.80 per share. The Company has calculated the estimated fair market value of these options using the Black-Scholes Option Pricing model and the following assumptions: term 4.5 years, stock price \$3.45, exercise price \$3.80, 72.1% volatility, 1.54% risk free rate.

On May 18, 2015, the Company amended the expiry period of 630,000 stock options, originally granted on November 25, 2011. The expiration period was extended from three to four years for all 630,000 stock options.

On July 23, 2015, the Company granted options to purchase 327,000 shares, at an exercise price of \$4.00 per share. All of the 327,000 options will vest on January 23, 2016 and will expire on January 23, 2020. The Company has calculated the estimated fair market value of these options using the Black-Scholes Option Pricing model and the following assumptions: term 4.5 years, stock price \$3.55, exercise price \$4.00, 88.3% volatility, 1.65% risk free rate.

On August 14, 2015, the Company amended the vesting date of 10,000 stock options, originally granted on August 18, 2014, from August 18, 2015 to August 16, 2015.

On August 17, 2015, the Company granted options to purchase 75,000 shares, at an exercise price of \$3.75 per share. All of the 75,000 options vested on August 17, 2015 and will expire on August 17, 2020. The Company has calculated the estimated fair market value of these options using the Black-Scholes Option Pricing model and the following assumptions: term 5.0 years, stock price \$3.31, exercise price \$3.75, 87.9% volatility, 1.58% risk free rate.

During the nine month period ended September 30, 2015, 40,000 options expired unexercised following the cessation of a consultant s contract.

Below is a table summarizing the options issued and outstanding as of September 30, 2015, which have a weighted average exercise price of \$3.50 per share and a weighted average remaining contractual life of 3.9 years.

					Proceeds to Company
Date	Number	Exercise	Contractual	Expiration	if
Issued	Outstanding	Price \$	Life (Years)	Date	Exercised \$
11/25/11	630,000	3.00-5.00	4.5-7.0	05/25/16-11/25/18	2,520,000
09/01/12	30,000	4.31-6.31	3.0	03/01/16-09/01/18	159,300
12/13/12	100,000	3.01	3.0	12/13/15	301,000
03/20/13	37,000	2.35-4.35	3.0	09/20/16-03/20/19	123,950
09/02/13	16,300	2.35-4.35	3.0	03/02/14-09/02/16	54,605
05/16/14	25,000	3.00-5.00	3.0-5.5	11/16/17-05/16/20	100,000
08/18/14	670,000	2.50-3.00	4.5-5.5	02/18/19-02/18/20	1,842,500
08/18/14	20,000	3.00	0.5-1.4	11/17/15	60,000
05/18/15	20,000	3.80	4.5	11/18/19	76,000
07/23/15	327,000	4.00	4.5	01/23/20	1,308,000
08/17/15	75,000	3.75	5.0	08/17/20	281,250
	1,950,300				6,826,605

Total remaining unrecognized compensation cost related to non-vested stock options is approximately \$651,235 and is expected to be recognized over a period of two years.

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 9 - Fair Value Measurements

On a recurring basis, we measure certain financial assets and liabilities based upon the fair value hierarchy. The following table presents information about the Company s liabilities measured at fair value as of September 30, 2015:

Liabilities	Level 1	Level 2	Level 3	Fair Value at September 30, 2015
Derivative				
Liability	\$	- \$ -	\$ -	\$ -
T - L 11-4	Level 1	Level 2	Level 3	Fair Value at December 31, 2014
Liabilities Derivative				
Liability	\$	- \$ 1,577,640	\$-	\$ 1,577,640

The fair value changes in the fair value of recurring fair value measurements using model-derived valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data (Level 2), relate solely to the derivative liability as follows:

Balance as of December 31, 2014	\$ 1,577,640
Exercise of warrants attached to derivative	
liability	\$ (74,347)

Adjustment due to expiry of derivative liability	\$ (1,163,549)
Fair value adjustments	\$ (339,744)
Balance as of September 30, 2015	\$ -

Note 10 - Derivative Financial Instruments

The balance sheet caption derivative liability consisted of derivative features embedded in exercisable warrants which had a ratchet provision within their agreements. The balance at September 30, 2015 and December 31, 2014 was \$nil and \$1,577,640, respectively.

The valuation of the derivative liability is determined using a Black-Scholes Model because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions used in the Black-Scholes model at September 30, 2015 and December 31, 2014 include the following:

September 30, 2015Risk-free interest rate0%Estimated volatility0%Dividend rateNoneEstimated term in years 0

December	31,	2014
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Risk-free interest rate	1.65%
Estimated volatility	232.6%
Dividend rate	None
Estimated term in years	4

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 11 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 1,178,289 (1,048,020) to help fund the research endeavors of the Company in the area of colorectal cancer. 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 353,487 (314,406) of this amount by installments over the period June 30, 2014 to June 30, 2023. The Company has recorded the balance of 824,802 (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 percent 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 353,487 (314,406) and the 6 percent 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 353,487 (314,406) and the 6 percent 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 353,487 (314,406) and the 6 percent royalty on such revenue, is twice the amount of funding received. As at September 30, 2015, a total of 291,651 (259,406) was outstanding to be repaid to the Walloon Region under this agreement.

b) Administrative Support Agreement

On August 6, 2010 (and as amended, effective from October 1, 2011 and March 1, 2015), the Company entered into agreements with a related party to rent office space, contract for office support staff, and have consulting services provided on behalf of the Company. From March 1, 2015, the agreements require the Company to pay \$7,950 (\$7,720 for January and February 2015) per month for office space and staff services as well as approximately \$8,000 (\$6,500 for January and February 2015) per month in fees for one senior executive. The rental of the office space and the provision of staff services under the terms of the Agreement were discontinued by mutual agreement on July 31, 2015. From September 1, 2015, the agreement for payment of fees for one senior executive was amended to \$21,115 per month. The Company is also required to pay for all reasonable expenses incurred. The contract is in force for 12 months with automatic extensions of 12 months with a 3 month prior notice required for termination of the contract.

