

VOLITIONRX LTD  
Form 10-K  
March 10, 2017

**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, 2016**

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

**For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number: 001-36833**

**VOLITIONRX LIMITED**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

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

**1 Scotts Road**

**#24-05 Shaw Centre**

**Singapore 228208**

(Address of principal executive  
offices)

**Telephone: +1 (646) 650-1351**

(Registrant's telephone number,  
including area code)

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

| <u>Title of Each Class:</u>                      | <u>Name of Each Exchange on Which Registered:</u> |
|--|---|
| <b>Common Stock, par value \$0.001 per share</b> | <b>NYSE MKT LLC</b>                               |

**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  .

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  .

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  No  .

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

Edgar Filing: VOLITIONRX LTD - Form 10-K

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.

.

---

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

Large accelerated filer  . Accelerated filer  .  
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company  X .

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

As of June 30, 2016, the aggregate market value of the voting common stock held by non-affiliates of the registrant was \$56,228,820 (based upon the \$3.15 closing price for shares of the registrant's common stock as reported by the NYSE MKT, on June 30, 2016, the last trading date of the registrant's most recently completed second fiscal quarter).

As of March 10, 2017, there were approximately 26,128,049 shares of the registrant's common stock, \$0.001 par value, outstanding.

**Documents incorporated by reference: None**

**Table of Contents**

|  | <b><u>Page</u></b> |
|--|--------------------|
| <b>PART I</b>  |                    |
| <b>Item 1</b> Business   | 2                  |
| <b>Item 1A</b> Risk Factors  | 20                 |
| <b>Item 1B</b> Unresolved Staff Comments   | 30                 |
| <b>Item 2</b> Properties   | 30                 |
| <b>Item 3</b> Legal Proceedings  | 30                 |
| <b>Item 4</b> Mine Safety Disclosures  | 30                 |
| <b>PART II</b>   |                    |
| <b>Item 5</b> Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 31                 |
| <b>Item 6</b> Selected Financial Data  | 31                 |
| <b>Item 7</b> Management's Discussion and Analysis of Financial Condition and Results of Operations                        | 32                 |
| <b>Item 7A</b> Quantitative and Qualitative Disclosures about Market Risk  | 36                 |
| <b>Item 8</b> Financial Statements and Supplementary Data  | F-1                |
| <b>Item 9</b> Changes in and Disagreements with Accountants on Accounting and Financial Disclosure                         | 37                 |
| <b>Item 9A</b> Controls and Procedures   | 37                 |
| <b>Item 9B</b> Other Information   | 38                 |
| <b>PART III</b>  |                    |
| <b>Item 10</b> Directors, Executive Officers and Corporate Governance  | 40                 |
| <b>Item 11</b> Executive Compensation  | 47                 |
| <b>Item 12</b> Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters              | 56                 |
| <b>Item 13</b> Certain Relationships and Related Transactions, and Director Independence                                   | 59                 |
| <b>Item 14</b> Principal Accountant Fees and Services  | 60                 |
| <b>PART IV</b>   |                    |
| <b>Item 15</b> Exhibits, Financial Statement Schedules   | 61                 |
| Signatures   | 65                 |

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-K for the fiscal year ended December 31, 2016 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, 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, our are references to VolitionRx Limited and its wholly-owned subsidiaries, Singapore Volition Pte. Limited, Belgian Volition SPRL, Hypergenomics Pte Limited, 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®, Nu.Q™ and HyperGenomics® 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

##### *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(1) of Delaware General Corporation Law, the Company was revived under the new name of 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 has two subsidiaries, Belgian Volition SPRL, a Belgium private limited liability company, or Belgian Volition, which it acquired on September 22, 2010, and HyperGenomics Pte Limited, a Singapore registered company, or HyperGenomics, which it formed on March 7, 2011. Belgian Volition has two subsidiaries, Volition Diagnostics UK Limited, which it formed on November 13, 2015, and Volition America, Inc., which it 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](http://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.

#### BUSINESS

##### *Description of Our Business*

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

As cancer screening programs become more widespread, our products aim to assist in diagnosing a range of cancers quickly, simply, accurately and cost effectively. Early diagnosis has the potential to not only prolong the life of



patients, but also to improve their quality of life.

Volition's research and development activities are currently centered in Belgium, with additional smaller offices in London, New York, Texas and Singapore. The Company's focus is to bring its diagnostic products to market first in Europe, then to some markets in Asia, the U.S. and ultimately, worldwide.

We are transitioning from a purely clinical stage company to a commercialized company with the achievement of the CE Mark for our first product, the Nu.Q™ Colorectal Cancer Screening Triage Test in December 2016. We will continue to research and develop additional assays and products across a range of cancers as we continue to develop our commercial operations.

### ***Research & Development***

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

We have developed thirty-nine blood-based assays to date to detect specific biomarkers that can be used individually or in combination to generate a profile which forms the basis of a product for a particular cancer or disease.

We 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. We believe our frontline blood test for CRC has the potential to have significantly higher compliance from patients compared to fecal tests and colonoscopies which are invasive and/or unpleasant. Our frontline blood test, currently in development, could be of significant benefit to approximately 148 million 50-74 year olds in the European Union that, according to the available data from the Organisation for Economic Co-operation and Development, the European Union recommends be screened for CRC.



