VOLITIONRX LTD
Form 10-K
March 13, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 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	**1 Scotts Road**	**91-1949078**
(State or other jurisdiction of incorporation or organization)	**#24-05 Shaw Centre** **Singapore 228208**	(I.R.S. Employer Identification No.)

(Address of principal executive offices)

+1 (646) 650-1351

(Registrant's telephone number,

including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Name of Each Exchange on Which Registered:
Common Stock, par value $0.001 per share	**NYSE American, LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] No [X]

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or

information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[ ]

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

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

As of June 29, 2018, the last trading day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting common stock held by non-affiliates of the registrant was $48,292,650 (based upon the $2.00 per share closing price for the registrant's common stock as reported by the NYSE American on such date). This calculation does not reflect a determination that persons deemed to be affiliates for this purpose are affiliates for any other purpose.

As of March 12, 2019, there were 37,813,991 shares of the registrant's $0.001 par value common stock issued and outstanding.

Documents incorporated by reference:

Portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders, to be filed on or before April 30, 2019, are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K.

Table of Contents

PART I **Page**

Item 1. **BUSINESS** 2

Item 1A. **RISK FACTORS** 8

Item 1B. **UNRESOLVED STAFF COMMENTS** 17

Item 2. **PROPERTIES** 17

Item 3. **LEGAL PROCEEDINGS** 17

Item 4. **MINE SAFETY DISCLOSURES** 17

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS **AND ISSUER PURCHASES OF EQUITY SECURITIES** 18

Item 6. **SELECTED FINANCIAL DATA** 18

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND **RESULTS OF OPERATIONS** 19

Item 7A. **QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK** 23

Item 8. **FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA** F-1

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND **FINANCIAL DISCLOSURE** 24

Item 9A. **CONTROLS AND PROCEDURES** 24

Item 9B. OTHER INFORMATION…….….25

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE……..…26

Item 11. EXECUTIVE COMPENSATION…….....…26

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND **RELATED STOCKHOLDER MATTERS**…….……26

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR **INDEPENDENCE**…….....…26

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES……...26

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES……..…27

Item 16. FORM 10-K SUMMARY…….….31

SIGNATURES …..……..……..……32

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which we refer to as 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, which statements are subject to considerable risks and uncertainties. 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. 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," "plans," "forecasts," "goal," "aim," "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). In particular, forward-looking statements contained in this Report relate to, 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, including commercialization and market acceptance; statements concerning industry trends and industry size; statements regarding anticipated demand for our products and market opportunity, 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; the effect of critical accounting policies; 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.

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. We discuss these risks and uncertainties in greater detail in the section entitled "Risk Factors" in Part I, Item 1A of this Report, and the other documents that we have filed 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, including 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.

Use of Terms

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

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

PART I

ITEM 1. BUSINESS

Overview

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

Our Solution/Science

Our 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 principle behind what we are doing relies on bringing together two main lines of research and is, in concept, very simple: the chromosomes of cancer cells differ from those of healthy cells – both in terms of DNA sequence (due to genetic cancer mutations) and in protein structure - due to epigenetic changes. There are chromosome fragments from dead cancer cells circulating in the blood as nucleosomes. Each such circulating nucleosome contains a small (approx. 140bp) fragment of tumor DNA.

Our Nucleosomics technology exploits the different compositions of circulating nucleosome structures present in the blood of cancer patients to detect and identify cancer diseases.

We are developing a novel suite of blood assays for epigenetically altered circulating nucleosomes as biomarkers in cancer and other diseases. Nu.Q™ products aim to be simple, low-cost, enzyme-linked immunosorbent assay, or ELISA, platform tests and can incorporate other biomarkers such as anti-inflammatory markers and/or off-patent low-cost ELISA tests in our panels (e.g. CEA, PSA, CA125) for higher accuracy.

Many companies and medical schools are developing circulating tumor DNA, or ctDNA, tests based on sequencing the DNA attached to these nucleosomes.

Our diagnostic target in the blood is the same tumor chromosome fragment, 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.

How is Nu.Q different from ctDNA?

When a cancer cell dies the nuclear components are metabolized into 20 million individual DNA-Nu complexes and released into circulation. A cancer mutation will occur in one of the DNA-Nu complexes.

ctDNA sequencing methods (in development) must target that one-in-a million DNA-Nu complex.

Nu.Q targets all 20 million circulating DNA-Nu complexes because nucleosome modifications occur globally.

Nu.Q is a simple low-cost ELISA and can incorporate other ELISA tests in our panels.

Additionally we are working on complete Nucleosome analysis (Nu.Q Capture). The goal of this project is to investigate ways to specifically target for ctDNA. The ability of enriching for ctDNA will allow us to use Mass Spectrometry to analyze histone and DNA modifications and to sequence the DNA present around the nucleosomes. This extremely valuable information may enable cancer diagnosis and to identify the tissue of origin of that given cancer.

Using our Nucleosomics technology, we are developing epigenetic Nu.Q assays, which are designed to detect the level and structure of nucleosomes in blood. Epigenetics is the science of how genes are switched “on” or “off” in the body’s cells. A major factor controlling the switching “on” and “off” is the structuring of DNA. The DNA in human cells is packaged as protein complexes in a “beads on a string” structure. Each individual protein/DNA “bead” is called a nucleosome. These nucleosomes then form additional structures with increasingly dense packing, culminating in chromosomes containing hundreds of thousands of nucleosomes as depicted in Figure 1 below.

Figure 1 – A nucleosome

Cancer is characterized by uncontrolled and often rapid cell growth which exceeds the corresponding rate of cell death. When cells die, the DNA fragments into individual nucleosomes which are released into the blood as illustrated in Figure 2 below. The cell debris in the bloodstream is eventually recycled back into the body. When a cancer is present, the number of dying cells can overwhelm the recycling process, leaving the excess fragments, including the nucleosomes, in the blood. Importantly, the structure of nucleosomes is not uniform but subject to immense variety, and nucleosomes in cancer cells have differences in structure from those in healthy cells.

Figure 2 – Release of nucleosomes into blood

Blood nucleosome levels can be raised in conditions other than cancer including in auto-immune disease, inflammatory disease, endometriosis, sepsis, and in the immediate aftermath of major trauma (for example following a heart attack, surgery or car accident). Our primary focus is on cancer diagnosis, but we are also pursuing diagnostic opportunities in other disease areas.

Research and Development

We are developing blood-based tests for the most prevalent cancers focusing on colorectal cancer, lung cancer, prostate cancer and pancreatic cancer, using our Nucleosomics biomarker discovery platform. Our development pipeline includes assays to be used for symptomatic patients, asymptomatic (screening) patients and high-risk 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 approaches such as bisulfite conversion and polymerase chain reaction, or PCR.

We are developing blood-based Nu.Q immunoassays 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.

Listed below are the major studies we have underway in colorectal cancer, pancreatic cancer and a study involving 27 cancers.

Institution	Condition	Sample Collection	Cohort	Timing
Early Detection Research Network of the U.S. National Cancer Institute (EDRN)	Colorectal Cancer	9,000 Prospective, 4,600 Retrospective	13,500 + Screening Population	Collection Ongoing to 2020.
National Taiwan University	Colorectal Cancer	Prospective	5,000 Asymptomatic Patients	Collection Ongoing to 2021.
National Taiwan University	Colorectal Cancer	Prospective	2,000 Symptomatic Patients	Collection Ongoing to 2021.
Hvidovre Hospital, University of Copenhagen	Colorectal Cancer	Prospective	14,000 Screening Population	Collection completed and Analysis Ongoing.
Hvidovre Hospital, University of Copenhagen	Colorectal Cancer	Prospective	30,000 Screening Population	Collection completed and Analysis Ongoing.
Hvidovre Hospital, University of Copenhagen	Colorectal Cancer	Retrospective	4,800 Symptomatic Patients	Collection completed and Analysis Ongoing.
University of Bonn	27 Most Prevalent Cancers	Prospective	4,500 Subjects	Collection completed and Analysis Ongoing.
German Cancer Research Center (DKFZ)	Pancreatic Cancer	Retrospective	750 Subjects	Collection completed and Analysis Ongoing.

Commercialization Strategy

We are transitioning from a purely clinical stage company to a commercial company. We will continue to research and develop additional assays and products across a range of cancers as we continue to develop our commercial operations. We plan to develop multiple products across the whole range of cancers falling into the categories listed below:

Frontline General Population Screening Tests	**High Risk Screening "Triage" Tests**	**Diagnostic / Adjunct Diagnostic Tests**	**Treatment Selection/ Disease Monitoring Tests**
For asymptomatic subjects for the most prevalent cancers.	To work in conjunction with existing tests to improve sensitivity and/or specificity.	To aid the diagnosis of disease in symptomatic patients and/or high-risk patients.	To help identify the most appropriate treatment for the disease.
For example, lung, colorectal, gastric and breast cancers.	For example, with the fecal immunochemical test, or the FIT, for colorectal cancer.	For example, with low dose CT scans for lung cancer or Type II diabetes patients for pancreatic cancer.	For example, prostate cancer.

We believe that given the global prevalence of cancer and the low-cost, accessible and routine nature of our tests, Nu.Q could potentially be used throughout the world. Our launch sequence is determined to a large extent by regulatory hurdles - consequently, we aim to launch our products first in Europe and Asia, and subsequently in the United States. We plan to work with partners and/or distributors to commercialize Nu.Q worldwide.

In addition to human diagnostics, we are also researching the use of the Nu.Q technology in veterinary applications. An initial proof-of-concept study demonstrated that nucleosomes can be detected in dogs and therefore have the potential to differentiate cancer from other diseases. We will now test the Nu.Q platform in larger trials in veterinary medicine.

The United States is currently the largest veterinary market in the world and has a clearly defined regulatory pathway through the U.S. Department of Agriculture, or the USDA, requiring fewer and smaller clinical studies than the U.S. Food and Drug Administration, or the FDA, process for human diagnostics. This generally allows for a much faster route to revenue for veterinary products as compared to human products.