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 618,875 (€550,454). The leased equipment is amortized on a straight line basis over five years. Total accumulated amortization related to the leased equipment is \$41,258 (€36,697) for the nine months ended September 30, 2015 and \$nil (€nil) for the nine months ended September 30, 2014.

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, 2015.

Present value of minimum lease payments	\$ 413,616
Less: Amount representing interest	\$ 24,651
Total minimum lease payments	\$ 438,267
2020	\$ 44,767
2019	\$ 92,588
2018	\$ 92,588
2017	\$ 92,588
2016	\$ 92,588
2015	\$ 23,148

Notes to the Condensed Consolidated Financial Statements

September 30, 2015 and December 31, 2014

(Unaudited)

Note 11 Commitments and Contingencies (continued)

The Company also leases premises and facilities under operating leases with terms ranging from 12 months to 36 months. The annual non-cancelable operating lease payments on these leases are as follows:

2016	\$ 92,063
2017	\$ 2,595
Thereafter	\$ nil
Total	\$ 192,170

d) Bonn University Agreement

On July 11, 2012, the Company entered into a collaborative research agreement with Bonn University, Germany, relating to a program of samples testing. The agreement was for a period of two years from June 1, 2012 to May 31, 2014. The total payments made by the Company in accordance with the agreement were \$438,477 (€390,000). On April 16, 2014, the Company entered into an extension of this agreement, for a period of a further two years from June 1, 2014 to May 31, 2016. The total payments to be made by the Company in accordance with the extension of the agreement are \$438,477 (€390,000).

e) Hvidovre Hospital, Denmark Agreement

On August 8, 2014, the Company entered into a collaborative research agreement with Hvidovre Hospital, University of Copenhagen in Denmark, relating to a program of samples testing associated with colorectal cancer. The agreement will expire on August 8, 2016. Total payments (inclusive of local taxes) to be made by the Company under the agreement are \$1,543,922 (DKR 10,245,000). On April 15, 2015, the Company amended the aforementioned collaborative research agreement with an additional commitment for samples costing \$50,000, to be provided over a two year period, expiring on April 15, 2017.

f) Legal Proceedings

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

Note 12 Subsequent Events

On October 6, 2015, 100,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$220,000. As a result, a total of 100,000 shares of common stock were issued.

On October 28, 2015, 300,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$660,000. As a result, a total of 300,000 shares of common stock were issued.

On October 30, 2015, the Company adopted and approved the 2015 Equity Incentive Plan for the directors, officers, employees and consultants to the Company. Pursuant to the Plan, the Company is authorized to issue 1,000,000 shares of the Company s common stock.

END NOTES TO FINANCIALS

ITEM 2.

MANAGEMENT'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, 2015, or the Report, contains forward-looking 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. 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 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; 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, plan, project. anticipate, expect, estimate, should, continue, potential, 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 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 18, 2015, 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

We are a clinical stage life sciences company focused on developing bodily fluid based diagnostic tests that meet the need for accurate, fast, cost effective and scalable tests for detecting and diagnosing cancer and other diseases. We have developed over twenty blood assays to detect specific biomarkers to date that can be used individually or in combination to generate a profile which forms the basis of a test for a particular cancer or disease. We intend to commercialize our products in the future through various channels within the European Union, the United States and eventually throughout the rest of the world.

We do not anticipate earning significant revenues until such time as we are able to fully market our intended products on the clinical in-vitro diagnostics, or IVD, market. For this reason, our auditors stated in their report on our most recent audited financial statements that our losses and negative cash flow from operations raise substantial doubt that we will be able to continue as a going concern without further financing. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our plan of operations, obtain financing and eventually attain profitable operations.

Overview of Plan of Operations

Management has identified the specific processes and resources required to achieve the near and medium term objectives of the 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, in particular the progression of clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market. However, at this point, the most significant risk to the Company is that it will not succeed in obtaining additional financing in the medium term.

Liquidity and Capital Resources

As of September 30, 2015, the Company had cash of \$6,851,526, prepayments and other current assets of \$411,109 and current liabilities of \$1,085,710. This represents a working capital surplus of \$6,176,925.

The Company used \$6,683,776 in net cash for the nine months ended September 30, 2015, compared to \$3,148,158 for the nine months ended September 30, 2014. The increase in cash used year over year was primarily due to an increase in research and development expenditure and legal costs associated with our up-listing onto the NYSE MKT. Please see Results of Operations, below for more detail.

Net cash used in investing activities increased year over year by \$28,332 to \$325,939 in the 2015 period, mainly as a result of the purchase of the Nucleosomics® WO2005019826: Detection of Histone Modifications in Cell-Free Nucleosomes patent (i.e. the patent that underlies the NuQ[®]-M tests) from Chroma Therapeutics Limited for \$55,000 and payments under a capital lease for three Tecan machines (automated liquid handling robots).

Net cash provided by financing activities amounted to \$11,700,801 for the nine months ended September 30, 2015, compared to \$5,004,350 for the nine months ended September 30, 2014. The Company raised approximately \$9.7 million in net proceeds in February 2015, when approximately 2.8 million shares of common stock were issued in a public offering at the time of our up-listing to the NYSE MKT. We also raised another \$1.5 million from further issuances in a private placement during the first quarter of 2015. A capital lease for three Tecan machines also

financed \$203,051 over this period. This resulted in an increase of cash of \$4,712,562 for the nine month period to September 30, 2015, compared to an increase of \$1,530,963 for the nine month period to September 30, 2014.

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, but there is no assurance that we will be successful in raising further funds.