We focused our early trials in Europe given that our laboratories are based in Belgium and that we have strong relationships with world class collaborators in the region. All research and development operations are currently in Belgium due to its favorable environment for small companies including a well-trained technical work force, low cost quality research facilities and access to government support, such as some of our funding from the Walloon Region.

We have collaborated with Hvidovre Hospital, University of Copenhagen in Denmark for many years. We have access to two sample sets - a 14,000 CRC screening cohort and a 4,800 patient cohort with symptoms indicative of CRC. We have also started a prospective longitudinal study of 30,000 subjects with Hvidovre Hospital. In this prospective longitudinal study we will initially gain access to one blood sample from each subject, who screened negative for CRC in a national fecal CRC screening test. We also have an option to collect a further 60,000 blood samples (two blood samples from each of the same 30,000 subjects at two year intervals), commencing in late 2018. All blood samples will be accompanied by up to 120 clinical information data points, including lifestyle factors and a wide range of other diseases, allowing us to use the study in the context of other cancers/diseases.

### ***Regulatory Approach***

Commercialization of our future products in the clinical in-vitro diagnostics, or 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 United States Food and Drug Administration's, or 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.

We obtained our first CE Mark in September 2015, for a single biomarker for CRC, and two further CE Marks in April 2016, for two biomarkers for CRC and pancreatic cancer. In December 2016, we achieved a CE Mark for our first product - the Nu.<sup>TM</sup> Colorectal Cancer Screening Triage Test.

We are currently working on different products such as a frontline screening test and a symptomatic test for CRC. We expect that we will be required to perform additional clinical trials in the United States to obtain FDA clearance or approval for these CRC tests. We are committed to obtaining FDA clearance or approval to allow patient access to our tests in the United States as soon as practicable. We intend to initiate the 510(k) and the PMA process in 2017.

We also expect that we will be required to do trials in China to achieve CFDA approval for our various tests, provided we can ensure adequate protection of our intellectual property in China. Local validation studies will be required to support sales of our CE Marked CRC test in many Asian markets for the private payer market. We plan to seek distribution partners for the major Asian markets.

Our Nucleosomics® biomarker platform is a technology that can potentially be used for a wide variety of cancers. We are currently developing Nucleosomics® tests for a number of major cancers including CRC, pancreatic, lung and aggressive prostate.

### *The Market*

Cancer is one of the leading causes of death worldwide, accounting for around 8.2 million annual deaths globally. In the United States alone, there were an estimated 13.8 million cancer survivors in 2010. By 2020, this figure is expected to rise to 18.1 million. The Agency for Healthcare research and Quality estimated the health economic burden for cancer relating to direct medical costs at approximately \$88.7 billion for 2011. The annualized cost of cancer care based on analysis of Medicare payments linked to Surveillance, Epidemiology, and End Results Program data is projected to reach \$157 billion by 2020. These figures are mirrored across the globe and we expect they will continue to grow as populations age. This is a large potential addressable market for which we believe early diagnosis will play a significant part. Incidence of, and mortality due to, CRC in the U.S. have been steadily falling since the mid-1980 s with an acceleration of reduction in both men (3% per annum) and women (2.3% per annum) over the last 15 years. This is largely due to early detection and removal of polyps via colonoscopy. The Papanicolaou (Pap) test has had a similar impact in improving 5-year survival rates in women with precancerous and cancerous cervical lesions.

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. This 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. There are currently no commonly used approved blood tests for screening for lung, pancreatic or CRC.

Further, current methods of cancer diagnosis are either invasive, not cost effective, have low acceptance or cannot provide accurate results. The inadequacy of existing diagnostic products means that most cancers are only diagnosed once the patient experiences symptoms and the cancer is well established. By this stage, it will often have spread beyond the primary tumor (metastatic cancers), making it substantially more difficult to treat. For example, CRC is one of the more survivable diseases if caught early: it has an observed five-year survival rate of 92% in stage I, but only 11% in stage IV. We believe that early, non-invasive, accurate cancer diagnosis remains a significant unmet medical need and a huge commercial opportunity. For these reasons, cancer diagnostics is an active field of research and development both academically and commercially.

The global IVD market is forecast to reach \$65 billion in 2018, driven by the increasing health care demands of an aging population. In the United States, the IVD market is made up of:

Immunochemistry of tissue samples (expected to grow 6.8% per annum from 2011-2018, with an expected value of \$25.5 billion by 2018). These are mostly used to confirm cancer diagnosis post-surgery and to determine cancer sub-type;

Immunoassay (chemical tests used to detect a substance in blood or body fluid), is expected to be the second largest market with a value of more than \$19.1 billion by 2018. These tests are mostly used to monitor for disease progress and relapse. This market segment includes our future Nucleosomics<sup>®</sup> products, which will be blood-based immunoassay tests for modified nucleosomes for the diagnosis of cancer.

Testing is carried out at three principal locations:

Testing at hospital laboratories: \$30 billion annual revenue for 8 billion tests in 2011;

.

Testing at CLIA laboratories: \$20 billion annual revenue for 3 billion tests in 2011; and

.

Testing at physician office laboratories: \$3 billion annual revenue for 1.2 billion tests in 2011.