If we do not have enough funds to fully implement our business plan, we will be forced to scale back our plan of operations and our business activities, increase our anticipated timeframes to complete each milestone or seek additional funding. In the event that additional financing is delayed, we will prioritize the maintenance of our research and development personnel and facilities, primarily in Belgium.

The Market Opportunity

Cancer is one of the leading causes of death worldwide, accounting for around 8.2 million annual deaths globally. There are over 14 million new cases of cancer diagnosed each year and given the aging population this is expected to grow rapidly to over 21.5 million new cases annually by 2030. Currently, in the United States there are more than three new cases of cancer diagnosed and one person dies of a cancer-related death every minute.

Statistically, the chances of surviving cancer are greatly improved by early detection and treatment. However, there are currently very few blood tests for diagnosis of cancer in common clinical use. The only blood test commonly used for screening any cancer is the Prostate-Specific Antigen, or PSA, test for prostate cancer. We consider the PSA test to have relatively poor diagnostic accuracy (detecting approximately 70% of prostate cancers and misdiagnoses of about 30% of healthy men as positive for cancer) but it is widely used because it is the best product currently available. The PSA test is intended to be used to monitor patients after definitive diagnosis or treatment. The American Cancer Society recommends that prostate cancer screening should not occur without an informed decision-making process regarding risks. In 2012, the U.S. Preventative Services Task Force recommended against PSA-based screening for healthy men because of a “moderate or high probability” that the service has no benefit or that the harms outweigh the benefits.

We believe that early, non-invasive, accurate cancer diagnosis remains a significant unmet medical need and a significant commercial opportunity. For these reasons, cancer diagnostics is an active field of research and development both academically and commercially.

The global in vitro diagnostic medical device, or IVD, market was $64.5 billion in 2017 and is forecasted to reach $93.6 billion by 2025, registering a compound annual growth rate, or CAGR, of 4.8% from 2018 to 2025. The forecasted growth is due primarily to the increasing health care demands of an aging population.

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 than typically occurs currently, and testing of individuals who, for reasons such as time, cost or aversion to current methods, are not currently being tested.

Competition

We believe that Epigenomics AG, or Epigenomics, is our main competitor in the blood-based diagnostic market. Epigenomics' methylated DNA-based PCR, test in colon cancer (Epi proColon®) is available in the United States, Europe, China and select other countries and its lung cancer test (Epi proLung®) has been CE-Marked in Europe. CellMax Life Inc. is another cancer diagnostics company offering non-invasive tests for early cancer detection and management; however, currently, its tests have limited clinical data and are available only in Taiwan or via Clinical Laboratory Improvement Amendments, or CLIA, certified labs, in the United States. In colon cancer, we also face potential competition from alternative procedures including flexible sigmoidoscopy, colonoscopy and virtual colonoscopy as well as traditional tests such as the stool guaiac and FIT. Exact Sciences Corporation has FDA and reimbursement approval for its stool-based DNA screening test, Cologuard®. In addition, there are two relatively new entrants to the market, Guardant Health, Inc. and Freenome Inc., although their initial focus appears to be on treatment selection and monitoring, rather than on frontline diagnosis.

In the area of lung cancer our competitors include OncoCyte Corporation with DetermaVu™ (expected to launch in the second half of 2019) and Oncimmune Holdings Plc with *Early* CDT® (currently available via CLIA certified labs).

In the area of prostate cancer potential competitors include OpKo Health Inc. with its 4KScore® test (available in the United States via CLIA certified labs) and MDNA Life Sciences with its Mitomic™ Prostate Test (available in the United Kingdom and to be distributed exclusively in the United States by LabCorp.).

We anticipate facing competition primarily from healthcare, pharmaceutical and diagnostic companies such as Epigenomics, Exact Sciences Corporation, Abbott Laboratories Inc., Cepheid Inc., Philips, GE Healthcare, Siemens, Gen-Probe Incorporated, MDxHealth SA, and Roche Diagnostics. There may also be other companies developing products competitive with ours of which we are unaware.

We hope that our future products will have a competitive edge compared to those offered by competitors on the basis that our tests are being developed to be accurate, cost-effective and attractive from a government reimbursement perspective, easy to use, non-invasive, technologically advanced, and compatible with ELISA systems, based on strong intellectual property and to be used for mass screenings.

Many of our competitors have substantially greater financial, technical, and other resources and larger, more established marketing, sales and distribution systems than we have. Many of our competitors also offer broad product lines outside of the diagnostic testing market and have brand recognition. Moreover, our competitors may make rapid technological developments that may result in our intended technologies and products becoming obsolete before we are able to enter the market, recover the expenses incurred to develop them or generate significant revenue. Our success will depend, in part, on our ability to develop our intended products in a timely manner, keep our future products current with advancing technologies, achieve market acceptance of our future products, gain name recognition and a positive reputation in the healthcare industry, and establish successful marketing, sales and distribution efforts.

Government Regulations

The health care industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change.

Both United States federal and state governmental agencies continue to subject the health care industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the marketing, labeling, promotion, manufacturing and export of diagnostic health care products. Our diagnostic products fall within the IVD medical device category and are subject to FDA clearance or approval in the United States.

The federal government also has increased funding in recent years to fight health care fraud, and various agencies, such as the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, or OIG, and state Medicaid fraud control units, are coordinating their enforcement efforts.

In Europe, medical devices are regulated by self-certification through the CE Mark system. Under the system, developers and manufacturers must operate a Quality System and validate medical devices in a limited clinical trial to demonstrate the manufacturer has met analytical and clinical performance criteria. We have implemented an

International Organization for Standardization standard - ISO 13485 - quality management system for the design and manufacture of medical devices. ISO 13485 addresses managerial awareness of regulatory requirements, control systems, inspection and traceability, device design, risk and performance criteria as well as verification for corrective and preventative measures for device failure. Medical device companies such as ours are subject to pre-market compliance assessments from Notified Bodies, a certification organization which the national authority (the competent authority) of a European Union member state designates to carry out one or more of the conformity assessment procedures. ISO 13485 certification establishes conformity to specific European Union directives related to medical devices and allows CE Marking and sale of the device.

The new European In Vitro Diagnostic Regulation (IVDR - 2017/746), or the EU IVDR, became effective as of May 25, 2017, marking the start of a transition period for manufacturers selling IVD devices into Europe. The EU IVDR, which replaces IVD Directive (98/79/EC), or the Directive, has a transition period of five years, after which the EU IVDR will apply in full, and no new applications pursuant to the Directive will be accepted. Manufacturers have the duration of the five-year transition period to update their technical documentation and processes to meet the new, more stringent European Union regulatory requirements. We believe that the most challenging areas under the EU IVDR will be regarding the classification of products, which will bring almost all IVDs under the direct control of Notified Bodies, and the performance evaluation of IVDs, which will not only include the classic clinical performance and analytical performance but also scientific validity, the role and responsibilities of the economic actors of the supply chain, the traceability and the transparency of the devices with, in particular, the introduction of the Unique Device Identification, or UDI-system and an expanded European Databank on Medical Devices, or EUDAMED database.

Notified Bodies can begin auditing to the EU IVDR once they have been designated as a Notified Body under the EU IVDR by their Competent Authority. For now, we expect the first Notified Bodies to be notified according to the EU IVDR by the end of 2019 and we anticipate that TÜV SÜD will be one of these. In practice, it will not be possible to CE Mark a product according to the EU IVDR beforehand. For Class C devices (our devices should be Class C), the conformity assessment procedure will be a combination of the Quality Management System audits and Technical Documentation assessments. The assumed assessment time needed for a Technical Documentation assessment of a Class C device is expected to last from about 2 months to 6 months. We have already begun discussions with the TÜV SÜD in order to ensure compliance with the EU IVDR as soon as possible.

We will also be required to comply with numerous other federal, state, and local laws relating to matters such as safe working conditions, industrial safety, and labor laws. We may incur significant costs to comply with such laws and regulations in the future, and lack of compliance could have material adverse effects on our operations.

We believe that we have structured our business operations to comply with applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise, which could have a material adverse impact on our business.

Regulatory Approach

Commercialization of our future products in the clinical IVD market (e.g., for patient diagnosis in hospitals, clinics, etc.) requires government approval (CE Marking in Europe, FDA approval in the United States, and Chinese Food and Drug Administration, or CFDA, approval in China).

In the United States, we anticipate that our tests will have to be cleared through the FDA's premarket notification, or 510(k), process or its premarket approval, or PMA, process. The determination of whether a 510(k) or a PMA is necessary will depend in part on the proposed indications for use and the FDA's assessment of the risk associated with the use of the IVD for a particular indication. A similar system operates in China through the CFDA. In the European Union, our tests can be marketed after a declaration and marking that the test conforms to the essential requirements of the relevant European health, safety and environmental protection legislation, or CE Marking. The CE Mark is also recognized in certain Asian territories, including India, for the private payer market.

Intellectual Property

We have 20 patent families related to our diagnostic tests, with 7 patents granted in the United States and 7 patents granted in the European Union and a further 25 patents granted worldwide. This portfolio also covers veterinary medicine applications.

We intend to continue our development of the Nucleosomics® technologies and will continue to apply for patents for future product developments. Our strategy is to protect the technologies and gain market exclusivity with patents in Europe and the United States and in other strategic countries. The patents on the technologies underlying our products should provide broad coverage for each product, including protection through at least 2031 for products developed using the Nu.Q technologies.

Employees

As of December 31, 2018, we (including our subsidiaries) had 44 full-time equivalents compared to 37 as of December 31, 2017.

Corporate History

The Company was incorporated on September 24, 1998 in the State of Delaware under the name "Standard Capital Corporation". On September 22, 2011, the Company filed a Certificate for Renewal and Revival of Charter with the Secretary of State of Delaware. Pursuant to Section 312 of Delaware General Corporation Law, the Company was revived under the new name of "VolitionRX Limited" (which name was subsequently amended in October 2016 to reflect **"**VolitionRx Limited"). The Company acquired its wholly-owned operating subsidiary, Singapore Volition Pte. Limited, a Singapore registered company, or Singapore Volition, on October 6, 2011. Singapore Volition currently has one subsidiary, Belgian Volition SPRL, a Belgium private limited liability company, or Belgian Volition, which it acquired on September 22, 2010. Belgian Volition has two subsidiaries, Volition Diagnostics UK Limited, which was formed on November 13, 2015, and Volition America, Inc., which was formed on February 3, 2017.

