

VOLITIONRX LTD
Form 10-Q
November 07, 2018

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

FORM 10-Q

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

For the quarterly period ended September 30, 2018

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

For the transition period from _____ to _____

Commission File Number: 001-36833

VOLITIONRX LIMITED

(Exact name of registrant as specified in its charter)

Delaware **91-1949078**
(State or other jurisdiction of incorporation (I.R.S. Employer Identification No.)
or organization)

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 every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). [X] Yes [] No

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

| | | | |
|-------------------------|--|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input type="checkbox"/> |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

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

As of November 2, 2018, there were 35,335,378 shares of the registrant's \$0.001 par value common stock issued and outstanding.

VOLITIONRX LIMITED
QUARTERLY REPORT ON FORM 10-Q
FOR THE THREE AND NINE-MONTHS ENDED SEPTEMBER 30, 2018

TABLE OF CONTENTS

| | PAGE | |
|----------------|---|----|
| PART I | FINANCIAL INFORMATION | |
| ITEM 1. | FINANCIAL STATEMENTS | 3 |
| ITEM 2. | MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS | 17 |
| ITEM 3. | QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK | 25 |
| ITEM 4. | CONTROLS AND PROCEDURES | 25 |
| PART II | OTHER INFORMATION | |
| ITEM 1. | LEGAL PROCEEDINGS | 26 |
| ITEM 1A. | RISK FACTORS | 26 |
| ITEM 2. | UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS | 26 |
| ITEM 3. | DEFAULTS UPON SENIOR SECURITIES | 26 |
| ITEM 4. | MINE SAFETY DISCLOSURES | 26 |
| ITEM 5. | OTHER INFORMATION | 26 |
| ITEM 6. | EXHIBITS | 27 |
| SIGNATURES | | 28 |

Use of Terms

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

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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

| | PAGE |
|--|-------------|
| Condensed Consolidated Balance Sheets | 4..... |
| Condensed Consolidated Statements of Operations and Comprehensive Loss | 5..... |
| Condensed Consolidated Statements of Cash Flows | 6..... |
| Notes to the Condensed Consolidated Financial Statements | 7..... |

VOLITIONRX LIMITED

Condensed Consolidated Balance Sheets

(Expressed in United States Dollars, except share numbers)

| | September 30, 2018 | December 31, 2017 |
|---|-------------------------------|----------------------------------|
| | \$ | \$ |
| ASSETS | | |
| | (UNAUDITED) | |
| Current Assets | | |
| Cash and cash equivalents | 16,374,428 | 10,116,263 |
| Prepaid expenses | 460,124 | 248,661 |
| Other current assets | 229,780 | 202,295 |
| Total Current Assets | 17,064,332 | 10,567,219 |
| Property and equipment, net | 3,157,140 | 3,480,782 |
| Intangible assets, net | 494,422 | 576,397 |
| Total Assets | 20,715,894 | 14,624,398 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities | | |
| Accounts payable | 857,121 | 351,735 |
| Accrued liabilities | 1,244,636 | 1,278,428 |
| Management and directors' fees payable | 57,411 | 35,397 |
| Current portion of long-term debt | 337,156 | 443,908 |
| Current portion of capital lease liabilities | 137,383 | 139,084 |
| Current portion of grants repayable | 40,637 | 41,930 |
| Total Current Liabilities | 2,674,344 | 2,290,482 |
| Long-term debt, net of current portion | 1,871,361 | 1,312,785 |
| Capital lease liabilities, net of current portion | 744,322 | 874,684 |
| Grants repayable, net of current portion | 317,731 | 188,579 |

| | | |
|-------------------------------|-----------|-----------|
| Total Liabilities | 5,607,758 | 4,666,530 |
| Commitments and Contingencies | - | - |

STOCKHOLDERS' EQUITY

Common Stock

Authorized: 100,000,000 shares of common stock, at \$0.001 par value

| | | |
|---|--------------|--------------|
| Issued and outstanding: 35,031,225 shares and 26,519,394 shares, respectively | 35,031 | 26,519 |
| Additional paid-in capital | 84,444,318 | 65,774,870 |
| Accumulated other comprehensive income (loss) | 64,111 | (129,343) |
| Accumulated deficit | (69,435,324) | (55,714,178) |

| | | |
|----------------------------|------------|-----------|
| Total Stockholders' Equity | 15,108,136 | 9,957,868 |
|----------------------------|------------|-----------|

| | | |
|--|------------|------------|
| Total Liabilities and Stockholders' Equity | 20,715,894 | 14,624,398 |
|--|------------|------------|

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

VOLITIONRX LIMITED

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(Expressed in United States Dollars, except share numbers)

| | Three-Months Ended | | Nine-Months Ended | |
|--|---------------------------|--------------------|--------------------------|---------------------|
| | September 30, | | September 30, | |
| | 2018 | 2017 | 2018 | 2017 |
| | \$ | \$ | \$ | \$ |
| Revenue | - | - | - | - |
| Operating Expenses | | | | |
| Research and development | 2,737,856 | 2,133,470 | 7,847,531 | 5,619,085 |
| General and administrative | 1,450,383 | 1,555,770 | 4,949,716 | 4,374,736 |
| Sales and marketing | 259,302 | 185,795 | 845,253 | 662,245 |
| Total Operating Expenses | 4,447,541 | 3,875,035 | 13,642,500 | 10,656,066 |
| Operating Loss | (4,447,541) | (3,875,035) | (13,642,500) | (10,656,066) |
| Other Expense | | | | |
| Interest expense | 29,108 | 17,619 | 78,646 | 50,259 |
| Net Loss | (4,476,649) | (3,892,654) | (13,721,146) | (10,706,325) |
| Other Comprehensive Income (Loss) | | | | |
| Foreign currency translation adjustments | 46,350 | (32,399) | 193,454 | 60,415 |
| Net Comprehensive Loss | (4,430,299) | (3,925,053) | (13,527,692) | (10,645,910) |
| Net Loss per Share – Basic and Diluted | (0.14) | (0.15) | (0.46) | (0.41) |
| Weighted Average Shares Outstanding – Basic and Diluted | 32,826,924 | 26,512,195 | 30,071,635 | 26,343,101 |