### ***Our Product Candidates***

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 CFDA approval in China). We obtained our first biomarker CE Mark in September 2015 and received two further CE Marks in April 2016 for biomarkers for CRC and pancreatic cancer. Additionally, in December 2016 we achieved a CE Mark on our first product the Nu.Q™ Colorectal Cancer Screening Triage Test.

The technology behind the products that we are currently developing is described in detail below:

#### **Nu.Q™ Suite of Epigenetic Cancer Blood Tests**

Using our Nucleosomics® technology, we have developed thirty-nine 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.

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 also intend to pursue diagnostic

opportunities in other disease areas.

To date we have developed thirty-nine Nu.Q<sup>TM</sup> blood assays that fall into the five main types set forth below and are intended to complement each other and, together, to provide a total solution.

.  
*Nu.Q<sup>TM</sup>-X:* We have developed two blood assays in the Nu.Q<sup>TM</sup>-X family to detect nucleosomes containing specific nucleotides.

.  
*Nu.Q<sup>TM</sup>-V:* We have developed four blood assays in the Nu.Q<sup>TM</sup>-V family to detect nucleosomes containing specific histone variants. Through our research, we have found that the pattern of blood levels of the different types of histone variants in nucleosomes is different for different cancer types.

.  
*Nu.Q<sup>TM</sup>-M:* We have developed eighteen blood assays in the Nu.Q<sup>TM</sup>-M family to detect nucleosomes containing modified histones, the proteins that package and order DNA into nucleosomes.

.  
*Nu.Q<sup>TM</sup>-A:* We have developed fourteen blood assays in the Nu.Q<sup>TM</sup>-A family to detect nucleosome-protein adducts.

.  
*Nu.Q<sup>TM</sup>-T:* We have developed one Nu.Q<sup>TM</sup>-T assay to detect total blood nucleosome levels.



Generally, the assays described above are being developed to work in combination, collectively called a Nu.Q™ panel, for the IVD market. In our biggest independent clinical trial to date, we have used Nu.Q™ panel prototypes to test approximately 4800 samples from patients with symptoms associated with CRC.

We are part way through a trial of 14,000 asymptomatic (screening) subjects. This cohort is split into 8,000 fecal immunochemical test, or FIT, positive subjects and 6,000 FIT negative subjects.

The Nu.Q™ Colorectal Cancer Screening Triage Test, which achieved the CE Mark in December 2016, is a single normalized assay blood test that is designed to be combined with a patient's FIT score to reduce false positive referrals for non screen-relevant colonoscopies.

The most frequently used first line screening test for colorectal cancer across Europe is the FIT. Patients with a positive score following FIT are then referred for colonoscopy. However, more than 90% of people who test positive with FIT do not have colorectal cancer. This means there are a significant number of unnecessary expensive and invasive colonoscopies performed, placing a severe burden on both the patient and the healthcare system. For countries utilizing the Nu.Q test, patients with a positive FIT score would subsequently be given the blood-based Nu.Q™ Colorectal Cancer Screening Triage Test and then only be referred for colonoscopy if the combined test results indicate that it is necessary.

Results of our Nu.Q™ Colorectal Cancer Screening Triage Test developed using 1,907 FIT positive individuals (the training set), were presented at the European Society for Medical Oncology in October 2016. The test demonstrated the potential to reduce the number of colonoscopies by up to 25% while maintaining almost 97% detection of colorectal cancer.

The test was validated in 1,961 distinct FIT positive individuals (the validation set) from the same average risk population achieving 28.6% reduction in colonoscopies with a sensitivity for CRC of 91.2%. These results were presented at the World Congress of GI Endoscopy in February of 2017.

Additionally, prototype Nu.Q™ panels have been used to test a small number of blood samples from lung and prostate cancer patients.

**Figure 3 Example of lab instrument for running ELISA tests**

Nu.Q™ Clinical Diagnostic Products

There are three basic platforms in the clinical IVD market that we intend to adapt our Nu.Q™ products to in the future.

*Centralized Laboratory Market:* Centralized laboratories test thousands of patient blood samples taken every day, mostly using fully-automated enzyme-linked immunosorbent assay, or ELISA, systems, commonly known as random access analyzers, usually supplied by one of the global diagnostics companies. Tests run on ELISA systems use components of the immune system and chemicals to detect antibody interactions with target analytes.

ELISA systems analyze thousands of blood samples every day and can run dozens of different ELISA tests in any combination on any sample and for many samples simultaneously. The systems are highly automated and rapid (as little as ten minutes for many tests), and can be run at low costs. Additionally, ELISA instruments are used in all major hospitals throughout the United States and Europe and therefore, are well understood by clinicians and laboratory staff. It is more cost-effective and technically simple for hospitals and clinics to run several blood samples simultaneously using ELISA tests compared to non-ELISA tests or alternative methods for screening cancer. All of the Nu.Q™ tests that we are in the process of developing are designed for ELISA systems. A typical example of an automated ELISA system is shown below in Figure 4.

Figure 4 Example of an Automated ELISA System

One option that may be available to us in the future is to license our Nucleosomics® technology to a global diagnostics company. We do not have an anticipated timeframe for licensing our Nucleosomics® technology.

Another option that may be available to us is to sell 96 well ELISA plates for use by these laboratories for manual or semi-automated analysis using liquid handling systems. The Nu.Q™ Colorectal Cancer Screening Triage Test CE Mark allows this to be processed either manually or via an automated DS2 workstation from Dynex Technologies.