Our principal executive office is located at 1 Scotts Road, #24-05 Shaw Centre, Singapore 228208. Our telephone number is +1 (646) 650-1351. Our website is located at *www.volitionrx.com*. The information that can be accessed through our website is not incorporated by reference into this Report and should not be considered to be a part hereof.

Financial Information

See our consolidated financial statements and accompanying notes to the consolidated financial statements included in this Report.

Where You Can Get Additional Information

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act electronically with the SEC. You can access these reports and other filings electronically on the SEC's web site, *www.sec.gov*.

ITEM 1A. RISK FACTORS

An investment in our securities involves certain risks, including those set forth below and elsewhere in this Report. In addition to the risks set forth below and elsewhere in this Report, other risks and uncertainties may exist that could adversely affect our business and financial condition. If any of the following risks actually materialize, our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of your investment. You should carefully consider the risks described below as well as other information and data included in this Report.

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 transitioning to a commercial company and have incurred losses since our formation. As of December 31, 2018, we have an accumulated total deficit of approximately $73.7 million. As we continue the discovery and development of our future diagnostic products, our expenses are expected to increase significantly. 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 or if we will 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.

We will require additional capital to fully fund our current strategic plan, which includes successfully commercializing our Nu.Q cancer pipeline and developing future products. If we incur delays in commencing commercialization of our Nu.Q cancer pipeline or other future 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 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 symptomatic and screening populations;
- the demand for our intended products;
- 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;
- our success in collecting payments from third-party payors and customers;
- 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 are focused on developing our pipeline for future products. Our efforts will result in significant growth in the number of our consultants, advisors, and employees and the scope of our operations. 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, or to successfully engage third party providers for such services, 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. In 2015, we decided to focus our sales strategy on the clinical IVD market with the CE Marking of our first product in Europe. Following CE Marking of our first product in Europe we intend to enter the European markets and, following the completion of any necessary regulatory clearances, certain Asian markets. Even when we have received a CE Mark, we must still seek regulatory clearance in other jurisdictions. A failure to obtain these regulatory clearances in other jurisdictions could negatively affect our business. Pending completion of our review of the regulatory environment in the United States, including the effect of recent pronouncements regarding Laboratory Developed Tests, or LDTs, by the FDA, we may decide to enter the United States market through a CLIA certified laboratory. We remain firmly committed to pursuing FDA approval as our primary objective. FDA approval can consist of PMA or 510(k) clearance depending on the test complexity and risk posed to patients. We intend to pursue the most appropriate approval pathway for each individual product developed. 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 we currently intend to engage a network of distributors to help commercialize our products worldwide. Any failure to build and manage a direct sales and marketing team effectively, or to successfully engage third party providers for such services, 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;
- protect intellectual property rights;
- 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 Second Amended and Restated Certificate of Incorporation exculpates our officers and directors from certain liability to our Company and our stockholders.

Our Second 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.

We have identified material weaknesses in our internal control over financial reporting that have not yet been remediated, and the failure to address these material weaknesses, or the identification of any others, could impact the reliability of our financial reporting and harm investors' views of us, which could adversely impact our stock price.

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.

We have determined that we have material weaknesses in our internal control over financial reporting as of December 31, 2018. See *Item 9A. Controls and Procedures* of this Report for a complete discussion of these material weaknesses in our internal control over financial reporting and remediation efforts. Although we are undertaking steps to address these material weaknesses, the existence of a material weakness is an indication that there is more than a remote likelihood that a material misstatement of our financial statements will not be prevented or detected in the current or any future period. There can be no assurance that we will be able to fully implement our plans and controls, as further described in *Item 9A*, to address these material weaknesses, or that the plans and controls, if implemented, will be successful in fully remediating these material weaknesses. In addition, we may in the future identify further material weaknesses in our internal control over financial reporting that we have not discovered to date. If we fail to successfully remediate the identified material weaknesses, or we identify further material weaknesses in our internal controls, the market's confidence in our financial statements could decline and the market price of our common stock could be adversely impacted. 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.

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.

Our management has broad discretion over the use of our available cash and might not spend available cash in ways that increase the value of your investment.

As of December 31, 2018, we had $13.4 million in combined cash and cash equivalents compared to $10.1 million as of December 31, 2017. Our management currently expects to deploy these resources primarily to expand our commercialization activities, to fund our product development efforts and for general corporate and working capital purposes. However, our management has broad discretion to pursue other objectives. You will be relying on the judgment of our management regarding the application and prioritization of our resources. Our management might not apply our cash in ways that increase or permit any return of your investment.

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. 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 the Nu.Q tests and other 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, Asia 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.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials which, in turn, could have a material adverse effect on our business.

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. We may be required to demonstrate through large, long-term outcome trials that our product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, results of operations and financial condition 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 by the FDA in the United States, the Conformité Européenne in Europe, the CFDA in China, 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, China and Europe, we will be required to obtain clearance or approval of our future products from the FDA and the CFDA with respect to the United States and China, respectively, and receive a CE Mark with respect to Europe.

The European Union has recently adopted regulations that may impose additional requirements to obtain a CE Mark, which could result in delays and further expense, in terms of staff costs to us as compared to the current CE Mark process. The new regulations will require each product submission to be thoroughly audited by Notified Bodies, instead of the current self-certification process. The European Medical Device Regulations (MDR - 2017/745), or the EU MDR, will be fully applicable in 2020 and the EU IVDR will be fully applicable in 2022.

Additionally, even if we receive the required government clearance or 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 currently able to self-certify that they meet the appropriate regulatory requirements (which are subject to change with the EU MDR and the EU IVDR noted above) 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 European Union.

Reductions or changes in reimbursement policies could limit our ability to sell our products.

Market acceptance and sales of our products will depend, in part, on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels for those products. To manage healthcare costs, many governments and third-party payors in the United States increasingly scrutinize the pricing of new products and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. We cannot be sure that reimbursement will be available for our products and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our future products.

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. If our research and studies do not satisfy providers, payors and others as to the reliability and effectiveness, we may experience reluctance or refusal on the part of the physician to use our future products. 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, Roche Diagnostics and Exact Sciences Corporation, as well as several relatively new entrants to the market, including CellMax Life Inc., Guardant Health, Inc. and Freenome Inc. Most of these companies are either publicly traded or a division of a publicly traded company, and enjoy 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
- greater financial and other resources for product development, sales and marketing, and intellectual property protection.

Many of 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 may allow them to respond more quickly to new or emerging technologies and changes in consumer requirements. We also face competition in our search for third parties to assist us with sales and marketing of our product candidates, which may negatively impact our ability to enter into favorable sales and marketing arrangements. 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.

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 may contribute to increased volatility and diminished expectations for the global economy. If the economic climate deteriorates, our business, including our access to the Research Use Only, or 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.

On June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit”. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty, and withdrawal negotiations began in June 2017. European Union rules provide for a two-year negotiation period, beginning on the withdrawal notification date, unless an extension is agreed to by the parties. The negotiations between the parties have yet to produce an overall structure for their ongoing relationship following Brexit. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on imports and exports between the European Union countries and the United Kingdom and increased regulatory complexities. These changes may adversely affect our ability to market our future products in the United Kingdom which could have an adverse effect 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;

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;

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, the European Union and other countries, so that we can seek to prevent others from unlawfully using our inventions and proprietary information. We have 20 patent families related to our diagnostic tests, with 7 patents granted in the United States, 7 patents granted in the European Union and a further 25 patents granted worldwide.

If we are not able to protect our proprietary technology and information, our competitors may use our inventions to develop competing products. 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.

Our ability to successfully commercialize our intended products depends on our ability to protect our proprietary technology and information. 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. Additionally, we cannot be certain of the level of protection, if any, that will be provided by our patents if they are challenged in court, where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license.

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.

Defects in our products may subject us to substantial damages which could materially harm our business or financial condition.

The products we develop could lead to product liability claims based on allegations that one or more of our products contained a design or manufacturing defect which resulted in the failure to detect the disease for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

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;
- comments by securities analysts regarding our business or prospects;
- additions or departures of key personnel;
- our ability to execute our business plan;
- issuance of common stock or other securities;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- 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 executive 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 March 12, 2019, our executive officers and directors beneficially owned, in the aggregate, approximately 15.8% of our outstanding shares. As a result, if the executive officers and directors were to oppose a third party's acquisition proposal for, or a change in control of, the Company, such 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 charter documents to:

issue additional shares of common stock without having to obtain stockholder approval for such action;

fill vacant directorships except for vacancies created by the removal of a director;

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

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 have never declared or paid cash dividends on our common stock. 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 Second Amended and Restated Certificate of Incorporation authorizes the issuance of 100,000,000 shares of common 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 issued in the future on an arbitrary basis. The issuance of common 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, including, without limitation, through the exercise of warrants and/or options to purchase common stock, 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. If one or more equity analysts cover us and publish research reports about our common stock, the price of our stock could decline rapidly if one or more securities analysts downgrade our stock or if those analysts issue or offer inaccurate or unfavorable commentary or cease publishing reports about us. 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 a non-accelerated filer and we cannot be certain if the reduced disclosure requirements applicable to our filing status, as well as the exemption from the requirement to provide an auditor's attestation report regarding the effectiveness of our internal controls, 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 $250 million measured as of the last business day of our most recently completed second fiscal quarter. "Smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings 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. We are also a "non-accelerated filer," meaning we have a public float of less than $75 million measured as of the last business day of our most recently completed second fiscal quarter. As a "non-accelerated filer," we 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. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" and as a "non-accelerated filer" may make it harder for investors to analyze our results of operations and financial prospects and may make our common stock a less attractive investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2018, we occupied approximately 17,300 square feet at our primary laboratory facility in Namur, Belgium, which we acquired in October 2016. The purchase price for the property was €1.2 million Euros, exclusive of any closing costs.