In the event that additional financing is delayed, the Company will prioritize the maintenance of its research and development personnel and facilities, primarily in Belgium, and the maintenance of its 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, we may be obliged to discontinue operations, which will adversely affect the value of our common stock.

Results of Operations

Three Months Ended September 30, 2015 and September 30, 2014

The following table sets forth the Company s results of operations for the three months ended September 30, 2015 and the comparative period for the three months ended September 30, 2014.

	Three Months Ended September 30,		Three Months Ended September 30,	Increase/	Increase/
	2015		2014	Decrease	Decrease
Revenues	\$ -	9	\$ 14,785	\$ (14,785)	(100%)
Operating Expenses Other Expenses Income Taxes Net Loss	\$ (2,967,230) 4,604 (2,962,626)	S	(1,778,167) (4,130,562) \$ (5,893,944)	\$ (1,189,063) 4,130,562 4,604 2,931,318	67% (100%) (50%)
Basic and Diluted Net Loss Per Common Share	\$ (0.16)	5	\$ (0.44)	\$ 0.28	(64%)
Weighted Average Shares Outstanding - Basic - Diluted	18,042,087 18,042,087		13,524,998 13,524,998	4,517,089 4,517,089	33% 33%

Revenues

The Company had no revenues from operations in the three months ended September 30, 2015, and had revenues of \$14,785 from operations in the comparative period for the three months ended September 30, 2014. The Company s operations are still predominantly in the development stage.

Operating Expenses

For the three months ended September 30, 2015, the Company s operating expenses increased by \$1,189,063, or 67%, in comparison to the three months ended September 30, 2014. Operating expenses are comprised of salaries and office administrative fees, research and development expenses, professional fees, and other general and administrative expenses.

Salaries and office administrative fees increased by \$153,807 in the 2015 period. The increase was mainly due to the cost of additional stock option expense (relating to options granted in August 2014 and 2015), offset by a reduction in the cost of warrants issued to consultants. The incremental cost of a director appointed in June 2014 and additional compensation for senior executives of the Company also contributed to the increase. Research and development expenses increased by \$790,131 in the 2015 period. An additional \$577,013 was incurred on the purchase of samples, antibodies and chemicals used for testing and an additional \$45,095 was spent on a study at Hvidovre Hospital in Denmark that started in August 2014. Other areas of cost increase included depreciation, patent related costs and increased stock options amortization. Professional fees increased by \$233,089, which included additional fees of \$53,309 for investor relations services to raise the profile of the Company and NYSE MKT registration fees of \$8,750. In addition, within professional fees, legal costs increased by \$86,929, due to increased contractual activity and the preparation and filing of a resale registration statement. General and administrative expenses increased by \$12,036. This was mainly due to increased insurance costs and higher travel related to an increase in investor relations activity.

Other Expenses

For the three months ended September 30, 2015, the Company recognized other expenses of \$nil, as compared to other expenses of \$4,130,562 for the three months ended September 30, 2014, relating to a loss on the re-measurement of a derivative liability, which did not occur in the 2015 comparable period, as the derivative liability expired on February 27, 2015.

Net Loss

For the three months ended September 30, 2015, our net loss was \$2,962,626 a decrease of \$2,931,318, or 50%, in comparison to a net loss of \$5,893,944 for the three months ended September 30, 2014. The change is a result of the factors described above.

Nine Months Ended September 30, 2015 and September 30, 2014

The following table sets forth the Company s results of operations for the nine months ended September 30, 2015 and the comparative period for the nine months ended September 30, 2014.

	Nine Months Ended September 30,	Nine Months Ended September 30,	Increase/	Increase/
	2015	2014	Decrease	Decrease
Revenues	\$ -	\$ 14,785	\$ (14,785)	(100%)
Operating Expenses Other Income / (Net Other Expenses) Income Taxes Net Loss	\$ (7,334,679) 486,556 4,604 (6,843,519)	\$ (4,066,778) (3,219,574) - (7,271,567)	\$ (3,267,901) 3,706,130 4,604 428,048	80% (115%) (6%)
Basic and Diluted Net Loss Per Common Share	\$ (0.39)	\$ (0.56)	\$ 0.17	(30%)
Weighted Average Basic and Diluted Common Shares Outstanding - Basic - Diluted	17,504,026 17,504,026	13,057,866 13,057,866	4,446,160 4,446,160	34% 34%

Revenues

The Company had no revenues from operations in the nine months ended September 30, 2015, and revenues of \$14,785 from operations in the comparative period for the nine months ended September 30, 2014. The Company s operations are still predominantly in the development stage.

Operating Expenses

For the nine months ended September 30, 2015, the Company s operating expenses increased by \$3,267,901, or 80%, in comparison to the nine months ended September 30, 2014. Operating expenses are comprised of salaries and office administrative fees, research and development expenses, professional fees, and other general and administrative expenses.

Salaries and office administrative fees increased by \$581,587 in the 2015 period. The increase was primarily due to \$429,709 of increased costs of amortization of share options issued in August 2014 and 2015, offset by a decrease in the cost of valuation of a consultant s warrants of \$196,873. There was also additional compensation for senior executives of the Company and an additional director appointed in June 2014. Research and development expenses increased by \$1,696,145 in the 2015 period, due to \$433,177 being incurred on the Hvidovre Hospital Study in Denmark as well as \$1,026,767 being expensed for samples, services, antibodies and chemicals associated with testing. Increased amortization costs of share options for research and development resources of \$194,095 also contributed to the variance between the comparable periods. Professional fees increased by \$728,597, which included additional fees of \$138,293 for investor relations services to raise the profile of the Company and NYSE MKT listing fees of \$98,333. In addition, within professional fees, legal costs increased by \$405,960 year over year. Increased legal activity associated with the up-list to the NYSE MKT, capital raising activities and other contractual areas explained this change. General and administrative expenses increased by \$261,572. This was mainly due to an increase in capital raising services expense of \$33,494, additional insurance costs of \$97,383 and increased travel and subsistence costs of \$96,823, owing to increased travelling associated with investor relations and conference attendance.