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

VOLITIONRX LIMITED

Condensed Consolidated Statements of Cash Flows (Unaudited)

(Expressed in United States Dollars)

| | Nine-Months Ended | |
|---|--------------------------|--------------|
| | September 30, | |
| | 2018 | 2017 |
| | \$ | \$ |
| Operating Activities | | |
| Net Loss | (13,721,146) | (10,706,325) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 474,536 | 371,362 |
| Loss on disposal of property and equipment | 1,766 | 11,262 |
| Stock based compensation | 1,875,507 | 1,827,604 |
| Warrants issued for services | 6,453 | 38,806 |
| Changes in operating assets and liabilities: | | |
| Deferred grant income | - | (50,855) |
| Prepaid expenses | (204,673) | (75,723) |
| Other current assets | 202,290 | 12,749 |
| Accounts payable and accrued liabilities | 261,383 | 264,266 |
| Net Cash Used in Operating Activities | (11,103,884) | (8,306,854) |
| Investing Activities: | | |
| Purchases of property and equipment | (183,541) | (1,340,230) |
| Net Cash Used in Investing Activities | (183,541) | (1,340,230) |
| Financing Activities: | | |
| Net proceeds from issuance of common shares | 16,796,000 | 998,412 |
| Proceeds from grants repayable | 177,079 | - |
| Proceeds from long-term debt | 875,418 | 908,075 |
| Payments from long-term debt | (369,915) | (29,807) |
| Payments on grants repayable | (40,864) | (38,487) |
| Payments on capital lease obligations | (103,999) | (94,227) |
| Net Cash Provided by Financing Activities | 17,333,719 | 1,743,966 |

Edgar Filing: VOLITIONRX LTD - Form 10-Q

| | | |
|--|------------|-------------|
| Effect of foreign exchange on cash | 211,871 | 65,314 |
| Net Change in Cash | 6,258,165 | (7,837,804) |
| Cash and cash equivalents – Beginning of Period | 10,116,263 | 21,678,734 |
| Cash and cash equivalents – End of Period | 16,374,428 | 13,840,930 |
| Supplemental Disclosures of Cash Flow Information: | | |
| Interest paid | 78,845 | 50,234 |
| Income tax paid | - | - |
| Non-Cash Financing Activities: | | |
| Common Stock issued on cashless exercises of stock options | 12 | - |
| Offering costs from stock issuances | 604,000 | - |

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

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 1 – Nature of Operations

The Company was incorporated under the laws of the State of Delaware on September 24, 1998. On September 22, 2011, the Company filed a Certificate for Renewal and Revival of Charter with Secretary of State of Delaware. Pursuant to Section 312(1) of the Delaware General Corporation Law, the Company was revived under the new name of “VolitionRx Limited”. The name change to VolitionRx Limited was approved by FINRA on October 7, 2011 and became effective on October 11, 2011.

On October 6, 2011, the Company entered into a share exchange agreement with Singapore Volition Pte. Limited, a Singapore corporation which was incorporated on August 5, 2010 (“Singapore Volition”), and the shareholders of Singapore Volition. Pursuant to the terms of the share exchange agreement, the former shareholders of Singapore Volition held 85% of the issued and outstanding common shares of the Company. The issuance was deemed to be a reverse acquisition for accounting purposes. Singapore Volition, the acquired entity, is regarded as the predecessor entity as of October 6, 2011. The number of shares outstanding and per share amounts have been restated to recognize the recapitalization.

The Company’s principal business objective through its subsidiaries is to develop and bring to market simple, easy to use, cost effective blood tests designed to help diagnose a range of cancers. The tests are based on the science of Nucleosomics[®], which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid – an indication that disease is present. The Company has one wholly-owned subsidiary, Singapore Volition. Singapore Volition has two wholly-owned subsidiaries, Belgian Volition SPRL, a Belgium private limited liability company (formerly ValiBio SA, “Belgian Volition”), which it acquired as of September 22, 2010, and Hypergenomics Pte. Limited (“Hypergenomics”), which it formed as of March 7, 2011. Belgian Volition, has two wholly-owned subsidiaries, Volition Diagnostics UK Limited (“Volition Diagnostics”), which it formed as of November 13, 2015 and Volition America, Inc. (“Volition America”), which it formed as of February 3, 2017. Following the acquisition of Singapore Volition, the Company’s fiscal year end was changed from August 31 to December 31.

Note 2 – Going Concern

The Company’s condensed consolidated financial statements are prepared using accounting principles generally accepted in the United States of America (“U.S. GAAP”) applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has incurred losses

since inception of \$69,435,324, has negative cash flows from operations, and currently has no revenues, which creates substantial doubt about its ability to continue as a going concern for a period of one year from the date of issuance of these condensed consolidated financial statements.

The future of the Company as an operating business will depend on its ability to obtain sufficient capital contributions, financing and/or generate revenues as may be required to sustain its operations. Management plans to address the above as needed by: (a) securing additional grant funds; (b) obtaining additional financing through debt or equity transactions; (c) granting licences to third parties in exchange for specified up-front and/or back end payments; and (d) developing and commercializing its products on an accelerated timeline. Management continues to exercise tight cost controls to conserve cash.

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

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by 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, 2018, and for all periods presented herein, have been made.

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 3 – Summary of Significant Accounting Policies (continued)

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. It is suggested that these unaudited condensed consolidated financial statements be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 1, 2018. The results of operations for the periods ended September 30, 2018 and 2017 are not necessarily indicative of the operating results for the full years. The condensed consolidated financial statements of the Company are expressed in United States Dollars. The Company's fiscal year end is December 31.

Use of Estimates

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

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

Principles of Consolidation

The accompanying condensed consolidated financial statements for the period ended September 30, 2018 include the accounts of the Company and its wholly-owned subsidiaries, Singapore Volition, Belgian Volition, Hypergenomics, Volition America and Volition Diagnostics. All significant intercompany balances and transactions have been

eliminated in consolidation.

Basic and Diluted Net Loss Per Share

The Company computes net loss per share in accordance with Accounting Standards Codification (“ASC”) 260, “Earnings Per Share,” which requires presentation of both basic and diluted earnings per share (EPS) on the face of the income statement. Basic EPS is computed by dividing net loss available to common shareholders (numerator) by the weighted average number of shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. As of September 30, 2018, 10,291,897 dilutive potential common shares from warrants and options were excluded from the diluted EPS calculations as their effect is anti-dilutive.