Listed below are our current facilities:

Location	Primary Function	Approx. Square Feet	Leased or Owned

Namur, Belgium	Research and development	17,300	Owned
London, UK [1]	Sales and marketing	690	Leased, expiring 2020
Shaw Centre, Singapore [2]	Executive suite	150	Leased, expiring 2019

[1] Volition Diagnostics UK signed a one-year lease for this property located at 93-95 Gloucester Place, London, W1U 6JQ, United Kingdom, commencing January 30, 2019, at an annual rent of £118,800 GBP.

[2] Singapore Volition signed a one-year lease for this property, commencing August 1, 2018, located at 1 Scotts Road, #24-05 Shaw Centre, Singapore 228208, at an annual rent of SGD 30,290.

ITEM 3. 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 are not aware of any threatened or pending litigation that we expect will have a material adverse effect on our business operations, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently traded on the NYSE American under the symbol "VNRX".

Holders

As at March 12, 2019, there were 37,813,991 shares of our common stock outstanding held by 164 holders of record, based on information provided by our transfer agent. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividends

We have not declared or paid any cash dividends on our common stock since inception and presently anticipate that all earnings, if any, will be retained for development of our business and that no dividends on our common stock will be declared in the foreseeable future. Any future dividends will be subject to the discretion of our board of directors and will depend upon, among other things, future earnings, operating and financial conditions, capital requirements, general business conditions and other pertinent facts. Therefore, there can be no assurance that any dividends on our common stock will be paid in the future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required under this item is incorporated by reference from our definitive proxy statement related to our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, on or before April 30, 2019.

Recent Sales of Unregistered Securities

From January 1, 2018 through December 31, 2018, we sold the following securities on an unregistered basis for which disclosure under Item 701 of Regulation S-K was not previously provided in a Form 10-Q or Form 8-K filed with the SEC:

Between February 5 and June 4, 2018, 29,375 warrants were exercised to purchase shares of common stock at a price of $2.00 per share in a cashless exercise that resulted in the issuance of 11,831 shares of common stock and no cash proceeds to the Company.

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

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

We did not utilize any underwriters for any of the sales of securities on an unregistered basis. We relied on an exemption to the registration requirements of the federal securities laws pursuant to Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder for each of the sales of securities on an unregistered basis. At the time of their issuance, unless registered for resale under an effective registration statement filed with the SEC, the shares were deemed to be restricted securities for purposes of the Securities Act and the certificates representing the shares shall bear legends to that effect.

Repurchase of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

We are currently a smaller reporting company and are not required to disclose this information.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

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 consolidated 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 December 31, 2018, we had cash and cash equivalents of approximately $13.4 million.

Net cash used in operating activities was approximately $14.7 million and $12.2 million for the years ended December 31, 2018 and December 31, 2017, respectively. The increase in cash used in operating activities for the period ended December 31, 2018 when compared to same period in 2017 was primarily due to increased expenditures on research

and development activities, and sales and marketing activities.

Net cash used in investing activities was approximately $0.3 million and $1.4 million for the years ended December 31, 2018 and December 31, 2017, respectively. The decrease in cash used in investing activities for the period ended December 31, 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 approximately $18.0 million and $2.0 million for the years ended December 31, 2018 and December 31, 2017, respectively. The increase in cash provided by financing activities for the period ended December 31, 2018 when compared to same period in 2017 was primarily the result of $7.6 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, $8.9 million in net cash proceeds raised in August 2018 through a private placement of 5.0 million shares of common stock and the purchase of 0.3 million shares of common stock by warrant holders which resulted in $0.7 million in gross cash proceeds to the Company. During 2018, the Company also received debt funding of $1.4 million from the Walloon Region, offset by debt payments of $0.6 million.

The following table summarizes our approximate contractual payments due by period as of December 31, 2018:

Approximate Payments (Including Interest) Due by Period

Description	Total $	2019 $	2020 - 2023 $	2024 + $
Capital Lease Obligations	994,739	165,708	313,022	516,009
Operating Lease Obligations	295,492	216,493	78,999	-
Grants Repayable	351,136	40,094	202,597	108,445
Long-Term Debt (1)	2,985,751	484,799	2,122,308	378,644
Collaborative Agreements Obligations	4,792,241	2,904,978	1,887,263	-
Total	9,419,359	3,812,072	4,604,189	1,003,098

(1) Long-term debt includes the total value of the SOFINEX line of credit of €1.0 million Euros, although only €750,000 Euros had been drawn down as of December 31, 2018, and €250,000 Euros remain available to draw. See Note 10(d) to the consolidated financial statements for further details.

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, to provide sufficient funding to execute our strategic plan. 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. In such instance, 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 stated in their report on our audited financial statements for the fiscal year ended December 31, 2018 an explanatory paragraph regarding factors that raise substantial doubt that we will be able to continue as a going concern.

Results of Operations

Comparison of the Years Ended December 31, 2018 and December 31, 2017

The following table sets forth our results of operations for the years ended on December 31, 2018 and December 31, 2017, respectively:

	2018	2017	Increase (Decrease)	Percentage Increase (Decrease)
	$	$	$	%
Revenue	-	-	-	0%
Research and development	(10,906,871)	(8,026,206)	2,880,665	36%
General and administrative	(5,821,072)	(5,833,394)	(12,322)	0%
Sales and marketing	(1,169,756)	(836,474)	333,282	40%
Total Operating Expenses	(17,897,699)	(14,696,074)	3,201,625	22%
Interest expense	(110,924)	(73,133)	37,791	52%
Net Loss	(18,008,623)	(14,769,207)	3,239,416	22%
Net Loss per Share – Basic and Diluted	(0.57)	(0.56)	0.01	2%
Weighted Average Shares Outstanding – Basic and Diluted	31,389,220	26,389,580	4,999,640	19%

Revenues

Our operations are still predominantly in the research and development stage and we had no revenues during the years ended December 31, 2018 and December 31, 2017, respectively.

Operating Expenses

For the reasons set forth below, total operating expenses increased to $17.9 million for the year ended December 31, 2018 from $14.7 million for the year ended December 31, 2017.

Research and Development Expenses

Research and development expenses increased to $10.9 million for the year ended December 31, 2018 from $8.0 million for the year ended December 31, 2017. This increase in overall research and development expenditures during the 2018 period was primarily related to increased headcount, higher laboratory consumable costs, additional antibody purchases and increased expenses associated with the 13,500 patient trial with the National Cancer Institute's early detection research network in collaboration with the University of Michigan.

	2018	2017	Change
	$	$	$
Personnel expenses	2,917,147	2,179,905	737,242
Stock-based compensation	811,902	625,515	186,387
Direct research and development expenses	5,309,172	4,013,242	1,295,930
Other research and development	1,265,967	695,874	570,093
Depreciation and amortization	602,683	511,670	91,013
Total research and development expenses	10,906,871	8,026,206	2,880,665

General and Administrative Expenses

General and administrative expenses were flat at $5.8 million for the years ended December 31, 2018 and December 31, 2017, respectively. While overall general and administrative expenses for the comparative periods were flat, during the 2018 period the Company experienced higher foreign exchange costs, offset by reduced legal costs in relation to the capital raises during such period.

	2018	2017	Change
	$	$	$
Personnel expenses	2,199,866	2,081,720	118,146
Stock-based compensation	1,505,900	1,750,526	(244,626)
Legal and professional fees	1,188,554	1,270,388	(81,834)
Other general and administrative	889,519	716,654	172,865
Depreciation and amortization	37,233	14,106	23,127
Total general and administrative expenses	5,821,072	5,833,394	(12,322)

Sales and Marketing Expenses

Sales and marketing expenses increased to $1.2 million for the year ended December 31, 2018, from the $0.8 million for the year ended December 31, 2017. This increase in overall sales and marketing expenditures was primarily due to increased stock-based compensation costs and personnel fees during the 2018 period.

	2018	2017	Change
	$	$	$
Personnel expenses	673,430	517,978	155,452
Stock-based compensation	275,069	113,557	161,512
Direct marketing and professional fees	221,257	204,939	16,318
Total sales and marketing expenses	1,169,756	836,474	333,282

Other Expenses

For the years ended December 31, 2018 and December 31, 2017, the Company's other expenses (comprised of interest expense) were $110,924 and $73,133, respectively.

Net Loss

For the year ended December 31, 2018, the Company's net loss was $18.0 million, an increase of approximately $3.2 million, or 22%, in comparison to a net loss of $14.8 million for the year ended December 31, 2017. The change was a result of the factors described above.

Going Concern

We have not attained profitable operations and are dependent upon obtaining external financing to continue to pursue our operational and strategic plans. For these reasons, management has determined that there is substantial doubt that the business 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.

Future Equity or Debt 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 consolidated 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.

We consider the following accounting policies to be critical:

Stock-Based Compensation

The Company records stock-based compensation in accordance with ASC 718, *Compensation – Stock Compensation* and ASC 505-50, *Equity-Based Payments to Non-Employees*. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. Equity instruments issued to employees and the cost of the services received as consideration are measured and recognized based on the fair value of the equity instruments issued and are recognized over the employees required service period, which is generally the vesting period.

Impairment of Long-Lived Assets

In accordance with ASC 360, *Property Plant and Equipment*, the Company tests long-lived assets or asset groups for recoverability when events or changes in circumstances indicate that their carrying amount may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of the asset; current period cash flow or operating losses combined with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectation that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life. Recoverability is assessed based on the carrying amount of the asset and its fair value which is generally determined based on the sum of the undiscounted cash flows expected to result from the use and the eventual disposal of the asset, as well as specific appraisal in certain instances. An impairment loss is recognized when the carrying amount is not recoverable and exceeds fair value. Impairment losses of $nil and $nil were recognized during the years ended December 31, 2018 and December 31, 2017, respectively.

Foreign Currency Translation

The Company has functional currencies in the Euro, the United States Dollar and British Pounds Sterling 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 of foreign currency denominated transactions are included in Other Comprehensive Income.