*Point-of-Care Devices:* Point-of-care devices are small instruments that perform tens of ELISA tests per day rapidly on blood taken from a finger prick. The instruments can be implemented in any oncology clinic and tests can be performed during patient consultations. We intend to contract with an instrument manufacturer to produce these instruments for point-of-care Nu.Q™ testing for the oncologist's office, general doctor's office or at home testing. We aim to enter the point-of-care clinical market in Europe and the United States about 18 months after launch on the manual and semi-automated platforms, as we will first need to adapt test prototypes to these small instruments and demonstrate their success in the greater diagnostics market before these products will be adopted by others in the industry. At this stage of its development, we cannot accurately predict the costs to manufacture these devices or their selling price. We are in discussion with several potential partners regarding development and manufacture of these

devices, however, there is no assurance that any of these discussions will result in an agreement. See Figure 5 for an example of a point-of-care device.

Figure 5 Example of a Point-of-Care Device

*The above photograph is an illustration of our intended products. To date, we have one product available for sale on the IVD market and there is no guarantee that any other products will be developed or commercialized on such market.*

*Disposable Tests for Doctor's Office or Home Use:* Disposable tests for use in a doctor's office or at home are single shot disposable devices which can be provided by a clinician as part of a screening program or purchased over the counter at any chemist shop or pharmacy and test a drop of blood taken from a finger prick. The test can be administered at a doctor's office using a point-of-care device or performed at home using a home testing kit, neither of which requires laboratory involvement. Thus, the patient experiences considerably lower costs using these tests as compared to traditional laboratory tests. The format of the self-use home testing kit is very easy to use and reproduce and does not rely on laboratory processing. There are currently no useful diagnostics tests suitable for mass screening for cancer in general through a simple self-use home testing kit. Figure 6 below shows a basic home use test on the left which displays the results of the test in the two windows, similar to a pregnancy test. The test on the right is more sophisticated and plugs into a meter or the USB port of a computer for analysis and interpretation allowing results to be sent directly to a clinician.

Figure 6 Examples of Disposable Tests for Doctor's Office or Home Use

*The above photograph is an illustration of our intended products. To date, we have one product available for sale on the IVD market and there is no guarantee that any other such products will be developed or commercialized on such market.*

We intend to contract with a specialist company to adapt the Nu.Q™ test prototypes to the doctor's office or home use system and to contract with a manufacturer for the production of these tests beginning approximately 18 months after launch on the manual platform. We have not entered into any agreements or contracts with a specialist company or manufacturer. Initially, we intend to sell these tests for professional use only (doctor's office) and to sell the tests for non-professional home use at a later time. We do not yet have an estimated timeframe for entering into this market. Further, at this early stage of our development, we cannot accurately determine the manufacturing costs or selling price of these tests.

Nu.Q™ tests for non-cancer conditions

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 also intend to pursue diagnostic opportunities in other disease areas. Our primary non-cancer focus is the development of a test for endometriosis.

Endometriosis is a progressive gynecological condition that affects one in ten women of childbearing age and approximately 176 million women worldwide. The disease is the leading cause of infertility in women, with up to 40% of all infertile women suffering from endometriosis. At present, there is currently no existing non-surgical diagnostic test for endometriosis. Diagnosis is typically made via invasive and expensive laparoscopy, followed by a histological examination of any lesions found to confirm the diagnosis. The lack of a suitable screening test has also held up development of a cure for the disease.

Singapore Volition acquired the patent application for an endometriosis test in June 2011 and we are now in the process of developing the test based on our existing Nucleosomics® technology. We designed the test to be a simple blood test taken at two stages of a woman's menstrual cycle, during menses and partway through the month. If the two measurements show quantitative differences in total nucleosome level, endometriosis is indicated. We are currently conducting hypothesis-testing and clinical proof of concept work (to demonstrate that the test is feasible and is effective) on the endometriosis test in our laboratory. We completed pilot studies of the test in 2012. The University of Oxford will provide serum and plasma samples from approximately 350 individuals including 150 with endometriosis, 130 with symptoms but no endometriosis and 70 with no symptoms as controls collected over a period of two years. Approximately half the samples were provided in 2016 with the remaining samples to be provided in 2017. Further samples from a prospective serial collection in 20 healthy women and 20 women with confirmed endometriosis were provided by Clinical Trials Laboratory Services (UK) in the first half of 2016. The test is too early in its development for us to accurately determinate the manufacturing costs and sale price of the test. In the short term the Company has decided to stay additional research and development in this area while it focuses on its cancer diagnostic products.

## HyperGenomics®

We are in the process of developing HyperGenomics® tissue and blood-based tests to determine disease subtype following initial diagnosis and to help decide the most appropriate therapy. In 2015, we decided to focus on our clinical IVD Nucleosomics® products and only continue with background work in HyperGenomics® until we have the capital and management resources to do multiple programs concurrently.