Reclassification

Certain amounts presented in previously issued financial statements have been reclassified to be consistent with the current period presentation. In the statement of operations and comprehensive loss, the Company has reclassified the prior year comparative three and nine-month amounts of research and development, sales and marketing and general and administrative expenses to be consistent with the current year classification.

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.

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 4 – Property and Equipment

The Company's property and equipment consist of the following amounts as of September 30, 2018 and December 31, 2017:

| | | Cost | Accumulated Depreciation | September 30, 2018 Net Carrying Value |
|--------------------------------|---------------|-----------|-----------------------------|--|
| | Useful Life | \$ | \$ | \$ |
| Computer hardware and software | 3 years | 348,782 | 151,455 | 197,327 |
| Laboratory equipment | 5 years | 1,562,635 | 863,200 | 699,435 |
| Office furniture and equipment | 5 years | 206,014 | 65,839 | 140,175 |
| Buildings | 30 years | 1,522,512 | 80,342 | 1,442,170 |
| Building improvements | 5-15 years | 652,379 | 67,231 | 585,148 |
| Land | Not amortized | 92,885 | - | 92,885 |
| | | 4,385,207 | 1,228,067 | 3,157,140 |

| | | Cost | Accumulated Depreciation | December 31, 2017 Net Carrying Value |
|--------------------------------|-------------|-----------|-----------------------------|---|
| | Useful Life | \$ | \$ | \$ |
| Computer hardware and software | 3 years | 239,133 | 93,422 | 145,711 |
| Laboratory equipment | 5 years | 1,575,354 | 653,636 | 921,718 |
| Office furniture and equipment | 5 years | 207,208 | 54,479 | 152,729 |
| Buildings | 30 years | 1,571,004 | 43,632 | 1,527,372 |

Edgar Filing: VOLITIONRX LTD - Form 10-Q

| | | | | |
|-----------------------|---------------|-----------|---------|-----------|
| Building improvements | 5-15 years | 673,157 | 35,748 | 637,409 |
| Land | Not amortized | 95,843 | - | 95,843 |
| | | 4,361,699 | 880,917 | 3,480,782 |

During the nine-month periods ended September 30, 2018 and September 30, 2017, the Company recognized \$406,986 and \$306,180, respectively, in depreciation expense.

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 5 – Intangible Assets

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

| | | | September 30, 2018 |
|---------|-----------|-----------------------------|-----------------------|
| | Cost | Accumulated Depreciation | Net Carrying Value |
| | \$ | \$ | \$ |
| Patents | 1,180,956 | 686,534 | 494,422 |

| | | | December 31, 2017 |
|---------|-----------|-----------------------------|-----------------------|
| | Cost | Accumulated Depreciation | Net Carrying Value |
| | \$ | \$ | \$ |
| Patents | 1,213,314 | 636,917 | 576,397 |

During the nine-month periods ended September 30, 2018 and September 30, 2017, the Company recognized \$69,584 and \$65,182, respectively, in amortization expense.

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

2018- remaining \$ 20,574

| | |
|-------------------------|------------|
| 2019 | \$ 90,121 |
| 2020 | \$ 90,121 |
| 2021 | \$ 90,121 |
| 2022 | \$ 90,121 |
| Greater than 5 years | \$ 113,364 |
| Total Intangible Assets | \$ 494,422 |

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, 2017. The result of this review confirmed that the ongoing value of the patents was not impaired as of December 31, 2017.

Note 6 – Related Party Transactions

See Note 7 for common stock issued to related parties and Note 8 for stock options and warrants issued to related parties. The Company has agreements with related parties for consultancy services which are accrued under management and directors' fees payable (see condensed consolidated balance sheets).

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 7 – Common Stock

As of September 30, 2018, the Company was authorized to issue 100 million shares of common stock par value \$0.001 per share, of which 35,031,225 and 26,519,394 shares were issued outstanding as of September 30, 2018 and December 31, 2017, respectively.

On March 13, 2018, the Company issued 3.5 million shares of common stock in a registered public offering at a price of \$2.40 per share, for aggregate gross proceeds of \$8.4 million. In connection with the transaction, \$0.6 million was incurred for legal and underwriting fees resulting in net proceeds of \$7.8 million. Pursuant to this offering, the underwriters had the option to purchase up to an additional 525,000 shares of common stock for 30 days following the pricing of the initial closing, which option was not exercised.

On August 10, 2018, the Company issued to Cotterford Company Limited in a private placement offering (PIPE) 5 million shares of common stock at a price of \$1.80 per share, for aggregate gross proceeds of \$9.0 million. Additionally, the Company issued a warrant to purchase up to an additional 5 million shares of common stock at an exercise price of \$3.00 per share payable in cash (see Note 8). This transaction resulted in Cotterford Company Limited being a significant shareholder and therefore a related party in accordance with accounting principles. The shares of common stock (including the shares underlying the warrant) were subsequently registered for resale on Form S-3 (declared effective by the SEC on October 15, 2018, File No. 333-227731).

On September 7, 2018, the Company entered into an equity distribution agreement with Oppenheimer & Co. Inc. (“Oppenheimer”), which agreement allows it to offer and sell shares of common stock having an aggregate offering price of up to \$10.0 million from time to time pursuant to a shelf registration statement on Form S-3 (declared effective by the SEC on September 28, 2018, File No. 333-227248) through Oppenheimer acting as the Company’s agent and/or principal. As of September 30, 2018, the Company had not sold any shares under the equity distribution agreement.

On September 7, 2018, an amendment to the 2015 Stock Incentive Plan (the “2015 Plan”) was approved by stockholders at the annual meeting to increase the number of shares of common stock available for issuance under the 2015 Plan by 750,000 shares to an aggregate maximum of 3,250,000 shares.

During the nine-month period ended September 30, 2018, 29,375 warrants were exercised to purchase shares of common stock at a price of \$2.00 per share in cashless exercises that resulted in the issuance of 11,831 shares of common stock.