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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are currently a smaller reporting company and are not required to disclose this information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

VOLITIONRX LIMITED

Consolidated Financial Statements

For the Years Ended December 31, 2018 and 2017

Index

Report of Independent Registered Public Accounting Firm	F – 2
	F – 3

Consolidated Balance Sheets

Consolidated Statements of Operations and Comprehensive Loss F – 4

Consolidated Statements of Cash Flows F – 5

Consolidated Statements of Stockholders' Equity F – 6

Notes to the Consolidated Financial Statements F – 7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of VolitionRx Limited:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of VolitionRx Limited (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows for each of the years in the two-year period ended December 31, 2018 and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred losses since inception, has accumulated a significant deficit, has negative cash flows from operations, and currently has no revenues. These factors raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with

the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Sadler, Gibb & Associates, LLC

We have served as the Company's auditor since 2011.

Salt Lake City, UT

March 13, 2019

VOLITIONRX LIMITED

Consolidated Balance Sheets

(Expressed in United States Dollars, except share numbers)

	December 31, 2018 $	December 31, 2017 $
ASSETS		
Current Assets		
Cash and cash equivalents	13,427,222	10,116,263
Prepaid expenses	245,441	248,661
Other current assets	229,755	202,295
Total Current Assets	13,902,418	10,567,219
Property and equipment, net	3,119,643	3,480,782
Intangible assets, net	466,905	576,397
Total Assets	17,488,966	14,624,398
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	807,162	351,735
Accrued liabilities	923,034	1,278,428
Management and directors’ fees payable	1,200	35,397
Current portion of long-term debt	416,553	443,908
Current portion of capital lease liabilities	145,150	139,084
Current portion of grant repayable	40,094	41,930
Total Current Liabilities	2,333,193	2,290,482
Long-term debt, net of current portion	1,984,262	1,312,785
Capital lease liabilities, net of current portion	720,013	874,684
Grant repayable, net of current portion	311,042	188,579
Commitments and contingencies	-	-

Total Liabilities	5,348,510	4,666,530
STOCKHOLDERS' EQUITY		
Common Stock		
Authorized: 100,000,000 shares of common stock, at $0.001 par value		
Issued and outstanding: 35,335,378 shares and 26,519,394 shares, respectively	35,335	26,519
Additional paid-in capital	85,604,271	65,774,870
Accumulated other comprehensive income (loss)	223,651	(129,343)
Accumulated deficit	(73,722,801)	(55,714,178)
Total Stockholders' Equity	12,140,456	9,957,868
Total Liabilities and Stockholders' Equity	17,488,966	14,624,398

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

VOLITIONRX LIMITED

Consolidated Statements of Operations and Comprehensive Loss

(Expressed in United States Dollars, except share numbers)

	For the year ended	
	December 31, 2018	**December 31, 2017**
	$	**$**
Operating Expenses		
Research and development	10,906,871	8,026,206
General and administrative	5,821,072	5,833,394
Sales and marketing	1,169,756	836,474
Total Operating Expenses	17,897,699	14,696,074
Operating Loss	(17,897,699)	(14,696,074)
Other Expense		
Interest expense	110,924	73,133
Net Loss	(18,008,623)	(14,769,207)
Other Comprehensive Income		
Foreign currency translation adjustments	352,994	63,953
Net Comprehensive Loss	(17,655,629)	(14,705,254)
Net Loss per Share – Basic and Diluted	(0.57)	(0.56)
Weighted Average Shares Outstanding – Basic and Diluted	31,389,220	26,389,580

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

VOLITIONRX LIMITED

Consolidated Statements of Cash Flows

(Expressed in United States Dollars)

	For the year ended	
	December 31, 2018	**December 31, 2017**
	$	**$**
Operating Activities		
Net loss	(18,008,623)	(14,769,207)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	636,380	528,166
Loss on disposal of property & equipment	403	38,941
Stock based compensation	2,570,095	2,435,088
Warrants issued for services	22,776	54,510
Changes in operating assets and liabilities:		
Deferred grant income	-	(50,855)
Prepaid expenses	10,012	(82,733)
Other current assets	(29,910)	(7,486)
Accounts payable and accrued liabilities	65,840	(339,662)
Net Cash Used In Operating Activities	(14,733,027)	(12,193,238)
Investing Activities:		
Purchases of property and equipment	(301,805)	(1,425,215)
Net Cash Used in Investing Activities	(301,805)	(1,425,215)
Financing Activities:		
Net proceeds from issuance of common shares	17,245,346	998,413
Proceeds from grants repayable	177,079	-
Proceeds from long term debt	1,159,836	1,201,980
Payments on long term debt	(436,784)	(52,420)
Payments on grants repayable	(40,877)	(45,422)
Payments on capital lease obligations	(137,513)	(135,597)
Net Cash Provided by Financing Activities	17,967,087	1,966,954
Effect of foreign exchange on cash and cash equivalents	378,704	89,028

Net Change in Cash and Cash Equivalents	3,310,959	(11,562,471)
Cash and Cash Equivalents – Beginning of Year	10,116,263	21,678,734
Cash and Cash Equivalents – End of Year	13,427,222	10,116,263
Supplemental Disclosures of Cash Flow Information:		
Interest paid	110,924	73,133
Income tax paid	-	-
Non - Cash Financing Activities:		
Common stock issued on cashless exercises of stock options	12	1
Capital lease obligations	28,605	-
Offering costs from common stock issuances	872,571	-

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

VOLITIONRX LIMITED

Consolidated Statements of Stockholders' Equity

For the Years Ended December 31, 2018 and 2017

(Expressed in United States Dollars, except share numbers)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Income/(Loss)	Deficit	Total
		$	$	$	$	$
Balance, December 31, 2016	26,126,049	26,126	62,287,252	(193,297)	(40,944,971)	21,175,110
Common stock issued for cash, net	392,651	392	998,021	-	-	998,413
Common stock issued for cashless exercise of stock options	694	1	(1)	-	-	-
Employee stock options granted for services	-	-	2,435,088	-	-	2,435,088
Warrants granted for services	-	-	54,510	-	-	54,510
Foreign currency translation	-	-	-	63,954	-	63,954
Net loss for the year	-	-	-	-	(14,769,207)	(14,769,207)
Balance, December 31, 2017	26,519,394	26,519	65,774,870	(129,343)	(55,714,178)	9,957,868
Common stock issued for cash, net	8,804,153	8,804	17,236,542	-	-	17,245,346
Common stock issued for cashless exercise of stock options	11,831	12	(12)	-	-	-
Employee stock options granted for services	-	-	2,570,095	-	-	2,570,095
Warrants granted for services	-	-	22,776	-	-	22,776
Foreign currency translation	-	-	-	352,994	-	352,994
Net loss for the year	-	-	-	-	(18,008,623)	(18,008,623)

Balance, December 31, 2018	35,335,378	35,335	85,604,271	223,651	(73,722,801)	12,140,456

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

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ 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 the 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 7, 2016, the Company filed a Second Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware that reflects the name "VolitionRx Limited".

On October 6, 2011, the Company entered into a share exchange agreement with Singapore Volition Pte. Limited, a Singapore corporation 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 and as such, Singapore Volition is regarded as the predecessor of the Company. The number of shares outstanding and per share amounts of the Company have been restated to recognize the foregoing 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 and other diseases. 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 one wholly-owned subsidiary, Belgian Volition SPRL, a Belgium private limited liability company formerly known as ValiBioSA ("Belgian Volition"), which it acquired as of September 22, 2010. Belgian Volition has two wholly-owned subsidiaries, Volition Diagnostics UK Limited ("Volition Diagnostics"), which was formed as of November 13, 2015 and Volition America, Inc. ("Volition America"), which was formed as of February 3, 2017. Following the acquisition of Singapore Volition in 2011, the Company's fiscal year end was changed from August 31 to December 31.

Note 2 - Going Concern

The Company's 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 approximately $73.7 million, 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 at least one year from the date of issuance of these 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 licenses 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 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 to eventually attain profitable operations. The accompanying 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 consolidated financial statements of the Company have been prepared in accordance with U.S. GAAP and are expressed in United States dollars. The Company's fiscal year end is December 31.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (Continued)

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, impairment analysis of intangible assets and valuations of equity-based payments.

The Company bases its estimates and assumptions on current facts, historical experiences 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 could be affected.

Principles of Consolidation

The accompanying consolidated financial statements for the year ended December 31, 2018 include the accounts of the Company and its wholly-owned subsidiaries, Volition America, Singapore Volition, Belgian Volition, Hypergenomics Pte. Limited (an inactive entity commencing in 2019) and Volition Diagnostics UK Limited. All significant intercompany balances and transactions have been eliminated in consolidation.

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. At December 31, 2018 and December 31, 2017, the Company had $13,427,222 and $10,116,263, respectively, in cash and cash equivalents. At December 31, 2018 and December 31, 2017, the Company had $12,899,095 and $9,636,185, respectively, in its domestic accounts in excess of Federal Deposit Insurance Corporation insured limits. At December 31, 2018 and December 31, 2017, the Company had $451,468 and $1,921,115, respectively, in its foreign accounts in excess of the Belgian Deposit Guarantee insured limits. At December 31, 2018 and December 31, 2017, the Company had $76,665 and $161,189, respectively, in its foreign accounts in excess of the Singapore Deposit Insurance Scheme. At December 31, 2018 and December 31, 2017, the Company had $55,398 and $184,234, respectively, in its foreign accounts in excess of the UK Deposit Protection Scheme.

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 of December 31, 2018, 9,606,418 potential common shares equivalents from warrants and options were excluded from the diluted EPS calculation as their effect is anti-dilutive. As of December 31, 2017, 4,670,813 potential common shares equivalents from warrants and options were excluded from the diluted EPS calculation as their effect is anti-dilutive.

Foreign Currency Translation

The Company has functional currencies in the Euro, the United States Dollar and British Pounds Sterling 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 of foreign currency denominated transactions are included in Other Comprehensive Income/(Loss).

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (Continued)

Financial Instruments

Pursuant to ASC 820, *Fair Value Measurements and Disclosures*, an entity is required to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 establishes a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used to measure fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. ASC 820 prioritizes the inputs into three levels that may be used to measure fair value:

Level 1

Level 1 applies to assets or liabilities for which there are quoted prices in active markets for identical assets or liabilities.

Level 2

Level 2 applies to assets or liabilities for which there are inputs other than quoted prices that are observable for the assets or liabilities such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical assets or liabilities in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.