Selecting the correct treatment approach can significantly improve outcome, reduce side effects and deliver cost savings. The HyperGenomics® tests will be performed on cancer tissue obtained either by biopsy or during surgical resection to determine the cancer subtype and to determine optimal treatment regimens. The HyperGenomics® profiling tests are being developed to provide detailed epigenetic characterization of tumors in a cost effective way. A new protocol for analyzing white blood cells – a precursor to applications in leukemia - was developed in 2012. We commenced development of a bioinformatics pipeline to analyze the complex data sets generated from the biological samples in 2012 and continued development of the algorithms in 2013. A new in-house methodology patent for HyperGenomics® was filed in 2015.

We plan to allocate resources to the HyperGenomics® research use only, or RUO, kit as soon as is practical (likely in 2018) given our focus on the Nucleosomics® clinical IVD products. Beta-testing is expected to take approximately six months to complete once initiated and we expect it to cost approximately \$50,000. If beta-testing is successful, we expect to launch HyperGenomics® research kits into the RUO market in Europe and in the United States.

Further exemplification work on the HyperGenomics® platform is being carried out through a PhD studentship at the German Cancer Centre in Heidelberg funded by Volition. The program includes development of HyperGenomic® profiles in a range of cells and cancer models and comparison to established industry standard analytical techniques.

We plan to launch the HyperGenomics® test into the IVD market in Europe and the United States following the commercialization of the test into the RUO market. The estimated timeframe for its launch into the IVD market has not yet been determined and will depend upon the speed of clinical trials and market approval. The HyperGenomics® test is too early in its development for us to accurately determinate the manufacturing costs and sale price of the test.

## *Clinical Studies*

We have completed two clinical studies in CRC, one study in pancreatic cancer, one study in prostate cancer and one study in lung cancer with the results announced as set forth below.

Completed Colorectal Cancer Studies

Results of a completed clinical study in CRC were announced in the fourth quarter of 2015. The study included 121 patients referred for colonoscopy at the university hospital, CHU Dinant Godinne - UCL Namur, in Belgium, who either presented with symptoms suggesting the presence of CRC or were high-risk subjects. Analysis of the results revealed that a panel test of four Nu.Q™ biomarker assays, adjusted for age, detected 91% of CRC cases at 90% specificity. In addition, the results showed equally accurate detection of early and late-stage cancers. The analysis also revealed that the same panel test detected 67% of the type of polyps most likely to develop into cancer.

Results of a completed blinded retrospective clinical study in colorectal adenomas and CRC in collaboration with Hvidovre Hospital in Denmark were announced in the first quarter of 2016. The primary objective of the study was to identify new nucleosome biomarkers to improve precancerous polyp/adenoma detection. A secondary objective was to identify new nucleosome biomarkers to improve early stage CRC detection. In the study approximately 430 samples from patients with single or multiple precancerous polyp(s) (181 patients), subjects with no polyps or CRCs and without other diseases (160 subjects); plus 88 early stage (I/II) CRC patients were investigated. The cohort comprised high and low risk polyps of various histologies. The samples were analyzed using 18 Nu.Q™ assays. Use of newly developed Nu.Q™ assays, as part of a panel of five of the Company's Nu.Q™ biomarker blood assays, accurately detected 75% of colorectal adenomas, or polyps, that were most likely to become cancerous in an age adjusted analysis. A Nu.Q™ panel also detected 86% of early stage I CRCs in an age adjusted analysis.



#### Completed Pancreatic Cancer Study

Results of a completed clinical study in pancreatic cancer were announced in the third quarter of 2015. The peer-reviewed study was conducted in collaboration with Lund University, Sweden, and led by Roland Andersson, MD, PhD, Professor of Surgery and Vice-Dean, Faculty of Medicine. This study assessed blood samples from 59 individuals, including 25 patients with stage 2 pancreatic cancer, 10 patients with other pancreatic diseases and 24 healthy individuals, using our Nucleosomics® technology platform. Analysis of the blood samples demonstrated that a panel of five Nu.Q™ assays distinguished 84% (21 of 25) of the early-stage pancreatic cancer cases from healthy subjects, with only two false positive results among the healthy subjects. The detection rate of the test was improved further to 92% (23 of 25) of cancer cases by inclusion of the classical CA19-9 cancer biomarker with no false positives results among the healthy subjects. Full results of the study have been published in Clinical Epigenetics, the official journal of the Clinical Epigenetics Society.

#### Completed Prostate Cancer Study

Results of a completed retrospective study in prostate cancer were announced in the second quarter of 2016. The study was conducted with Surrey Cancer Research Institute, University of Surrey, UK with 550 blood samples collected from patients attending the hospital and analyzed using a panel of Nu.Q™ biomarker assays. Three groups of patients were assessed: those with aggressive prostate cancer; those with indolent or slow-growing prostate cancer; and age-matched healthy controls. Analysis of the study showed that a single Nu.Q™ biomarker assay detected 71% of early state I prostate cancer cases at 93% specificity.

#### Completed Lung Cancer Study

Results of a completed clinical study in lung cancer were announced in the fourth quarter of 2014. The lung cancer study tested both sputum and blood samples taken from 46 patients attending the Pneumology department of the Centre Hospitalier Universitaire, or CHU, de Liege in Belgium. The patients were diagnosed either with non-small cell lung cancer, chronic obstructive pulmonary disease, or COPD, or with no disease (healthy). In sputum samples, our Nu.Q™ test was able to detect 18 of 21 lung cancer cases (85%) with no false positive results for healthy subjects (0 of 13). The sputum assay data is age and smoking independent. In blood the Nu.Q™ assays were able to detect 16 of the 21 patients with cancer (76%) with a single false positive result from a healthy subject (1 of 13). The blood assay data is adjusted for age and smoking risk.