Note 8 – Warrants and Options

a) Warrants

The following table summarizes the changes in warrants outstanding of the Company during the nine-month period ended September 30, 2018:

| | Number of Warrants | Weighted Average Exercise Price (\$) |
|-----------------------------------|-------------------------------|---|
| Outstanding at December 31, 2017 | 1,731,680 | 2.36 |
| Granted | 5,000,000 | 3.00 |
| Exercised | (29,375) | 2.00 |
| Expired | (24,375) | 2.98 |
| Outstanding at September 30, 2018 | 6,677,930 | 2.84 |
| Exercisable at September 30, 2018 | 1,552,930 | 2.35 |

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 8 – Warrants and Options (continued)**a) Warrants (continued)**

On August 10, 2018, in conjunction with the PIPE transaction (see Note 7), the Company issued to Cotterford Company Limited a warrant to purchase up to 5.0 million shares of common stock at an exercise price of \$3.00 per share payable in cash (subject to adjustment pursuant to the terms of the warrant). The warrant has an expiration date of August 10, 2019 and is exercisable for a period of 6 months commencing on February 10, 2019.

Below is a table summarizing the warrants issued and outstanding as of September 30, 2018, which have a weighted average exercise price of \$2.84 per share and an aggregate weighted average remaining contractual life of 0.82 years.

| Number Outstanding | Number Exercisable | Exercise Price (\$) | Weighted Average Remaining Contractual Life (Years) | Proceeds to Company if Exercised (\$) |
|-----------------------|-----------------------|------------------------|--|---|
| 948,475 | 948,475 | 2.20 | 0.41 | 2,086,645 |
| 520,455 | 520,455 | 2.40 | 0.19 | 1,249,092 |
| 150,000 | 25,000 | 2.47 | 3.93 | 370,500 |
| 5,000,000 | - | 3.00 | 0.86 | 15,000,000 |
| 19,000 | 19,000 | 3.75 | 0.13 | 71,250 |
| 40,000 | 40,000 | 4.53 | 2.13 | 181,200 |
| 6,677,930 | 1,552,930 | | | 18,958,687 |

Warrant expense of \$6,453 and \$38,806 was recorded in the nine-months ended September 30, 2018 and September 30, 2017, respectively. Total remaining unrecognized compensation cost related to non-vested warrants is approximately \$19,137 and is expected to be recognized over a period of 2.3 years. As of September 30, 2018, the total intrinsic value of warrants was \$486,792.

b) Options

The following table summarizes the changes in options outstanding of the Company during the nine-month period ended September 30, 2018:

| | Number of Options | Weighted Average Exercise Price (\$) |
|-----------------------------------|------------------------------|---|
| Outstanding at December 31, 2017 | 2,939,134 | 4.09 |
| Granted | 805,000 | 4.00 |
| Exercised | - | - |
| Expired/Cancelled | (130,167) | 5.00 |
| Outstanding at September 30, 2018 | 3,613,967 | 4.03 |
| Exercisable at September 30, 2018 | 2,813,967 | 4.04 |

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 8 – Warrants and Options (continued)**b) Options (continued)**

Effective January 23, 2018, the Company granted stock options to purchase a total of 780,000 shares of common stock to various Company personnel (including directors, executives, members of management and employees) for services to the Company. These options vest on January 23, 2019 and expire 5 years after the vesting date, with an exercise price of \$4.00 per share. The Company has calculated the estimated fair market value of these options at \$1,930,265, using the Black-Scholes model and the following assumptions: term 6 years, stock price \$3.75, exercise price \$4.00, 75.4% volatility, 2.55% risk free rate, and no forfeiture rate.

Effective September 28, 2018, the Company granted stock options to purchase 25,000 shares of common stock to the Company controller for services to the Company. These options vest on September 28, 2019 and expire 5 years after the vesting date, with an exercise price of \$4.00 per share. The Company has calculated the estimated fair market value of these options at \$39,733, using the Black-Scholes model and the following assumptions: term 6 years, stock price \$2.59, exercise price \$4.00, 77.59% volatility, 3.01% risk free rate, and no forfeiture rate.

Below is a table summarizing the options issued and outstanding as of September 30, 2018, all of which were issued pursuant to the 2011 Plan (for option issuances prior to 2016) or the 2015 Plan (for option issuances commencing in 2016) and which have a weighted average exercise price of \$4.03 per share and an aggregate weighted average remaining contractual life of 3.36 years. As of September 30, 2018, an aggregate of 789,000 shares of common stock remained available for future issuance under the 2015 Stock Incentive Plan.

| Number Outstanding | Number Exercisable | Exercise Price (\$) | Weighted Average Remaining Contractual Life (Years) | Proceeds to Company if Exercised (\$) |
|-----------------------|-----------------------|------------------------|---|---|
| 17,766 | 17,766 | 2.35 | 1.45 | 41,750 |
| 322,500 | 322,500 | 2.50 | 0.39 | 806,250 |

Edgar Filing: VOLITIONRX LTD - Form 10-Q

| | | | | |
|------------------|------------------|------|------|-------------------|
| 322,500 | 322,500 | 3.00 | 1.39 | 967,500 |
| 17,767 | 17,767 | 3.35 | 2.45 | 59,519 |
| 20,000 | 20,000 | 3.80 | 1.13 | 76,000 |
| 1,915,333 | 1,115,333 | 4.00 | 4.60 | 7,661,332 |
| 17,767 | 17,767 | 4.35 | 3.45 | 77,286 |
| 50,000 | 50,000 | 4.80 | 4.26 | 240,000 |
| 930,334 | 930,334 | 5.00 | 3.01 | 4,651,670 |
| 3,613,967 | 2,813,967 | | | 14,581,307 |

Stock option expense of \$1,875,507 and \$1,827,604 was recorded in the nine-months ended September 30, 2018 and September 30, 2017, respectively. Total remaining unrecognized compensation cost related to non-vested stock options is approximately \$647,899 and is expected to be recognized over a period of 0.99 years. As of September 30, 2018, the total intrinsic value of stock options was \$33,289.

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 9 – Commitments and Contingencies**a) Capital Lease Obligations**

In 2015, the Company entered into an equipment capital lease to purchase three Tecan machines (automated liquid handling robots) for €550,454 Euros. As of September 30, 2018, the balance payable was \$162,357.