Other Income / Net Other Expenses

For the nine months ended September 30, 2015, the Company recognized other income of \$486,556, as compared to net other expenses of \$3,219,574 for the nine months ended September 30, 2014. Other income for the nine months ended September 30, 2015 consisted of \$146,812 in grant funds received from public bodies in respect of approved expenditures, where there is no obligation to repay, as well as \$339,744 recorded as a result of a gain on re-measurement of a derivative liability. For the nine months ended September 30, 2014, net other expenses consisted of \$143,987 in grant funds and a loss of \$3,363,561 on the re-measurement of a derivative liability.

Net Loss

For the nine months ended September 30, 2015, our net loss was \$6,843,519, a decrease of \$428,048, or 6%, in comparison to a net loss of \$7,271,567 for the nine months ended September 30, 2014. The change is a result of the factors described above.

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, 2014 that they have substantial doubt that we will be able to continue as a going concern without further financing.

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.

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 applied on a consistent basis. The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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 new accounting pronouncements that are in effect. The Company does not believe that there are any other 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 Securities Exchange Act of 1934 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 its 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, 2014, March 31, 2015 and June 30, 2015, respectively, that our disclosure controls and procedures continue to not be effective as of September 30, 2015 because of material weaknesses in our internal control over financial reporting, as described below and in detail in our Annual Report for the year ended December 31, 2014 on Form 10-K as filed with the SEC on March 18, 2015, as well as our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015.

Changes in Internal Control over Financial Reporting

The Audit Committee of the Board of Directors meets regularly with our financial management and counsel, 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. In addition, the Audit Committee and the independent registered public accounting firm have discussed the independent registered public accounting firm s 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 Public Company Accounting Oversight Board Rule 3526 Communicating with Audit Committees Concerning Independence .

As at September 30, 2015, we did not maintain sufficient internal controls over financial reporting for all of the cash process, including failure to segregate cash handling and accounting functions, and did not require dual signature on some of the Company s bank accounts. We have developed, and are currently implementing, a remediation plan for this material weakness. We will continue to execute our remediation plan, which includes changing bank mandates to ensure dual authorization is present on all of our bank accounts and rationalizing the number of bank accounts held by us. The successful remediation of this material weakness will require review and evidence of the effectiveness of the related internal controls as part of our next annual assessment of our internal controls over financial reporting as of December 31, 2015.

Additionally, previously we did not implement appropriate information technology controls. For instance, the Company retains copies of all financial data and material agreements; and the main Volition trading subsidiary, Belgian Volition S.A. follows a formal off-site daily backup of data procedure, however, there was no formal off-site backup procedure in place for Volition s other subsidiaries. Consequently, the Company identified this material weakness and completed a remediation plan and automatic backups have now been implemented in the other subsidiaries of the Company. Management will review the evidence of the effectiveness of the related internal controls as part of our next annual assessment of our internal controls over financial reporting as of December 31, 2015.

Except as disclosed above, there have been no changes in our internal controls over financial reporting that occurred during the fiscal quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

The Company is not required by current SEC rules to include, and does not include, an auditor's attestation report. Consequently, the Company's registered public accounting firm has not attested to management's reports on the Company's internal control 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 director, officer or any affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to our interest.

ITEM 1A.

RISK FACTORS

The risk factors listed below should be considered with the information provided elsewhere in this Quarterly Report on Form 10-Q, which could materially adversely affect our business, financial condition or results of operations.

Risks Associated with our Company

We have not generated any significant revenue since our inception and we may never achieve profitability.

We are a clinical stage company and since our inception, we have not generated any significant revenue. As we continue the discovery and development of our future diagnostic products, our expenses are expected to increase significantly. Accordingly, we will need to generate significant revenue to achieve profitability. Even as we begin to market and sell our intended products, we expect our losses to continue as a result of ongoing research and development expenses, as well as increased manufacturing, sales and marketing expenses. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders equity. Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and then maintain profitability, our business, financial condition and results of operations will be negatively affected and the market value of our common stock will decline.

We may need to raise additional capital in the future. If we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our plan of operations.

If we incur delays in commencing commercialization of our intended products or in achieving significant product revenue, or if we encounter other unforeseen adverse business developments, we may exhaust our capital resources prior to the commencement of commercialization.

We cannot be certain that additional capital will be available when needed or that our actual cash requirements will not be greater than anticipated. Financing opportunities may not be available to us, or if available, may not be available on favorable terms. The availability of financing opportunities will depend on various factors, such as market conditions and our financial condition and outlook. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we are unable to obtain financing on terms favorable to us, we may be unable to execute our plan of operations and we may be required to cease or reduce development or commercialization of any future products, sell some or all of our technology or assets or merge with another entity.

It is difficult to forecast our future performance, which may cause our financial results to fluctuate unpredictably.

Our limited operating history and the rapid evolution of the market for diagnostic products make it difficult for us to predict our future performance. A number of factors, many of which are outside of our control, may contribute to fluctuations in our financial results, such as:

Our ability to develop or procure antibodies for clinical use in our future products;

Our ability to translate preliminary clinical results to larger prospective screening populations;

The demand for our intended products;

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Our ability to obtain any necessary financing;

Our ability to market and sell our future products;

Market acceptance of our future products and technology;

Performance of any future strategic business partners;

Our ability to obtain regulatory clearances or approvals;

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Changes in technology that may render our future products uncompetitive or obsolete;

Competition with other cancer diagnostics companies; and

Adverse changes in the healthcare industry.

Our future success depends on our ability to retain our officers and directors, scientists, and other key employees and to attract, retain and motivate qualified personnel.