We currently have clinical studies underway in CRC, lung cancer, pancreatic and prostate cancer as well as a pan-cancer study in 27 cancers as set forth below. Further studies in lung and pancreatic cancer are planned to commence in 2017.

#### Current Colorectal Cancer Studies

A retrospective symptomatic CRC study with Hvidovre Hospital in Denmark with full access to all Danish national registries and databases analyzing approximately 4,800 previously collected samples from patients with CRC, polyps or adenomas, benign bowel diseases, other malignancies, or no findings, all of whom have undergone a colonoscopy, which we refer to as the Retrospective CRC Trial. The Retrospective CRC Trial is designed to (i) establish a Nu.Q™ profile for the detection of CRC in an initially blinded cohort, which we refer to as Phase I; and (ii) validate that profile in a second blind cohort, which we refer to as Phase II. As part of Phase I, at the end of the third quarter 2015, we announced detection of 81% of CRC cases at 78% specificity in an age adjusted analysis. Additional Nu.Q™ assays are currently being tested on these Phase I samples. Phase II commenced using the best Nu.Q™ assays on the blind sample cohort in 2015 and was paused in 2016 to focus on the Nu.Q™ Colorectal Cancer Screening Triage Test. The results from this study were also used to support CE Marking of specific Nu.Q™ assays in the second half of 2016.

A prospective FIT screening CRC study with Hvidovre Hospital in Denmark which will include approximately 14,000 blood samples collected from subjects who have taken a FIT test. Approximately 6,000 (of the 14,000) samples will be collected from subjects who tested negative in FIT and approximately 8,000 (of the 14,000) samples from patients who tested positive. All subjects testing positive will be offered a colonoscopy. The Prospective CRC Study is designed for the development of a CRC screening test in a large screening cohort and includes full access to all FIT and colonoscopy results as well as subjects' medical history. FIT positive and negative samples will be analyzed in batches throughout the collection period to develop Nu.Q™ Colorectal Cancer Screening Triage Tests for European markets.

In addition, the FIT positive samples have been used to develop a Nu.Q™ Colorectal Cancer Screening Triage Test which, when combined with FIT, has the potential to offer up to a 25% reduction in colonoscopies while maintaining almost 97% detection of CRC.



A prospective clinical study of 30,000 patients conducted with Hvidovre Hospital, University of Copenhagen, Denmark. Under the terms of the study, an initial 30,000 blood samples will be collected from 30,000 patients who have tested negative in a national fecal CRC screening test. We also have an option to collect a further 60,000 blood samples (two blood samples from each of the same 30,000 subjects at two year intervals), commencing in late 2018. We will test whether, and how early, our Nu.Q™ assays detect cancer in blood samples taken before the definitive diagnosis of CRC. All blood samples will be accompanied by up to 120 clinical information data points, including life style factors and a wide range of other diseases, allowing us to use this study in a wider context for other cancers.

#### Current Lung Cancer Studies

A prospective lung cancer study conducted with the Liege University Hospital (Belgium) with 240 subjects collected from subjects with lung cancer, COPD and with healthy lungs. The trial is designed to evaluate the potential of a Nu.Q™ based test alone and with additional patient data, to detect the most common non-small cell lung cancer. Preliminary results from the first 73 subjects released in the fourth quarter of 2015 demonstrated that, when combined with details of smoking history, a panel of four Nu.Q™ biomarker assays detected 93% of non-small cell lung cancer cases (27 of 29), with 91% specificity (2 false positive results among 22 healthy subjects). Collection and full analysis is expected to complete in the third quarter of 2017. Additional preliminary results from the first 87 subjects were released in the first quarter of 2016 demonstrating that a single Nu.Q™ biomarker assay detected 86% of subjects with a deadly lung disease called Idiopathic Pulmonary Fibrosis.

#### Current Pancreatic Cancer Studies

A 750 patient study is being conducted with DKFZ, the German Cancer Research Center, to evaluate our Nu.Q™ blood tests for the detection of pancreatic cancer. This study was put on hold in 2016 to focus on the Nu.Q™ Colorectal Cancer Screening Triage Test and we expect to reinstate it in the second half of 2017.

#### Current Prostate Cancer Studies

A retrospective study to evaluate Nu.Q™ assays in a treatment selection setting to distinguish anaplastic cancer, a particularly aggressive form of prostate cancer, from typical castration resistant prostate cancer, or CRPC, the less aggressive form. This study is in progress and no results have been announced to date.

A prospective prostate cancer study, carried out by Immune Health, with 120 patients with aggressive prostate cancer; those with indolent or slow-growing prostate cancer; and age-matched healthy controls. The study is currently in the recruiting phase and the analysis of the panel of Nu.Q™ assay data is expected to be complete in the first quarter of 2017. The study will also assess the ability to distinguish clinically actionable, aggressive prostate cancer from non-actionable slow growing disease. This study is in collection and no results have been announced to date.