In 2016, the Company entered into a real estate capital lease with ING Asset Finance Belgium S.A. (“ING”) to purchase a property located in Belgium for €1.12 million Euros. As of September 30, 2018, the balance payable was \$719,348.

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, 2018.

| | |
|--|-------------------|
| 2018- remaining | \$ 39,517 |
| 2019 | \$ 158,066 |
| 2020 | \$ 108,679 |
| 2021 | \$ 62,450 |
| 2022 | \$ 62,449 |
| Greater than 5 years | \$ 585,445 |
| Total | \$ 1,016,606 |
| Less: Amount representing interest | \$ (134,901) |
| Present value of minimum lease payments | \$ 881,705 |

b) Operating Lease Obligations

The Company also leases premises and facilities under operating leases with terms ranging from 12 months to 60

months. As of September 30, 2018, the annual non-cancelable operating lease payments on these leases are as follows:

| | |
|--|-------------------|
| 2018- remaining | \$ 55,987 |
| 2019 | \$ 65,722 |
| 2020 | \$ 52,864 |
| 2021 | \$ 14,315 |
| Total Operating Lease Obligations | \$ 188,888 |

c) Grants Repayable

In 2010, the Company entered into an agreement with the Walloon Region government in Belgium for a colorectal cancer research grant for €1.05 million Euros. Per the terms of the agreement, €314,406 Euros of the grant is to be repaid. As of September 30, 2018, the grant balance repayable was \$182,758.

On July 2, 2018, the Company entered into an agreement with the Walloon Region government in Belgium for a colorectal cancer research grant for €605,000 Euros. Per the terms of the agreement, €181,500 Euros of the grant is to be repaid over 12 years commencing in 2020. As of September 30, 2018, the grant balance repayable was \$175,610.

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 9 – Commitments and Contingencies (continued)**c) Grants Repayable (continued)**

As of September 30, 2018, the balance repayable was \$358,368 and the annual payments remaining were as follows:

| | | |
|-------------------------------|-----------|----------------|
| 2018- remaining | \$ | - |
| 2019 | \$ | 40,637 |
| 2020 | \$ | 54,685 |
| 2021 | \$ | 51,673 |
| 2022 | \$ | 48,880 |
| Greater than 5 years | \$ | 162,493 |
| Total Grants Repayable | \$ | 358,368 |

d) Long-Term Debt

In 2016, the Company entered into a 7-year loan agreement with Namur Invest for €440,000 Euros with a fixed interest rate of 4.85%. As of September 30, 2018, the principal balance payable was \$430,596.

In 2016, the Company entered into a 15-year loan agreement with ING for €270,000 Euros with a fixed interest rate of 2.62%. As of September 30, 2018, the principal balance payable was \$283,578.

In 2017, the Company entered into a 4-year loan agreement with Namur Invest for €350,000 Euros with a fixed interest rate of 4.00%. As of September 30, 2018, the principal balance payable was \$333,282.

In 2017, the Company entered into a 7-year loan agreement with SOFINEX for up to €1 million Euros with a fixed interest rate of 4.50%. As of September 30, 2018, €500,000 Euros has been drawn down under this agreement and the principal balance payable was \$580,530.

On June 27, 2018, the Company entered into a 4-year loan agreement with Namur Innovation and Growth for €500,000 Euros with fixed interest rate of 4.00%. As of September 30, 2018, the principal balance payable was \$580,531.

As of September 30, 2018, the total balance for long-term debt was \$2,208,517 and the payments remaining were as follows:

| | |
|------------------------------------|---------------------|
| 2018- remaining | \$ 84,417 |
| 2019 | \$ 491,364 |
| 2020 | \$ 698,181 |
| 2021 | \$ 625,288 |
| 2022 | \$ 271,653 |
| Greater than 5 years | \$ 323,200 |
| Total | \$ 2,494,103 |
| Less: Amount representing interest | \$ (285,586) |
| Total Long-Term Debt | \$ 2,208,517 |

VOLITIONRX LIMITED

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(\$ expressed in United States Dollars)

Note 9 – Commitments and Contingencies (continued)

e) Collaborative Agreement Obligations

In 2015, the Company entered into a research sponsorship agreement with DKFZ, in Germany for a 3-year period for €338,984 Euros. As of September 30, 2018, \$87,079 is still to be paid by the Company under this agreement.

In 2016, the Company entered into a research co-operation agreement with DKFZ, in Germany for a 5-year period for €400,000 Euros. As of September 30, 2018, \$232,212 is still to be paid by the Company under this agreement.

In 2016, the Company entered into a collaborative research agreement with Munich University, in Germany for a 3-year period for €360,000 Euros. As of September 30, 2018, \$246,145 is still to be paid by the Company under this agreement.

In 2016, the Company entered into a phase one clinical research agreement with Hvidovre Hospital, University of Copenhagen in Denmark for a 2-year period for DKK 15 million Danish Kroner. As of September 30, 2018, \$333,309 is still to be paid by the Company under this agreement.

In 2017, the Company entered into a clinical study research agreement with the Regents of the University of Michigan (the “University of Michigan”) for a 3-year period for up to \$3 million. As of September 30, 2018, up to \$2.0 million is still to be paid by the Company under this agreement.

On July 9, 2018, the Company entered into a research collaboration agreement with the University of Taiwan for a 3-year period for a cost to the Company of up to \$2.55 million payable over such period. As of September 30, 2018, \$2.42 million is still to be paid by the Company under this agreement.

As of September 30, 2018, the total amount to be paid for future research and collaboration commitments was \$5.32 million and the annual payments remaining were as follows:

| | |
|--|---------------------|
| 2018- remaining | \$ 1,065,521 |
| 2019 | \$ 2,399,450 |
| 2020 | \$ 963,774 |
| 2021 | \$ 892,500 |
| Total Collaborative Agreement Obligations | \$ 5,321,245 |

f) Legal Proceedings

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

Note 10 – Subsequent Events

On October 16, 2018, 60,250 warrants were exercised at a price of \$2.20 per share, for net cash proceeds to the Company of \$132,550. As a result, a total of 60,250 shares of common stock were issued.