Level 3

Level 3 applies to assets or liabilities for which there are unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the assets or liabilities.

The Company's financial instruments consist principally of cash, accounts payable, accrued liabilities, debt obligations, and amounts due to related parties. Pursuant to ASC 820, the fair value of cash is determined based on "Level 1" inputs, which consists of quoted prices in active markets for identical assets. The Company believes that the recorded values of all of our other financial instruments approximate their current fair values because of their nature and respective maturity dates or durations.

Income Taxes

Potential benefits of income tax losses are not recognized in the accounts until realization is more likely than not. The Company has adopted ASC 740, *Accounting for Income Taxes* as of its inception. Pursuant to ASC 740, the Company is required to compute tax asset benefits for net operating losses carried forward. The potential benefits of net operating losses have not been recognized in these consolidated financial statements because the Company cannot be assured it is more likely than not it will utilize the net operating losses carried forward in future years.

Other Comprehensive Income/(Loss)

ASC 220, *Other Comprehensive Income/(Loss),* establishes standards for the reporting and display of other comprehensive loss and its components in the financial statements. At December 31, 2018, the Company had $223,651 of accumulated other comprehensive income, relating to foreign currency translation.

Research and Development

In accordance with ASC 730, the Company follows the policy of expensing its research and development costs in the period in which they are incurred. The Company incurred research and development expenses of approximately $10.9 million and $8.0 million during the years ended December 31, 2018 and 2017, respectively.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (Continued)

Impairment of Long-Lived Assets

In accordance with ASC 360, *Property Plant and Equipment*, the Company tests long-lived assets or asset groups for recoverability when events or changes in circumstances indicate that their carrying amount may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of the asset; current period cash flow or operating losses combined with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectation that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life. Recoverability is assessed based on the carrying amount of the asset and its fair value which is generally determined based on the sum of the undiscounted cash flows expected to result from the use and the eventual disposal of the asset, as well as specific appraisal in certain instances. An impairment loss is recognized when the carrying amount is not recoverable and exceeds fair value. Impairment losses of $nil and $nil were recognized during the years ended December 31, 2018 and December 31, 2017, respectively.

Stock-Based Compensation

The Company records stock-based compensation in accordance with ASC 718, *Compensation – Stock Compensation* and ASC 505-50, *Equity-Based Payments to Non-Employees*. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. Equity instruments issued to employees and the cost of the services received as consideration are measured and recognized based on the fair value of the equity instruments issued and are recognized over the employees required service period, which is generally the vesting period.

Grants Received

The Company receives funding from public bodies for a proportion of the costs of specific projects. Funds are received in line with claims submitted for the agreed expenditure. The Company recognizes grant income once claims submitted are approved and funds are received. General working capital funding received at the commencement of a project is treated as deferred income until it has been utilized for the expenditure claimed. Funding received that is repayable is shown as a liability.

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 amounts of research and development, sales and marketing and general and administrative expenses to be consistent with the current year classification.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842), or ASU 2016-02. ASU 2016-02 requires lessees to recognize for all leases (with the exception of short-term leases) at the commencement date, a lease liability which is a lessee‘s obligation to make lease payments arising from a lease measured on a discounted basis, and a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and should be applied with a modified retrospective transition approach, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-02 on its financial statements.

The Company has implemented all other 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.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 4 - Property and Equipment

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

				December 31, 2018
		Cost	**Accumulated Depreciation**	**Net Carrying Value**
	Useful Life	**$**	**$**	**$**
Computer hardware and software	3 years	344,383	166,750	177,633
Laboratory equipment	5 years	1,673,215	928,841	744,374
Office furniture and equipment	5 years	204,129	75,137	128,992
Buildings	30 years	1,502,171	91,785	1,410,386
Building improvements	5-15 years	643,663	77,049	566,614
Land	Not amortized	91,644	-	91,644
		4,459,205	1,339,562	3,119,643

				December 31, 2017
		Cost	**Accumulated Depreciation**	**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
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

The majority of capital expenditures in 2018 is related to €0.3 million Euros for software and laboratory equipment.

During the years ended December 31, 2018 and December 31, 2017, the Company recognized $548,005 and $454,490, respectively, in depreciation expense.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 5 - Intangible Assets

The Company's intangible assets consist of mainly of patents, mainly acquired in connection with 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.

	Cost	Accumulated Depreciation	December 31, 2018 Net Carrying Value
	$	$	$
Patents	1,167,383	700,478	466,905

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

During the years ended December 31, 2018, and December 31, 2017, the Company recognized $91,911 and $87,994, 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:

2019	$ 89,077

2020	$ 89,077
2021	$ 89,077
2022	$ 89,077
2023	$ 89,077
Greater than 5 years	$ 21,520
Total Intangible Assets	**$ 466,905**

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, 2018. The result of this review confirmed that the ongoing value of the patents was not impaired as of December 31, 2018.

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 the Consolidated Balance Sheet).

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 7 - Common Stock

2018

As of December 31, 2018, the Company was authorized to issue 100 million shares of common stock par value $0.001 per share, of which 35,335,378 and 26,519,394 shares were issued outstanding as of December 31, 2018 and December 31, 2017, respectively.

Between February 5 and June 4, 2018, 29,375 warrants were exercised to purchase shares of common stock at a price of $2.00 per share in a cashless exercise that resulted in the issuance of 11,831 shares of common stock.

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, approximately $0.8 million was incurred for legal and underwriting fees resulting in net proceeds of approximately $7.6 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 (“Cotterford”) in a private placement offering (PIPE) 5.0 million shares of common stock at a price of $1.80 per share, for aggregate gross proceeds of $9.0 million. In connection with the transaction, approximately $0.1 million was incurred for legal and other fees resulting in net proceeds of approximately $8.9 million. Additionally, the Company issued to Cotterford a warrant to purchase up to an additional 5.0 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 becoming a significant stockholder and therefore a related party in accordance with U.S. GAAP. 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 December 31, 2018, the Company had not sold any shares under the equity distribution agreement.

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

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

2017

During 2017, 32,500 warrants were exercised at a price of $2.20 per share, for gross cash proceeds to the Company of $71,500. As a result, a total of 32,500 shares of common stock were issued.

During 2017, 47,000 warrants were exercised at a price of $2.40 per share, for gross cash proceeds to the Company of $112,800. As a result, a total of 47,000 shares of common stock were issued.

During 2017, 313,151 warrants were exercised at a price of $2.60 per share, for gross cash proceeds to the Company of $814,193. As a result, a total of 313,151 shares of common stock were issued.

During 2017, 4,166 stock options were exercised to purchase shares of common stock at $3.00 per share in a cashless exercise that resulted in the issuance of 694 shares of common stock.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 8 – Warrants and Options

a) Warrants

The following table summarizes the changes in warrants outstanding of the Company during the year ended December 31, 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	(333,528)	2.33
Expired	(290,535)	2.54
Outstanding at December 31, 2018	6,107,617	2.88
Exercisable at December 31, 2018	982,617	2.31

On August 10, 2018, in conjunction with the PIPE transaction (see Note 7), the Company issued to Cotterford 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.

On November 13, 2018, the Board of Directors amended the terms of an aggregate of 29,392 outstanding warrants to purchase common stock of the Company originally issued in connection with an equity financing completed on or about December 31, 2013 to extend the expiration date from December 31, 2018 to December 31, 2019. As a result of this amendment $14,198 was recorded as additional warrant expense.

During 2018, 333,528 warrants were exercised for gross cash proceeds to the Company of $717,917. Refer to Note 7 for the details of the exercises.

During 2018, 290,535 warrants expired by their terms.

Below is a table summarizing the warrants issued and outstanding as of December 31, 2018, which have a weighted average exercise price of $ 2.88 per share, and an aggregate weighted average remaining contractual life of 0.63 years.

Number Outstanding	Number Exercisable	Exercise Price ($)	Weighted Average Remaining Contractual Life (Years)	Proceeds to Company if Exercised ($)
888,225	888,225	2.20	0.16	1,954,095
29,392	29,392	2.40	1.00	70,541
150,000	25,000	2.47	3.68	370,500
5,000,000	-	3.00	0.61	15,000,000
40,000	40,000	4.53	1.87	181,200
6,107,617	**982,617**			**17,576,336**

Warrant expense of $22,776 and $54,510 was recorded in the years ended December 31, 2018 and December 31, 2017, respectively. Total remaining unrecognized compensation cost related to non-vested warrants is $17,012 and is expected to be recognized over a period of 2.0 years. As of December 31, 2018, the total intrinsic value of warrants was $Nil.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 8 – Warrants and Options (Continued)

b) Options

The Company currently has options outstanding under both its 2011 Equity Incentive Plan (the "2011 Plan") (for option issuances prior to 2016) and its 2015 Plan (for option issuances commencing in 2016). Effective as of January 1, 2016, no additional awards were or may be made under the 2011 Plan.

The 2015 Plan was adopted by the Board of Directors on August 18, 2015 and approved by the stockholders at an annual meeting held on October 30, 2015. On August 5, 2016, the Board of Directors adopted an amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 750,000 shares to an aggregate maximum of 1,750,000 shares, which amendment was approved by the stockholders at an annual meeting held on October 7, 2016. On June 13, 2017, the Board of Directors adopted a subsequent amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 750,000 shares to an aggregate maximum of 2,500,000 shares, which amendment was approved by the stockholders at an annual meeting held on September 8, 2017. On June 15, 2018, the Board of Directors adopted a subsequent amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 750,000 shares to an aggregate maximum of 3,250,000 shares, which amendment was approved by the stockholders at an annual meeting held on September 7, 2018. The 2015 Plan permits the grant of incentive stock options, non-statutory stock options, restricted stock awards, stock bonus awards, stock appreciation rights, restricted stock units and performance awards. The primary purpose of the 2015 Plan is to enhance the Company's ability to attract and retain the services of qualified employees, officers, directors, consultants and other service providers upon whose judgment, initiative and efforts the successful conduct and development of the Company's business largely depends, and to provide additional incentives to such persons or entities to devote their utmost effort and skill to the advancement and betterment of the Company, by providing them an opportunity to participate in the ownership of the Company that is tied to the Company's performance, thereby giving them an interest in the success and increased value of the Company. The 2015 Plan is administered by the Compensation Committee comprised solely of members of the Board of Directors or by the Board of Directors as a whole.