Our success depends on our ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, we are highly dependent on Cameron Reynolds, our President and Chief Executive Officer, our other officers and directors, scientists and key employees. The loss of any of these persons or their expertise would be difficult to replace and could have a material adverse effect on our ability to achieve our business goals. In addition, the loss of the services of any one of these persons may impede the achievement of our research, development and commercialization objectives by diverting management s attention to the identification of suitable replacements, if any. There can be no assurance that we will be successful in hiring or retaining qualified personnel and our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

Recruiting and retaining qualified scientific personnel and, in the future, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among pharmaceutical, biotechnology and diagnostic companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. We do not maintain key person insurance on any of our employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research, development and commercialization strategies. Our consultants and advisors, however, may have other commitments or employment that may limit their availability to us.

We expect to expand our product development, research and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our consultants, advisors, and employees and the scope of our operations as we continue to develop and commercialize our current pipeline of intended products and new products. In order to manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

We have limited experience with direct sales and marketing and any failure to build and manage a direct sales and marketing team effectively could have a material adverse effect on our business.

Our products will require several dynamic and evolving sales models tailored to different worldwide markets, users and products. We have decided to focus our sales strategy on the clinical market in 2015 with the CE Marking of our first product in Europe. Pending completion of our review of the regulatory environment in the United States, including the effect of recent pronouncements regarding LDTs by the FDA, we aim initially to enter the United States market through a technology license for LDT development in a CLIA lab in the United States. We intend to progressively grow to large volumes of tests sold to centralized laboratories and eventually reach the mass diagnostics testing market. The exact nature of the ideal sales strategy will evolve as we continue to develop our intended products and seek entry into the IVD markets. We have limited experience with direct sales and marketing and any failure to build and manage a direct sales and marketing team effectively could have a material adverse effect on our business.

There are significant risks involved in building and managing our sales and marketing organization, as well as identifying and negotiating deals with the right sales and distribution partners, including risks related to our ability to:

Identify appropriate partners;

Negotiate beneficial partnership and distribution agreements;

Hire qualified individuals as needed;

Generate sufficient leads within our targeted market for our sales force;

Provide adequate training for effective sales and marketing;

Retain and motivate our direct sales and marketing professionals; and

Effectively oversee geographically dispersed sales and marketing teams.

Our failure to adequately address these risks could have a material adverse effect on our ability to increase sales and use of our future products, which would cause our revenues to be lower than expected and harm our results of operations.

Our Amended and Restated Certificate of Incorporation exculpates our officers and directors from certain liability to our Company or our stockholders.

Our Amended and Restated Certificate of Incorporation contains a provision limiting the liability of our officers and directors for their acts or failures to act, except for acts involving intentional misconduct, fraud or a knowing violation of law. This limitation on liability may reduce the likelihood of derivative litigation against our officers and directors and may discourage or deter our stockholders from suing our officers and directors based upon breaches of their duties to our Company.

Our internal controls may be inadequate, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Exchange Act Rule 13a-15(f), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, 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 and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and/or directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our internal controls may be inadequate or ineffective, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public. Investors relying upon this misinformation may make an uninformed investment decision. Additionally, for so long as we remain as a smaller reporting company, under current rules our accounting firm will not be required to provide an opinion regarding our internal controls over financial reporting.

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We have a going concern opinion from our auditors, indicating the possibility that we may not be able to continue to operate.

Our independent registered public accountants have expressed substantial doubt about our ability to continue as a going concern. This opinion could materially limit our ability to raise additional funds by issuing new debt or equity securities or otherwise. If we fail to raise sufficient capital when needed, we will not be able to complete our proposed business plan. As a result we may have to liquidate our business and investors may lose their investments. 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. Investors should consider our independent registered public accountant s comments when deciding whether to invest in the Company.

Risks Associated with our Business

Failure to successfully develop, manufacture, market, and sell our future products will have a material adverse effect on our business, financial condition, and results of operations.

We are in the process of developing a suite of diagnostic tests as well as additional products. To date, we have not placed any of our product prototypes on the clinical market. The successful development and commercialization of our intended products is critical to our future success. Our ability to successfully develop, manufacture, market, and sell our future products is subject to a number of risks, many of which are outside our control. There can be no assurance that we will be able to develop and manufacture products in commercial quantities at acceptable costs, successfully market any products, or generate revenues from the sale of any products. Failure to achieve any of the foregoing would have a material adverse effect on our business, financial condition, and results of operations.

Our business is dependent on our ability to successfully develop and commercialize diagnostic products. If we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations.

Our current business strategy focuses on discovering, developing and commercializing diagnostic products. The success of our business will depend on our ability to fully develop and commercialize the diagnostic products in our current development pipeline as well as continue the discovery and development of other diagnostics products.

Prior to commercializing diagnostic products, we will be required to undertake time-consuming and costly development activities with uncertain outcomes, including conducting clinical studies and obtaining regulatory clearance or approval in the United States and in Europe. Delays in obtaining approvals and clearances could have material adverse effects on us and our ability to fully carry out our plan of operations. We have limited experience in taking products through these processes and there are considerable risks involved in these activities. The science and methods that we are employing are innovative and complex, and it is possible that our development programs will ultimately not yield products suitable for commercialization or government approval. Products that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may still fail to obtain the necessary regulatory clearances or approvals. Few research and development projects result in commercial products, and perceived viability in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product, or we may be required to expend considerable resources obtaining additional clinical and nonclinical data, which would adversely impact the timing for generating potential revenue from those products. Further, our ability to develop and launch diagnostic tests is dependent on our receipt of substantial additional funding. If our discovery and development programs yield fewer commercial products than we expect, we may be unable to execute our business plan, and our business, financial condition and results of operations may be adversely affected.

Our failure to obtain necessary regulatory clearances or approvals on a timely basis would significantly impair our ability to distribute and market our future products on the clinical IVD market.