On October 16, 2018, 243,903 warrants were exercised at a price of \$2.40 per share, for net cash proceeds to the Company of \$585,367. As a result, a total of 243,903 shares of common stock were issued.

END NOTES TO CONDENSED CONSOLIDATED 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, 2018, or this 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, or the Exchange Act. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact included in this Report or incorporated by reference into this Report are forward-looking statements. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items; plans or expectations with respect to our development activities or business strategy; statements concerning clinical studies and results, statements concerning industry trends; statements regarding anticipated demand for our products, or the products of our competitors, statements relating to manufacturing forecasts, and the potential impact of our relationship with contract manufacturers and original equipment manufacturers on our business; statements relating to the commercialization of our products, assumptions regarding the future cost and potential benefits of our research and development efforts; forecasts of our liquidity position or available cash resources; statements relating to the impact of pending litigation; and statements relating to the assumptions underlying any of the foregoing. Throughout this Report, we have attempted to identify forward-looking statements by using words such as "may," "believe," "will," "could," "project," "anticipate," "expect," "estimate," "should," "continue," "potential," "plan," "forecasts," "goal," "seek," "intend," other forms of these words or similar words or expressions or the negative thereof (although not all forward-looking statements contain these words).

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

You should read this Report in its entirety, together with our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as filed with the SEC on March 1, 2018, or our Annual Report, the documents that we file as

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

Company Overview

VolitionRx is a multi-national life sciences company developing simple, easy to use, cost effective blood tests designed to help diagnose a range of cancers. We hope that through earlier diagnosis we can help save and improve the quality of many people's lives throughout the world.

Our tests are based mainly on the science of Nucleosomics[®], which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid - an indication that disease is present. We have developed a novel suite of blood assays for epigenetically altered circulating nucleosomes as biomarkers in cancer. Nu.Q[™] products are simple, low-cost, ELISA platform tests and can incorporate other off patent, low cost ELISA tests in our panels (e.g. CEA, PSA, and CA125) for higher accuracy.

Our diagnostic target in the blood includes the same tumor chromosome fragment as targeted by ctDNA tests, but our approach is to test for chromosome protein and nucleic acid changes in intact chromosome fragments by ELISA, rather than chemically extracting, amplifying, and sequencing the ctDNA and discarding the rest of the nucleosome. ELISA is possible because the targets of our tests occur globally across all nucleosomes within a tumor cell, whereas individual ctDNA changes must be identified within the three billion base-pair genomes. This means that the targets of our tests are exponentially more prevalent in circulating blood, and detectable using simple laboratory methods.

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

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

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

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

We believe that the only viable option to achieve high levels of compliance will come from affordable blood tests that use a small amount of blood taken as part of the patient's normal health check procedure. We aim to launch such a front-line CRC population screening test for asymptomatic people who are non-compliant with current screening methods in Europe in 2019 and in Asia soon after. This product will require a small amount of blood and will use the same established, robust, low-cost ELISA methodology employed in the PSA test for prostate cancer.

Overview of Plan of Operations

We have identified the specific processes and resources required to achieve the near and medium-term objectives of our business plan, including personnel, facilities, equipment, research and testing materials including antibodies and clinical samples, and the protection of intellectual property. To date, operations have proceeded satisfactorily in relation to our 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 our business plan, in particular the progression of clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market.

Our future as an operating business will depend on our ability to obtain sufficient capital contributions, financing and/or generate revenues as may be required to sustain our operations. Management plans to address the above as needed by: (a) securing additional grant funds; (b) obtaining additional equity or debt financing; (c) granting licenses to third parties in exchange for specified up-front and/or back end payments; and (d) developing and commercializing our products on an accelerated timeline. Management continues to exercise tight cost controls to conserve cash.

Our ability to continue as a going concern is dependent upon our accomplishment of the plans described in the preceding paragraph and eventually to attain profitable operations. The accompanying financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. If we are unable to obtain adequate capital, we could be forced to cease operations.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private placements and public offerings of our common stock. As of September 30, 2018, we had cash and cash equivalents of approximately \$16.4 million.

Net cash used in operating activities was \$11.1 million and \$8.3 million for the nine-months ended September 30, 2018 and September 30, 2017, respectively. The increase in cash used in operating activities for the period ended September 30, 2018 when compared to same period in 2017 was primarily due to increased expenditures on research and development activities and general and administrative activities.

Net cash used in investing activities was \$0.2 million and \$1.3 million for the nine-months ended September 30, 2018 and September 30, 2017, respectively. The decrease in cash used in investing activities for the period ended September 30, 2018 when compared to same period in 2017 was primarily a result of the purchase of equipment and facility improvements for the new research and development facility in Belgium in 2017.

Net cash provided by financing activities was \$17.3 million and \$1.7 million for the nine-months ended September 30, 2018 and September 30, 2017, respectively. The increase in cash provided by financing activities for the period ended September 30, 2018 when compared to same period in 2017 was primarily the result of \$7.8 million in net cash proceeds raised in March 2018 through the sale and issuance of 3.5 million shares of common stock in a public offering as well as \$9.0 million in gross cash proceeds raised in August 2018 through a private placement of 5.0 million shares of common stock and a warrant to purchase up to an additional 5.0 million shares of common stock.

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 equity or debt securities, or the sale of licensing rights. There is no assurance that we will be successful in raising further funds.

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

We have not attained profitable operations and are dependent upon obtaining financing to pursue any extensive activities. For these reasons, our auditors have included in their report on our audited financial statements for the fiscal year ended December 31, 2017 an explanatory paragraph regarding factors that raise substantial doubt that we will be able to continue as a going concern.

The following table summarizes our approximate contractual payments due by year as of September 30, 2018.