The following table summarizes the changes in options outstanding of the Company during the year ended December 31, 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	(245,333)	4.98
Outstanding at December 31, 2018	3,498,801	4.00
Exercisable at December 31, 2018	2,698,801	4.01

Effective January 23, 2018, the Company granted stock options to purchase 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.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 8 – Warrants and Options (Continued)

In December 2018, the Board of Directors amended the terms of certain outstanding options such that (i) the expiration date for outstanding options to purchase up to an aggregate of 645,000 shares of the Company's common stock, granted on August 18, 2014 under the 2011 Plan, was extended for both vesting installments from four (4) years from the vesting date of each installment to a single expiration date of August 18, 2020, (ii) the expiration date for outstanding options to purchase up to an aggregate of 20,000 shares of the Company's common stock, granted on May 18, 2015 under the 2011 Plan, was extended from four (4) years after the vesting date to May 18, 2021, and (iii) the expiration date for outstanding options to purchase up to an aggregate of 317,000 shares of the Company's common stock, granted July 23, 2015 under the 2011 Plan, was extended from four (4) years after vesting to five years and six months after vesting, or July 23, 2021. As a result of these amendments $209,308 was recorded as additional options expense.

Below is a table summarizing the options issued and outstanding as of December 31, 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 $4.00 per share and an aggregate weighted average remaining contractual life of 3.53 years. As of December 31, 2018, an aggregate of 799,000 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	1.20	41,750
322,500	322,500	2.50	1.63	806,250
322,500	322,500	3.00	1.63	967,500
17,767	17,767	3.35	2.20	59,519
20,000	20,000	3.80	2.38	76,000
1,911,167	1,111,167	4.00	4.62	7,644,669
17,767	17,767	4.35	3.20	77,286
50,000	50,000	4.80	4.01	240,000

819,334	819,334	5.00	2.98	4,096,670
3,498,801	**2,698,801**			**14,009,644**

Stock option expense of $2,570,095 and $2,435,088 was recorded in the years ended December 31, 2018 and December 31, 2017, respectively. Total remaining unrecognized compensation cost related to non-vested stock options is approximately $150,354 and is expected to be recognized over a period of 0.74 years. As of December 31, 2018, the total intrinsic value of stock options was $Nil.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 9 - Income Taxes

The Company has estimated net operating losses for the years ended December 31, 2018 and 2017 of approximately $15.2 million and $12.3 million, respectively, available to offset taxable income in future years. On December 22, 2017, a tax reform bill was signed into law that decreased the U.S. Federal corporate income tax rate to 21%. As a result, the deferred income tax benefit relating to the Company's net operating loss carry forward was reduced by approximately $2.0 million; however, the Company's net deferred tax assets of $0 was not impacted as a result of this new tax rate.

The significant components of deferred income taxes and assets as at December 31, 2018 are as follows:

Net Deferred Tax Liability	**December 31, 2018** **$**	**December 31, 2017** **$**
Excess of tax over book depreciation and amortization	(10,761)	-
Prepaid expenses	-	-
Allowance for doubtful accounts	-	-
Accrued expenses	1,154	1,154
Stock-based compensation	-	-
Net Operating Losses carry-forward	12,437,561	11,156,839
Research and development tax credits	337,507	-
Gross deferred tax assets	12,765,461	11,157,993
Valuation allowance	(12,765,461)	(11,157,993)
Net deferred tax asset	-	-
Change in Valuation Allowance	(1,607,468)	-

Summary Rate Reconciliation	**December 31, 2018** ***%***	**December 31, 2017** ***%***

Federal statutory rate	21.0	35.0
State income taxes, net of federal benefit	-	-
Permanent Differences	(15.1)	0.1
Stock based compensation	(3.2)	(5.8)
Federal Research & Development Credits	0.4	-
Foreign taxes	6.2	(3.1)
Federal Deferred Rate Decrease	-	(10.3)
Increase/(decrease) in valuation reserve	(9.3)	(15.9)
Total	-	-

Disclosure Amounts	**December 31, 2018**
Net Operating Losses - United States	15,260,855
Net Operating Losses - Foreign	36,684,445
Credit Carryforward - United States	-
Credit Carryforward - Foreign	337,507
Increase in Valuation Allowance	1,607,468

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 10 – 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 December 31, 2018, the balance payable was $137,514.

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 December 31, 2018, the balance payable was $698,845.

On August 20, 2018, the Company entered into a capital lease with BNP Paribas leasing solutions to purchase a freezer for the Belgium facility for €25,000 Euros. The leased equipment is amortized on a straight-line basis over 5 years. As of December 31, 2018, the balance payable was $28,804.

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 December 31, 2018:

2019	$ 165,708
2020	$ 116,982
2021	$ 71,370
2022	$ 63,055
2023	$ 61,615
Greater than 5 years	$ 516,009
Total	$ 994,739

Less: Amount representing interest	$ (129,576)
Present value of minimum lease payments	**$ 865,163**

b) Operating Lease Obligations

The Company also leases premises and facilities under operating leases with terms ranging from 12 to 36 months. As of December 31, 2018, the annual non-cancelable operating lease payments on these leases are as follows:

2019	$ 216,493
2020	$ 64,887
2021	$ 14,112
Total Operating Lease Obligations	**$ 295,492**

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 by installments over the period from June 30, 2014 to June 30, 2023. The Company has recorded the balance of €733,614 Euros to other income in previous years as there is no obligation to repay this amount. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 6% royalty on such revenue to the Walloon Region. The maximum amount payable to the Walloon Region, in respect of the aggregate of the amount repayable of €314,406 Euros and the 6% royalty on revenue, is twice the amount of funding received. As of December 31, 2018, the grant balance repayable was $180,316.

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 by installments over 12 years commencing in 2020. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 3.53% 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 €181,500 Euros and the 3.53% royalty on revenue, is equal to the amount of funding received. As of December 31, 2018, the grant balance repayable was $170,819.

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 10 – Commitments and Contingencies (Continued)

As of December 31, 2018, the balance repayable was $351,136 and the annual payments remaining were as follows:

2019	$ 40,094
2020	$ 53,955
2021	$ 50,984
2022	$ 48,228
2023	$ 49,430
Greater than 5 years	$ 108,445
Total Grants Repayable	**$ 351,136**

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 December 31, 2018, the principal balance payable was $401,382.

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 December 31, 2018, the principal balance payable was $275,450.

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 December 31, 2018, the principal balance payable was $292,046.

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 December 31, 2018, €750,000 Euros has been drawn down under this agreement and the

principal balance payable was $859,162.

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%. As of December 31, 2018, the principal balance payable was $572,775.

As of December 31, 2018, the total balance for long-term debt payable was $2,400,815 and the payments remaining were as follows:

2019	$ 484,799
2020	$ 688,854
2021	$ 616,934
2022	$ 457,326
2023	$ 238,792
Greater than 5 years	$ 202,949
Total	$ 2,689,654
Less: Amount representing interest	$ (288,839)
Total Long-Term Debt	**$ 2,400,815**

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2018 and 2017

($ expressed in United States Dollars)

Note 10 – 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 December 31, 2018, $85,916 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 December 31, 2018, $229,110 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 €476,000 Euros. As of December 31, 2018, $304,715 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 for a 3-year period for $3.0 million. As of December 31, 2018, $1.75 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 $2.55 million payable over such period. As of December 31, 2018, approximately $2.42 million is still to be paid by the Company under this agreement.

As of December 31, 2018, the total amount to be paid for future research and collaboration commitments was $4.79 million and the annual payments remaining were as follows:

2019	$ 2,904,978
2020	$ 994,763
2021	$ 892,500
Total Collaborative Agreement Obligations	**$ 4,792,241**

f) Legal Proceedings

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

Note 11 - Subsequent Events

On February 11, 2019, the Company granted stock options to purchase 730,000 shares of common stock. These options vest on February 11, 2020 and expire 5 years after the vesting date, with an exercise price of $3.25 per share.

During the period January to February 26, 2019, 754,475 warrants were exercised to purchase shares of our common stock at $2.20 per share resulting in the issuance of 754,475 shares of common stock for approximate gross proceeds of $1.66 million.

During the period January to February 26, 2019, 133,750 warrants expired by their terms.

Following approval of the Board of Directors and the Audit Committee, effective March 5, 2019 the Company entered into an amendment to an outstanding warrant to purchase up to an aggregate of 5.0 million shares of common stock of the Company originally issued to Cotterford in connection with an equity financing completed on or about August 10, 2018. The amendment temporarily reduced the exercise price of such warrant from $3.00 per share to $2.90 per share through the close of business on March 8, 2019. On March 8, 2019, Cotterford partially exercised the warrant for 1,724,138 shares of our common stock at $2.90 per share resulting in the issuance of 1,724,138 shares of common stock for gross proceeds of $5.0 million. The warrant remains exercisable through August 10, 2019 for the remaining balance of 3,275,862 shares of common stock at a price of $3.00 per share.

END NOTES TO FINANCIALS

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

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 that, as of December 31, 2018, our disclosure controls and procedures were not effective because of material weakness in our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles of U.S. GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may

deteriorate.

Under the supervision and with the participation of management, including the Principal Executive Officer and Principal Financial Officer, the Company conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of December 31, 2018, using the criteria established in "*Internal Control - Integrated Framework*" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. In its assessment of the effectiveness of internal control over financial reporting as of December 31, 2018, the Company determined that there were control deficiencies that constituted material weaknesses, as described below:

1. the Company did not maintain adequate segregation of duties in some areas of Finance;

2. the Company did not maintain sufficient oversight in the areas of Information Technology (IT) and Human Resources, where certain processes may affect the internal controls over financial reporting; and

3. the Company did not maintain sufficient monitoring review controls with respect to accounting for complex transactions.

Accordingly, the Company concluded that these control deficiencies resulted in a possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by the Company's internal controls.

As a result of the material weaknesses described above, management has concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework* issued by COSO. Management believes that the material weaknesses set forth above did not have an effect on our Company's financial results.