We are subject to regulation and supervision by the FDA in the United States, the Conformité Européenne in Europe and other regulatory bodies in other countries where we intend to sell our future products. Before we are able to place our intended products in the clinical IVD markets in the United States and Europe, we will be required to obtain approval of our future products from the FDA and receive a CE Mark, respectively. The European Union has recently proposed terms that would impose additional requirements to obtain a CE Mark, which could result in delays and further expense to us as compared to the current CE Mark approval process. It is expected that these proposed changes, if adopted, would become effective in the first half of 2016, however there is currently no definitive timeline for adoption. Delays in obtaining approvals and clearances for our products could have material adverse effects on us and our ability to fully carry out our plan of operations.

Additionally, even if we receive the required government approval of our intended products, we are still subject to continuing regulation and oversight. Under the FDA, diagnostics are considered medical devices and are subject to ongoing controls and regulations, including inspections, compliance with established manufacturing practices, device-tracking, record-keeping, advertising, labeling, packaging, and compliance with other standards. The process of complying with such regulations with respect to current and new products can be costly and time-consuming. Failure to comply with these regulations could have a material adverse effect on our business, financial condition, and results of operations. Furthermore, any FDA regulations governing our future products are subject to change at any time, which may cause delays and have material adverse effects on our operations. In Europe, IVD companies are able to self-certify that they meet the appropriate regulatory requirements but are subject to inspection for enforcement. European national agencies, such as customs authorities and/or the Departments of Health, Industry and Labor, conduct market surveillance to ensure the applicable requirements have been met for products marketed within the EU.

Recent announcements from the Federal Food and Drug Administration may impose additional regulatory obligations and costs upon our business.

On October 3, 2014, the FDA issued two draft guidance documents regarding oversight of laboratory developed tests, or LDTs, titled Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) and FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs). According to this guidance, the FDA plans to take a phased-in risk-based approach to regulating LDTs. The FDA plans to phase in enforcement of LDT premarket review, quality system oversight and adverse event reporting over a number of years. The FDA would require that laboratories providing LDTs, subject to certain limited exemptions, within six months after the guidance documents are finalized comply with (i) either a new notification procedure in which the laboratory must provide the FDA with certain basic information about each LDT offered by their laboratory or the FDA s device registration and listing requirements, and (ii) the medical device reporting, or MDR, requirements for LDTs offered by that laboratory. Under this new risk based approach, it is possible that some level of pre-market review may be required for our LDTs-either a 510(k) or PMA-which may require us to obtain additional clinical data.

It is unclear at this time when, or if, the draft guidance documents will be finalized and, if so, how the final framework might differ from the draft guidance. Therefore, we do not know what the additional costs and regulatory burdens will be, nor the impact of any final FDA guidance or FDA enforcement of its regulations on our business or operations.

If the FDA requires us to seek clearance or approval for any of our products (as opposed to simply licensing our technology to a CLIA lab), we may not be able to obtain such approvals on a timely basis, or at all. The cost of conducting clinical trials and otherwise developing data and information to support any applications may be significant. Failure to comply with applicable regulatory requirements of the FDA could result in enforcement action,

including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

If the marketplace does not accept the products in our development pipeline or any other diagnostic products we might develop, we may be unable to generate sufficient revenue to sustain and grow our business.

Our intended products may never gain significant acceptance in the research or clinical marketplace and therefore may never generate substantial revenue or profits. Physicians, hospitals, clinical laboratories, researchers or others in the healthcare industry may not use our future products unless they determine that they are an effective and cost-efficient means of detecting and diagnosing cancer. In addition, we will need to expend a significant amount of resources on marketing and educational efforts to create awareness of our future products and to encourage their acceptance and adoption. If the market for our future products does not develop sufficiently or the products are not accepted, our revenue potential will be harmed.

The cancer diagnostics market is highly competitive and subject to rapid technological change; accordingly, we will face fierce competition and our intended products may become obsolete.

The cancer diagnostics market is extremely competitive and characterized by evolving industry standards and new product enhancements. Cancer diagnostic tests are technologically innovative and require significant planning, design, development, and testing at the technological, product, and manufacturing process levels. These activities require significant capital commitments and investment. There can be no assurance that our intended products or proprietary technologies will remain competitive following the introduction of new products and technologies by competing companies within the industry. Furthermore, there can be no assurance that our competitors will not develop products that render our future products obsolete or that are more effective, accurate or can be produced at lower costs. There can be no assurance that we will be successful in the face of increasing competition from new technologies or products introduced by existing companies in the industry or by new companies entering the market.



We expect to face intense competition from companies with greater resources and experience than us, which may increase the difficulty for us to achieve significant market penetration.

The market for cancer diagnostics is intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. Our competitors include large multinational corporations and their operating units, including Abbott Laboratories Inc., Cepheid Inc., Philips, GE Healthcare, Siemens, Gen-Probe Incorporated, MDxHealth SA, EpiGenomics AG, Applied Proteomics Inc., Roche Diagnostics, Exact Sciences Corporation, Sequenom, Inc. and several others. These companies have substantially greater financial, marketing and other resources than we do. Each of these companies is either publicly traded or a division of a publicly traded company, and enjoys several competitive advantages, including:

Significantly greater name recognition;

Established relationships with healthcare professionals, companies and consumers;

Additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

Established supply and distribution networks; and

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Greater resources for product development, sales and marketing, and intellectual property protection.

These other companies have developed and will continue to develop new products that will compete directly with our future products. In addition, many of our competitors spend significantly greater funds for the research, development, promotion, and sale of new and existing products. These resources allow them to respond more quickly to new or emerging technologies and changes in consumer requirements. For all the foregoing reasons, we may not be able to compete successfully against our competitors.

Declining global economic or business conditions may have a negative impact on our business.