Approximate Payments (Including Interest) Due by Year

| Description | 2018 | | | |
|--------------------------------------|------------------|------------------|------------------|------------------|
| | Total | (Remaining) | 2019 - 2022 | 2023 + |
| | \$ | \$ | \$ | \$ |
| Capital Lease Obligations | 1,016,606 | 39,517 | 391,644 | 585,445 |
| Operating Lease Obligations | 188,888 | 55,987 | 132,901 | - |
| Grants Repayable | 358,368 | - | 195,875 | 162,493 |
| Long-Term Debt ⁽¹⁾ | 3,110,596 | 84,417 | 2,278,351 | 747,828 |
| Collaborative Agreements Obligations | 5,321,245 | 1,065,521 | 4,255,724 | - |
| Total | 9,995,703 | 1,245,442 | 7,254,495 | 1,495,766 |

⁽¹⁾ Long-term debt includes the total value of the SOFINEX line of credit of €1.0 million Euros although only €500,000 Euros had been drawn down as of September 30, 2018. See Note 9(d) to the Condensed Consolidated Financial Statements for further details.

Results of Operations

Comparison of the Three-Months Ended September 30, 2018 and September 30, 2017.

The following table sets forth our results of operations for the three-months ended on September 30, 2018 and September 30, 2017, respectively.

| | Three-Months Ended | | | Percentage Increase (Decrease) |
|----------------------------|--------------------|--------------------|---------------------|--------------------------------|
| | September 30, 2018 | September 30, 2017 | Increase (Decrease) | |
| | \$ | \$ | \$ | % |
| Revenue | - | - | - | - |
| Research and development | (2,737,856) | (2,133,470) | 604,386 | 28% |
| General and administrative | (1,450,383) | (1,555,770) | (105,387) | (7)% |
| Sales and marketing | (259,302) | (185,795) | 73,507 | 40% |

| | | | | |
|---|-------------|-------------|-----------|------|
| Total Operating Expenses | (4,447,541) | (3,875,035) | 572,506 | 15% |
| Interest expense | (29,108) | (17,619) | 11,489 | 65% |
| Net Loss | (4,476,649) | (3,892,654) | 583,995 | 15% |
| Net Loss per Share – Basic and Diluted | (0.14) | (0.15) | (0.01) | (7)% |
| Weighted Average Shares Outstanding - Basic and Diluted | 32,826,924 | 26,512,195 | 6,314,729 | 24% |

Revenues

Our operations are still predominantly in the research and development stage and we had no revenues during the three-months ended September 30, 2018 and September 30, 2017, respectively.

Operating Expenses

Total operating expenses increased to \$4.4 million for the three-months ended September 30, 2018 from \$3.9 million for the three-months ended September 30, 2017.

Research and Development Expenses

Research and development expenses increased to \$2.7 million for the three-months ended September 30, 2018 from \$2.1 million for the three-months ended September 30, 2017. This increase in overall research and development expenditures was primarily related to our participation in the trial with the University of Michigan and increased headcount during the period.

| | Three-Months Ended | | |
|--|-------------------------------|-------------|---------------|
| | September 30, | | |
| | 2018 | 2017 | Change |
| | \$ | \$ | \$ |
| Personnel expenses | 856,507 | 598,898 | 257,609 |
| Stock based compensation | 126,879 | 135,873 | (8,994) |
| Direct research and development expenses | 1,473,140 | 1,136,098 | 337,042 |
| Other research and development | 131,739 | 125,546 | 6,193 |
| Depreciation and amortization | 149,591 | 137,055 | 12,536 |
| Total Research and Development expenses | 2,737,856 | 2,133,470 | 604,386 |

General and Administrative Expenses

General and administrative expenses decreased to \$1.5 million for the three-months ended September 30, 2018, from \$1.6 million for the three-months ended September 30, 2017. This decrease in overall general and administrative expenditures was primarily due to lower stock-based compensation costs during the period.

| | Three-Months Ended | | |
|--------------------|-------------------------------|-------------|---------------|
| | September 30, | | |
| | 2018 | 2017 | Change |
| | \$ | \$ | \$ |
| Personnel expenses | 548,867 | 580,378 | (31,511) |

Edgar Filing: VOLITIONRX LTD - Form 10-Q

| | | | |
|---|-----------|-----------|-----------|
| Stock-based compensation | 328,153 | 442,255 | (114,102) |
| Legal and professional fees | 371,700 | 394,650 | (22,950) |
| Other general and administrative | 192,894 | 132,805 | 60,089 |
| Depreciation and amortization | 8,769 | 5,682 | 3,087 |
| Total General and Administrative expenses | 1,450,383 | 1,555,770 | (105,387) |

Sales and Marketing Expenses

Sales and marketing expenses increased to \$259,302 for the three-months ended September 30, 2018, from the \$185,795 for the three-months ended September 30, 2017. This increase in overall sales and marketing expenditures was primarily related to increased staff costs during the period.

| | Three-Months Ended | | |
|--|-------------------------------|-------------|---------------|
| | September 30, | | |
| | 2018 | 2017 | Change |
| | \$ | \$ | \$ |
| Personnel expenses | 206,527 | 89,913 | 116,614 |
| Stock-based compensation | 34,307 | 39,001 | (4,694) |
| Direct marketing and professional fees | 18,468 | 56,881 | (38,413) |
| Total Sales and Marketing expenses | 259,302 | 185,795 | 73,507 |

Other Expenses

For the three-months ended September 30, 2018, the Company's other expenses were \$29,108 compared to \$17,619 for the three-months ended September 30, 2017.

Net Loss

For the three-months ended September 30, 2018, the Company's net loss was \$4.5 million, an increase of approximately \$0.6 million, or 15%, in comparison to a net loss of \$3.9 million for the three-months ended September 30, 2017. The change was a result of the factors described above.

Comparison of the Nine-Months Ended September 30, 2018 and September 30, 2017.

The following table sets forth our results of operations for the nine-months ended on September 30, 2018, and September 30, 2017, respectively.

| | Nine-Months Ended | | | Percentage Increase (Decrease) % |
|---|--------------------------|--------------|---------------------------------------|---|
| | September 30, | | Increase (Decrease) \$ | |
| | 2018 | 2017 | | |
| | \$ | \$ | \$ | |
| Revenue | - | - | - | - |
| Research and development | (7,847,531) | (5,619,085) | 2,228,446 | 40% |
| General and administrative | (4,949,716) | (4,374,736) | 574,980 | 13% |
| Sales and marketing | (845,253) | (662,245) | 183,008 | 28% |
| Total Operating Expenses | (13,642,500) | (10,656,066) | 2,986,434 | 28% |
| Interest expense | (78,646) | (50,259) | 28,387 | 56% |
| Net Loss | (13,721,146) | (10,706,325) | 3,014,821 | 28% |
| Net Loss per Share – Basic and Diluted | (0.46) | (0.41) | 0.05 | 12% |
| Weighted Average Shares Outstanding - Basic and Diluted | 30,071,635 | 26,343,101 | 3,728,534 | 14% |

Revenues

Our operations are still predominantly in the research and development stage and we had no revenues during the nine-months ended September 30, 2018 and September 30, 2017, respectively.