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 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 of December 31, 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;

due to a lack of sufficient oversight in the areas of IT and Human Resources, where certain processes may affect the internal controls over financial reporting; and

due to a lack of sufficient monitoring review controls with respect to accounting for complex transactions.

We have developed, and are currently implementing, a remediation plan for these material weaknesses.

There have been no changes in our internal control over financial reporting during the fiscal fourth quarter of the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control 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.

Continuing Remediation Efforts to address deficiencies in Company's Internal Control over Financial Reporting

Once the Company is engaged in stable business operations and has sufficient personnel and resources available, then our Board of Directors, in particular and in connection with the aforementioned deficiencies, will establish the following remediation measures:

additional Finance and IT resources will be recruited to resolve the segregation of duties control weaknesses noted above.

internal audit resources will be contracted to review and advise on control weaknesses across the organization.

specialist resources in Human Resources will be recruited to recommend and implement relevant policy and processes to strengthen Human Resources internal controls associated with financial reporting.

ITEM 9B. OTHER INFORMATION

During the period from January to February 26, 2019, warrants originally issued to investors in connection with an equity financing completed on or about February 26, 2014 were exercised to purchase an aggregate of 754,475 shares of our common stock at $2.20 per share resulting in gross proceeds of $1.66 million.

Additionally, following approval of the Board of Directors and the Audit Committee on March 1, 2019, effective March 5, 2019 we entered into an amendment to an outstanding warrant to purchase up to an aggregate of 5.0 million shares of our common stock, originally issued to Cotterford Company Limited, a significant stockholder, in connection with an equity financing completed on or about August 10, 2018. The amendment temporarily reduced the exercise price of such warrant from $3.00 per share to $2.90 per share through the close of business on March 8, 2019. On March 8, 2019, Cotterford Company Limited partially exercised the warrant for 1,724,138 shares of our common stock at $2.90 per share resulting in gross proceeds of $5.0 million. The warrant remains exercisable through August 10, 2019 for the remaining balance of 3,275,862 shares of common stock at a price of $3.00 per share.

The issuance and sale of the shares of common stock upon exercise of the warrants referenced above were made pursuant to an exemption from the registration requirements of the Securities Act provided by Section 4(a)(2) thereof and Regulation D promulgated thereunder. At the time of their issuance, unless registered for resale under an effective registration statement filed with the SEC, the shares were deemed to be restricted securities for purposes of the Securities Act and the certificates representing the shares shall bear legends to that effect.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required under this item is incorporated by reference from our definitive proxy statement related to our 2019 Annual Meeting of Stockholders, or the Proxy Statement, to be filed pursuant to Regulation 14A, on or before April 30, 2019.

ITEM 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference from the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required under this item is incorporated herein by reference from the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required under this item is incorporated herein by reference from the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item is incorporated herein by reference from the Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Report:

1. *Financial Statements*. Included in Part II, Item 8 of this Report and are incorporated by reference herein.

2. *Financial Statement Schedules*. Financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. *Exhibits*.

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
2.1	Share Purchase Agreement by and between Singapore Volition and ValiRX dated September 22, 2010.	8-K/A	000-30402	2.01	5/8/12	
2.2	Supplementary Agreement to the Share Purchase Agreement by and between Singapore Volition and ValiRX dated June 9, 2011.	8-K/A	000-30402	10.15	1/11/12	
2.3	Share Exchange Agreement by and among Standard Capital Corporation, the controlling shareholders of Standard Capital Corporation and Singapore Volition dated September 26, 2011.	8-K	000-30402	2.1	9/29/11	
2.4	Agreement, Consent and Waiver by and between Standard Capital Corporation and	8-K/A	000-30402	10.28	4/5/12	

	its Shareholders dated September 27, 2011.				
3.1	Second Amended and Restated Certificate of Incorporation, as currently in effect.	8-K	001-36833	3.1	10/11/16
3.2	Amended and Restated Bylaws, as currently in effect.	S-8	333-208512	4.2	12/11/15
10.1	Patent License Agreement by and between ValiRX and Chroma dated October 3, 2007.	8-K/A	000-30402	10.04	1/11/12
10.2	Contract Repayable Grant Advance on the Diagnosis of Colorectal Cancer by “NucleosomicsTM” by and between ValiBio SA and The Walloon Region dated December 17, 2009.	8-K/A	000-30402	10.05	2/24/12
10.3	Non-Exploitation and Third Party Patent License Agreement by and among ValiBio SA, ValiRX and The Walloon Region dated December 17, 2009.	8-K/A	000-30402	10.06	2/24/12
10.4	Deed of Novation by and among Singapore Volition, ValiRX, ValiBio SA and Chroma dated September 22, 2010.	8-K/A	000-30402	10.09	2/24/12

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.5	Patent License Agreement by and between Singapore Volition and Belgian Volition dated November 2, 2010.	8-K/A	000-30402	10.12	1/11/12	
10.6	License Agreement by and between Singapore Volition and the European Molecular Biology Laboratory dated June 6, 2011.	8-K/A	000-30402	10.14	1/11/12	
10.7	Agreement by and between Belgian Volition and the Biobank of CHU UCL Mont-Godinne dated August 6, 2012.	S-1/A	333-183056	10.27	10/4/12	
10.8	Common Stock Purchase Agreement, by and among VolitionRx and the purchasers thereto dated February 26, 2014.	8-K	000-30402	10.1	2/28/14	
10.9#	Employment Agreement by and between VolitionRx and Jason Terrell MD, dated December 29, 2015.	10-K	001-36833	10.24	3/11/16	
10.10#	2011 Equity Incentive Plan dated November 17, 2011.	8-K	000-30402	4.01	11/18/11	
10.10(a)#	Form Stock Option Agreement.	8-K	000-30402	4.02	11/18/11	
10.10(b)#	Form Stock Award Agreement for Restricted Stock.	8-K	000-30402	4.03	11/18/11	
10.11#	2015 Stock Incentive Plan, as amended June 15, 2018.	8-K	001-36833	10.1	09/11/18	
10.11(a)#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.2	10/14/16	

10.11(b)#	Form of Notice of Restricted Stock Award and Restricted Stock Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.3	10/14/16
10.11(c)#	Form of Notice of Stock Bonus Award and Stock Bonus Award Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.4	10/14/16

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.11(d)#	Form of Notice of Stock Appreciation Right Award and Stock Appreciation Right Award Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.5	10/14/16	
10.11(e)#	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.6	10/14/16	
10.11(f)#	Form of Notice of Performance Shares Award and Performance Shares Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.7	10/14/16	
10.12#	Independent Director Agreement.	10-Q	001-36833	10.33	5/12/15	
10.13	Real Estate Capital Lease Agreement by and between Belgian Volition and ING Asset Finance Belgium S.A., dated October 4, 2016 (English translation of French original).	8-K	001-36833	10.1	10/31/16	
10.14	Deed of Sale to the Sale Agreement by and between and Gerard Dekoninck S.A., dated October 25, 2016 (English translation of French original).	8-K	001-36833	10.2	10/31/16	
10.15#	Employment Agreement by and between Volition Diagnostics UK Limited and Cameron Reynolds, dated March 7, 2017.	10-K	001-36833	10.27	03/10/17	
10.16#	Employment Agreement by and between Volition Diagnostics UK Limited and Jacob Micallef, dated March 7, 2017.	10-K	001-36833	10.28	03/10/17	
10.17#	Employment Agreement by and between Volition Diagnostics UK Limited and Rodney Rootsaert, dated March 7, 2017.	10-K	001-36833	10.29	03/10/17	

10.18#	Employment Agreement by and between Volition Diagnostics UK Limited and Martin Faulkes, dated March 7, 2017.	10-K	001-36833	10.30	03/10/17
10.19#	Employment Agreement by and between Volition Diagnostics UK Limited and David Vanston, dated April 10, 2017.	10-Q	001-36833	10.1	05/11/17
10.20	Unsecured Credit Agreement dated September 20, 2017, by and among VolitionRx Limited, Belgian Volition SPRL and SOFINEX (English translation of French original).	8-K	001-36833	10.1	09/21/17

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.21	Clinical Study Agreement, dated July 17, 2017, by and between Volition America, Inc. and the Regents of the University of Michigan.	10-Q	001-36833	10.1	11/09/17	
10.22	Common Stock Purchase Agreement, dated August 8, 2018, by and between VolitionRx and Cotterford Company Limited, including the form of Warrant attached as Exhibit B thereto.	8-K	001-36833	10.1	8/9/2018	
10.23	Equity Distribution Agreement, dated September 7, 2018, by and between VolitionRx and Oppenheimer & Co. Inc.	S-3	333-227248	1.2	9/10/2018	
21.1	List of Subsidiaries.					X
23.1	Consent of independent registered public accounting firm.					X
24.1	Power of Attorney (included on the signature page of this Report).					X
31.1	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
31.2	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
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to					X

	Section 906 of the Sarbanes-Oxley Act of 2002.	
10.1 INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X

# Indicates a management contract or compensatory plan or arrangement.

* The certifications attached as Exhibit 32.1 accompany this 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.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

VOLITIONRX LIMITED

Dated: March 13, 2019 By: */s/ Cameron Reynolds*
Cameron Reynolds
President, Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Cameron Reynolds and Rodney Rootsaert, and each or either of them, acting individually, his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or his, her or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report on Form 10-K has been signed below by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Cameron Reynolds	President, Chief Executive Officer and Director	March 13, 2019
Cameron Reynolds	(Principal Executive Officer)	
/s/ David Vanston	Chief Financial Officer and Treasurer	March 13, 2019
David Vanston	(Principal Financial and Accounting Officer)	

/s/ Dr. Martin Faulkes	Director	March 13, 2019
Dr. Martin Faulkes		
/s/ Guy Innes	Director	March 13, 2019
Guy Innes		
/s/ Dr. Alan Colman	Director	March 13, 2019
Dr. Alan Colman		
/s/ Dr. Habib Skaff	Director	March 13, 2019
Dr. Habib Skaff		
/s/ Dr. Edward Futcher	Director	March 13, 2019
Dr. Edward Futcher		