Continuing concerns over United States healthcare reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment precipitated a global economic slowdown and recession. If the economic climate does not improve or continues to deteriorate, our business, including our access to the RUO or clinical IVD markets for diagnostic tests, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

We will rely on third parties to manufacture and supply our intended products. Any problems experienced by these third parties could result in a delay or interruption in the supply of our intended products to our customers, which could have a material negative effect on our business.

We will rely on third parties to manufacture and supply our intended products. The manufacture of our intended diagnostic products will require specialized equipment and utilize complicated production processes that would be difficult, time-consuming and costly to duplicate. If the operations of third party manufacturers are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill our future sales orders. Any prolonged disruption in the operations of third party manufacturers could have a significant negative impact on our ability to sell our future products, could harm our reputation and could cause us to seek other third party manufacturing contracts, thereby increasing our anticipated development and commercialization costs. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards required by the FDA and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop products or receive approval of any products in a timely manner.

The manufacturing operations of our future third party manufacturers will likely be dependent upon third party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

The operations of our future third party manufacturers will likely be dependent upon third party suppliers. A supply interruption or an increase in demand beyond a supplier s capabilities could harm the ability of our future manufacturers to manufacture our intended products until new sources of supply are identified and qualified.

Reliance on these suppliers could subject us to a number of risks that could harm our business, including:

Interruption of supply resulting from modifications to or discontinuation of a supplier s operations;

Delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier s variation in a component;

A lack of long-term supply arrangements for key components with our suppliers;

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Inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;

Difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner;

Production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;

Delay in delivery due to suppliers prioritizing other customer orders over ours;

Damage to our brand reputation caused by defective components produced by the suppliers; and

Fluctuation in delivery by the suppliers due to changes in demand from us or their other customers.

Any interruption in the supply of components of our future products or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our future customers, which would have an adverse effect on our business.

We will depend on third party distributors in the future to market and sell our future products which will subject us to a number of risks.

We will depend on third party distributors to sell, market, and service our future products in our intended markets. We are subject to a number of risks associated with reliance upon third party distributors including:

Lack of day-to-day control over the activities of third party distributors;

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Third party distributors may not commit the necessary resources to market and sell our future products to our level of expectations;

Third party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us; and

Disagreements with our future distributors could result in costly and time-consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar.

If we fail to establish and maintain satisfactory relationships with our future third party distributors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which could harm our results of operations and financial condition.

If the patents that we rely on to protect our intellectual property prove to be inadequate, our ability to successfully commercialize our future products will be harmed and we may never be able to operate our business profitably.

Our success depends, in large part, on our ability to protect proprietary methods, discoveries and technologies that we develop under the patents and intellectual property laws of the United States, European Union and other countries, so that we can seek to prevent others from unlawfully using our inventions and proprietary information. We have

exclusive license rights to a number of patent applications related to our diagnostic tests under development, but do not have any issued patents in the United States and only one issued patent in Europe. Additionally, we have patent applications authored by both Singapore Volition and Belgian Volition, which are also currently pending. We cannot assure you that any of the pending patent applications will result in patents being issued. In addition, due to technological changes that may affect our future products or judicial interpretation of the scope of our patents, our intended products might not, now or in the future, be adequately covered by our patents.

If third parties assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent the development or commercialization of our future products.

Our ability to commercialize our intended products depends on our ability to develop, manufacture, market and sell our future products without infringing the proprietary rights of third parties. Third parties may allege that our future products or our methods or discoveries infringe their intellectual property rights. Numerous United States and foreign patents and pending patent applications, which are owned by third parties, exist in fields that relate to our intended products and our underlying methodologies, discoveries and technologies.

A third party may sue us for infringing its patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of third party proprietary rights. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation could divert our management s attention from other aspects of our business. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If we are found to infringe upon intellectual property rights of third parties, we might be forced to pay damages, potentially including treble damages. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some or all of our future products, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

If we are unable to protect our trade secrets, we may be unable to protect our interests in proprietary technology, processes and know-how that is not patentable or for which we have elected not to seek patent protection.

In addition to patented technology, we rely upon trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult or impossible to obtain or enforce. We may not be able to protect our trade secrets adequately. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential information into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us, which could adversely affect our competitive advantage.

Risks Associated with our Common Stock

The market prices and trading volume of our stock may be volatile.

The market price of our common stock is likely to be highly volatile and the trading volume may fluctuate and cause significant price variation to occur. We cannot assure you that the market prices of our common stock will not fluctuate or decline significantly in the future. Some of the factors that could negatively affect the prices of our shares or result in fluctuations in those prices or in trading volume of our common stock could include the following, many of which will be beyond our control:

competition;

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- additions or departures of key personnel;
- our ability to execute our business plan;
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- operating results that fall below expectations;
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- loss of any strategic relationship;
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- industry developments;
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- economic and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price and trading volume of our common stock.

Share ownership by our officers and directors make it more difficult for third parties to acquire us or effectuate a change of control that might be viewed favorably by other stockholders.

As of November 4, 2015, our executive officers and directors owned, in the aggregate, 27.61% of our outstanding shares. As a result, if the officers and directors were to oppose a third party s acquisition proposal for, or a change in control of, the Company, the officers and directors may have sufficient voting power to be able to block or at least delay such an acquisition or change in control from taking place, even if other stockholders would support such a sale or change of control.

Our corporate governance documents, and certain corporate laws applicable to us, could make a takeover attempt, which may be beneficial to our stockholders, more difficult.