#### Current Pan-Cancer Study

A large prospective study conducted with University Hospital in Bonn, Germany on approximately 4,700 patients to evaluate the performance of our Nu.Q™ assays on patients with the 27 most prevalent cancer types and other diseases, as well as healthy subjects. Collection of blood samples has commenced. Analysis of the blood samples will be performed with a wide range of Nu.Q™ assays. The primary objectives of this study are: (i) to identify further cancers that are highly amenable to detection by Nu.Q™ assays; and (ii) to identify Nu.Q™ assays suitable for the differential diagnosis between cancers. The study has been paused due to the focusing of our efforts on other studies and it is expected to resume in 2017.

#### ***Research and Development Expenditures***

For the years ended December 31, 2016 and 2015, our expenditures for research and development activities were \$6.8 million and \$6.1 million, respectively. Such research and development is focused on responding to the need for early, accurate diagnostic tests through the development of our proprietary technologies and product prototypes.

#### ***Intellectual Property***

We hold or have applied for eleven families of patents covering the products currently being developed. One is licensed from a world-class research institution, one was purchased and assigned from a pharmaceutical company and nine are applied for in the name of our subsidiaries.



Nucleosomics® Intellectual Property

Singapore Volition held an exclusive license to the following patent from Chroma Therapeutics Limited, or Chroma, until February 20, 2015, when it purchased and was assigned this patent from Chroma:

**Nucleosomics® WO2005019826:** Detection of Histone Modifications in Cell-Free Nucleosomes

Application Date: August 18, 2003

Status: Granted in Europe and United States

Singapore Volition holds this worldwide exclusive license in the field of cancer diagnosis and cancer prognosis for the following patent from the European Molecular Biology Laboratory:

**EMBL Variant Patent WO2011000573:** Diagnostic Method for Predicting the Risk of Cancer Recurrence based on MacroH2A Isoforms

Application Date: July 2, 2009

Status: Granted in Australia, Japan, Singapore, South Africa and China; Pending in Europe, United States, Canada, India, Brazil

VolitionRx's subsidiary is the applicant for the following patent application covering its total Nu.Q<sup>TM</sup> assay technology:

**Nucleosomics® WO2013030578:** Method for Detecting Nucleosomes

Application Date: September 1, 2011

Status: Granted in United States; Pending in Europe and Hong Kong

VolitionRx's subsidiary is the applicant for the following patent application covering its Nu.Q<sup>M</sup>-V technology:

**Nucleosomics® WO2013030579:** Method for Detecting Nucleosomes containing Histone Variants

Application Date: September 1, 2011

Status: Granted in United States and South Africa; Pending in Europe, Canada, Australia, India, Brazil, Japan, China, Singapore, Russia, South Korea, Mexico and Hong Kong

VolitionRx's subsidiary is the applicant for the following patent application covering its Nu.Q<sup>M</sup>-X technology:

**Nucleosomics® WO2013030577:** Method for detecting Nucleosomes containing Nucleotides

Application Date: September 1, 2011

Status: Granted in South Africa; Pending in Europe, United States, Canada, Australia, India, Brazil, Japan, China, Singapore, Russia, South Korea, Mexico and Hong Kong

VolitionRx's subsidiary is the applicant for the following patent application covering a Nu.Q<sup>M</sup>-A blood test for detecting nucleosome adducts of cancer origin that circulate in the blood of cancer patients. The patent application covers both the use of these adducts as biomarkers and the methods for their detection.

**Nucleosomics® WO2013084002:** Method for detecting Nucleosome Adducts

Application Date: December 7, 2011

Status: Granted in United States and South Africa; Pending in Europe, Canada, Australia, India, Brazil, Japan, China, Singapore, Russia, South Korea, Mexico and Hong Kong



VolitionRx's subsidiary is the applicant for the following patent application covering Nu.Q<sup>M</sup>-M blood tests for detecting nucleosomes containing modified histones of cancer origin that circulate in the blood of cancer patients. The patent application covers methods for their detection.

**Nucleosomics<sup>®</sup> Patent WO2014131841:** Method for detecting Histone Modifications in Nucleosomes

Application Date: February 28, 2013

Status: Pending in Europe and United States

.

VolitionRx's subsidiary is the applicant for the following patent application:

**WO2014131845:** Method for Predicting Therapy Efficacy using Nucleosome Structure Biomarkers

Application Date: February 28, 2013

Status: Pending in Europe and United States

.

VolitionRx's subsidiary is the applicant for the following patent application:

**WO2016067029:** Method for Enrichment of Circulating Tumor DNA

Application Date: October 29, 2016

Status: Pending Worldwide

.

VolitionRx's subsidiary is the applicant for the following patent application:

**WO2016092306:** Method for the Detection of Hormone Sensitive Disease Progression

Application Date: December 10, 2016

Status: Pending Worldwide

Endometriosis Intellectual Property

.

VolitionRx's subsidiary is the applicant for the following patent application for its endometriosis test:

**Endometriosis Diagnostic WO2012013955: Method for Detecting the Presence of a Gynaecological Growth**

Application Date: July 28, 2010

Status: Granted in Australia; Pending in United States, Canada, Europe and Hong Kong

Future Intellectual Property Strategy

We intend to continue our development of the Nucleosomics® and HyperGenomics® 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 U.S. 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™-X, Nu.Q™-V and Nu.Q™-A technologies.