Operating Expenses

Total operating expenses increased to \$13.6 million for the nine-months ended September 30, 2018 from \$10.7 million for the nine-months ended September 30, 2017.

Research and Development Expenses

Research and development expenses increased to \$7.8 million for the nine-months ended September 30, 2018 from \$5.6 million for the nine-months ended September 30, 2017. This increase in overall research and development expenditures was primarily related to antibody purchases, trial with the University of Michigan and increased headcount during the period.

| | Nine-Months Ended | | |
|--|--------------------------|-------------|---------------|
| | September 30, | | Change |
| | 2018 | 2017 | |
| | \$ | \$ | \$ |
| Personnel expenses | 2,685,961 | 1,900,835 | 785,126 |
| Stock based compensation | 466,908 | 484,262 | (17,354) |
| Direct research and development expenses | 4,031,317 | 2,249,950 | 1,781,367 |
| Other research and development | 213,774 | 628,920 | (415,146) |
| Depreciation and amortization | 449,571 | 355,118 | 94,453 |
| Total Research and Development expenses | 7,847,531 | 5,619,085 | 2,228,446 |

General and Administrative Expenses

General and administrative expenses increased to \$4.9 million for the nine-months ended September 30, 2018, from

\$4.4 million for the nine-months ended September 30, 2017. This increase in overall general and administrative expenditures was primarily due to higher foreign exchange costs and legal costs in relation to the capital raises during the 2018 period.

| | Nine-Months Ended | | |
|--|--------------------------|------------------|----------------|
| | September 30, | | |
| | 2018 | 2017 | Change |
| | \$ | \$ | \$ |
| Personnel expenses | 1,629,390 | 1,581,948 | 47,442 |
| Stock-based compensation | 1,278,634 | 1,308,271 | (29,637) |
| Legal and professional fees | 1,209,772 | 987,389 | 222,383 |
| Other general and administrative | 804,921 | 491,151 | 313,770 |
| Depreciation and amortization | 26,999 | 5,977 | 21,022 |
| Total General and Administrative expenses | 4,949,716 | 4,374,736 | 574,980 |

Sales and Marketing Expenses

Sales and marketing expenses increased to \$845,253 for the nine-months ended September 30, 2018, from the \$662,245 for the nine-months ended September 30, 2017. This increase in overall sales and marketing expenditures was primarily related to increased marketing professional fees during the period.

| | Nine-Months Ended | | |
|--|------------------------------|-------------|---------------|
| | September 30, | | |
| | 2018 | 2017 | Change |
| | \$ | \$ | \$ |
| Personnel expenses | 515,704 | 446,542 | 69,162 |
| Stock-based compensation | 136,418 | 73,876 | 62,542 |
| Direct marketing and professional fees | 193,131 | 141,827 | 51,304 |
| Total Sales and Marketing expenses | 845,253 | 662,245 | 183,008 |

Other Expenses

For the nine-months ended September 30, 2018, the Company's other expenses were \$78,646 compared to \$50,259 for the nine-months ended September 30, 2017.

Net Loss

For the nine-months ended September 30, 2018, the Company's net loss was \$13.7 million, an increase of approximately \$3.0 million, or 28%, in comparison to a net loss of \$10.7 million for the nine-months ended September 30, 2017. The change was a result of the factors described above.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to stockholders.

Future Financings

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

Critical Accounting Policies

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

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

Recently Issued Accounting Pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Our management carried out an evaluation under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer have concluded, as they previously concluded as of December 31, 2017, that our disclosure controls and procedures continue to not be effective as of September 30, 2018, because of material weaknesses in our internal control over financial reporting, as described below and in detail in our Annual Report.

Changes in Internal Control over Financial Reporting

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

As of September 30, 2018, we did not maintain sufficient internal controls over financial reporting:

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

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

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

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

There have been no changes in our internal controls over financial reporting that occurred during the fiscal quarter ended September 30, 2018, other than those described above, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Limitations of the Effectiveness of Disclosure Controls and Internal Controls

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

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

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

There have been no material changes in our assessment of risk factors affecting our business since those presented in Part I, Item 1A of our Annual Report.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filing Date | Filed Herewith |
|----------------|--|---------------------------|------------|---------|-------------|----------------|
| | | Form | File No. | Exhibit | | |
| <u>10.1</u> | Common Stock Purchase Agreement, dated August 8, 2018, by and between the Company and Cotterford Company Limited, including the form of Warrant attached as Exhibit B thereto. | 8-K | 001-36833 | 10.1 | 8/9/18 | |
| <u>10.2</u> | Equity Distribution Agreement, dated September 7, 2018, by and between the Company and Oppenheimer & Co. Inc. | S-3 | 333-227248 | 1.2 | 9/10/18 | |
| <u>10.3</u> | 2015 Stock Incentive Plan, as amended. | 8-K | 001-36833 | 10.1 | 9/11/18 | |
| <u>31.1</u> | Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended. | | | | | X |
| <u>31.2</u> | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended. | | | | | X |
| <u>32.1*</u> | Certifications of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | | X |
| 101.INS | XBRL Instance Document. | | | | | X |
| 101.SCH | XBRL Taxonomy Extension Schema Document. | | | | | X |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. | | | | | X |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. | | | | | X |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. | | | | | X |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. | | | | | X |

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

any such filing.

SIGNATURES

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

VOLITIONRX LIMITED

Dated: November 8, 2018 By: */s/ Cameron Reynolds*
Cameron Reynolds
President and Chief Executive Officer

(Authorized Signatory and Principal Executive Officer)

Dated: November 8, 2018 By: */s/ David Vanston*
David Vanston
Chief Financial Officer and Treasurer

(Authorized Signatory and Principal Financial
and Accounting Officer)