Our Board of Directors, or Board, has the power, under our articles of incorporation, to issue additional shares of common stock and create and authorize the sale of one or more series of preferred stock without having to obtain stockholder approval for such action. As a result, our Board could authorize the issuance of shares of a series of preferred stock to implement a stockholders rights plan (often referred to as a poison pill) or could sell and issue preferred shares with special voting rights or conversion rights, which could deter or delay attempts by our stockholders to remove or replace management, and attempts of third parties either to engage in proxy contests or to acquire control of the Company. In addition, our charter documents:

enable our Board to fill vacant directorships except for vacancies created by the removal of a director;

enable our Board to amend our bylaws without stockholder approval subject to certain exceptions; and

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require compliance with an advance notice procedure with regard to business to be brought by a stockholder before an annual or special meeting of stockholders and with regard to the nomination by stockholders of candidates for election as directors.

These provisions may discourage potential acquisition proposals and could delay or prevent a change of control, including under circumstances in which our stockholders might otherwise receive a premium over the market price of our common stock.

We do not expect to pay dividends in the foreseeable future.

We do not intend to declare dividends for the foreseeable future, as we anticipate that we will reinvest any future earnings in the development and growth of our business. Therefore, investors will not receive any funds unless they sell their common stock, and stockholders may be unable to sell their shares on favorable terms or at all. We cannot assure you of a positive return on investment or that you will not lose the entire amount of your investment in our common stock.

We may in the future issue additional shares of our common stock which would reduce investors ownership interests in the Company and which may cause our stock price to decline.

Our Certificate of Incorporation and amendments thereto authorize the issuance of 100,000,000 shares of common stock, par value \$0.001 per share and 1,000,000 shares of preferred stock, par value \$0.001 per share. The future issuance of all or part of our remaining authorized common stock may result in substantial dilution in the percentage of our common stock held by our then existing stockholders. We may value any common stock or preferred stock issued in the future on an arbitrary basis. The issuance of common stock or preferred stock for future services or acquisitions or other corporate actions may have the effect of diluting the percentage ownership of our stockholders and, depending upon the prices at which such shares are sold or issued, on their investment in our common stock and, therefore, could have an adverse effect on any trading market for our common stock.

Future sales of our common stock could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market or the perception that large sales of our shares could occur, could cause the market price of our common stock to decline or limit our future ability to raise capital through an offering of equity securities.

If equity research analysts do not publish research or reports about our business, or if they do publish such reports but issue unfavorable commentary or downgrade our common stock, the price and trading volume of our common stock could decline.

The trading market for our common stock could be affected by whether and to what extent equity research analysts publish research or reports about us and our business. We cannot predict at this time whether any research analysts will cover us and our common stock or whether they will publish research and reports on us. If one or more equity analysts cover us and publish research reports about our common stock, the price of our stock could decline if one or more securities analysts downgrade our stock or if those analysts issue other unfavorable commentary or cease publishing reports about us.

If any of the analysts who elect to cover us downgrade their recommendation with respect to our common stock, our stock price could decline rapidly. If any of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our common stock price or trading volume to decline and our common stock to be less liquid.

We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a smaller reporting company, meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$75 million and annual revenues of less than \$50 million during the most recently completed fiscal year. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

ITEM 2.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

1.

Quarterly Issuances:

On or about July 20, 2015, 25,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$55,000. As a result, a total of 25,000 shares of common stock were issued to one (1) U.S. Accredited Investor. The shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended, (Securities Act), and Rule 506 of Regulation D, on the basis that the securities were offered and sold in a non-public offering to an accredited investor as defined in Rule 501 of Regulation D. The shares were registered for resale on Form S-3 (Registration No. 333-195213).

On or about September 16, 2015, 12,500 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$27,500. As a result, a total of 12,500 shares of common stock were issued to one (1) U.S. Accredited Investor. The shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended, (Securities Act), and Rule 506 of Regulation D, on the basis that the securities were offered and sold in a non-public offering to an accredited investor as defined in Rule 501 of Regulation D. The shares were registered for resale on Form S-3 (Registration No. 333-195213).

2.

Subsequent Issuances:

On or about October 6, 2015, 100,000 warrants were exercised at a price of 2.20 per share, giving cash proceeds to the Company of 220,000. As a result, a total of 100,000 shares of common stock were issued to one (1) U.S. Accredited Investor. The shares were issued pursuant to Section 4(2) of the Securities Act, and Rule 506 of Regulation D, on the basis that the securities were offered and sold in a non-public offering to an accredited investor as defined in Rule 501 of Regulation D. The shares were registered for resale on Form S-3 (Registration No. 333-195213).

On or about October 28, 2015, 300,000 warrants were exercised at a price of \$2.20 per share, giving cash proceeds to the Company of \$660,000. As a result, a total of 300,000 shares of common stock were issued to one (1) U.S. Accredited Investor. The shares were issued pursuant to Section 4(2) of the Securities Act, and Rule 506 of Regulation D, on the basis that the securities were offered and sold in a non-public offering to an accredited investor as defined in Rule 501 of Regulation D. The shares were registered for resale on Form S-3 (Registration No. 333-195213).

ITEM 3.

DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4.

MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5.

OTHER INFORMATION

None.

ITEM 6.

EXHIBITS

Exhibit

Number	Description	Filing
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the	Filed Herewith.
	Sarbanes-Oxley Act of 2002.	
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the	Filed Herewith.
	Sarbanes-Oxley Act of 2002.	
32.1	Certifications of Principal Executive Officer and Principal Financial Officer	Furnished Herewith.
	pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	
101.INS*	XBRL Instance Document	Furnished Herewith.
101.SCH*	XBRL Taxonomy Extension Schema Document	Furnished Herewith.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document	Furnished Herewith.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document	Furnished Herewith.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document	Furnished Herewith.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document	Furnished Herewith.

*Pursuant to Regulation S-T, this interactive data file is deemed furnished and not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

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 4, 2015

/s/ Cameron Reynolds Cameron Reynolds Duly Authorized Officer, President and Principal Executive Officer

Dated: November 4, 2015

/s/ David Kratochvil David Kratochvil Duly Authorized Officer, Chief Financial Officer and Principal Financial and Accounting Officer