Trademarks

We also own a number of trademarks that protect our marks including Nu<sup>®</sup>, Nu<sup>™</sup>, Nucleosom<sup>®</sup>es and HyperGenom<sup>®</sup>ic.

***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 European Union has recently proposed terms that would 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 approval process, as the new regulations will require each product submission to be thoroughly audited by Notified Bodies, instead of the current self-certification process. The EU Medical Devices Regulation, or MDR, and IVD Regulation, or IVDR, are both in the final stages of the legislative procedure and are estimated to be furnished sometime in early 2017. The MDR and IVDR are expected to come into effect in 2020 and 2022, respectively.

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.

Please refer to the section below titled **Government Approval** for additional information.

### ***Government Approval***

All of our intended products are designed to be non-invasive, meaning they cannot harm the subject other than through misdiagnosis. Our strategy is to go through the process of obtaining regulatory approval for IVD products to be used clinically on cancer patients. Conformité Européenne, or CE Marking, is a mandatory conformity mark for certain products placed on the market in the European Union, including medical devices and IVD tests. CE Marking ensures that the manufacturer's product conforms to the essential requirements of the relevant European health, safety and environmental protection legislation. We intend to first focus on obtaining regulatory approval in Europe, due to the grant of the Nu.Q™ patent in Europe and the relatively fast European CE Marking process. We currently anticipate this will be followed closely by licensing to CLIA labs for a LDT in the United States, and/or regulatory submissions in the United States and in the rest of the world. In many territories, the European CE Mark is sufficient to place products on the clinical market and, where it is not, it often simplifies the regulation processes.

Europe CE Marking

Manufacturers in the European Union and abroad must meet CE Marking requirements, where applicable, in order to market their products in Europe. The CE Mark certifies that a product has met European Union health, safety, and environmental requirements which ensure consumer safety.

To receive the CE Mark, our diagnostic products must meet certain requirements as set forth in the In-Vitro Diagnostic Medical Devices Directive. The requirements to procure CE Marking for IVD medical device products are:

- .
- analytical validation of the products;
- .
- clinical validation of the products (which can be retrospective clinical studies using biobank patient samples, i.e. blood samples from historic patients);
- .
- implementation of regulatory compliant manufacture;
- .
- implementation of a Quality System; and
- .
- certification from the International Organization for Standardization (this last requirement is not technically required but will aid the regulatory approval process in Europe and the United States).

The first Nu.Q™-X assay received a CE Mark in September 2015 and our R&D, manufacturing and distribution facility, Belgian Volition received EN ISO 13485, 2012 certification (an internationally recognized quality system) at the start of 2016. In April 2016 we received a CE Mark for Nu.Q™-V (variant) and Nu.Q™-T (total) assays Nu.Q™-V001 and Nu.Q™-T003, respectively. Additionally, in December 2016 we received a CE Mark on our Nu.Q™ Colorectal Cancer Screening Triage Test. The requirements listed above are general requirements that apply to all of our intended products. In compliance with the In-Vitro Diagnostic Medical Devices Directive and the CE Marking process, we have ensured that all development and validation is carried out in a manner consistent with regulatory approval. Additionally, we have maintained proper records so that our future products can be approved as quickly and simply as possible. We have engaged a regulatory advisor to lead the Company in meeting the last requirement for all of our future products. All of these requirements must be completed prior to the submission of an application for CE Marking. We will submit applications, which will contain a dossier of all relevant analytical, clinical and manufacturing data following retrospective clinical studies which we expect will require a total of approximately six (6) months to complete. We estimate the cost of obtaining CE Marking will be approximately \$500,000 per Nu.Q™ panel. Sales of our clinical products can occur in Europe once CE Marking has been granted.

In Europe, IVD companies currently are able to self-certify that they meet the appropriate regulatory requirements and are subject to inspection for enforcement. European agencies conduct market surveillance to ensure the provisions of the applicable Directive have been met for products marketed within the European Union. In pursuit of this goal, surveillance authorities will:

.  
audit commercial, industrial and storage premises;

.  
visit work places and other premises where products are put into service and used;

.  
organize random checks; and

.  
take samples of products for examination and testing.

If a product is found to be noncompliant, corrective action will depend on and be appropriate to the level of noncompliance. Those responsible for noncompliance of the product will also be held accountable. Penalties, which may include imprisonment, are determined by national law.

### ***U.S. Regulations***

Food and Drug Administration

In the United States, IVD products are regulated by the FDA as medical devices. There are two principal regulatory pathways to receive authorization to market IVDs, a 510(k) or PMA. The FDA makes a risk-based determination as to which pathway a particular IVD is eligible. In addition, since July 2012 with the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, a *de novo* pathway is directly available for certain low to moderate risk devices that would not qualify for the 510(k) notification pathway due to lack of a predicate device. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of their level of risk and the controls deemed by the FDA to be necessary to reasonably assure their safety and effectiveness. Class I devices are subject to general controls, including establishment registration, device listing, labeling, reporting and recordkeeping, and adherence to FDA's quality system regulations, which are device-specific good manufacturing practices. Class II devices are subject to the general controls and also special controls, including guidance documents, performance standards, and postmarket surveillance. Class III devices are subject to most of the previously identified requirements as well as to a PMA. Most Class I devices are exempt from the requirement for 510(k) to the FDA; most Class II devices require the submission and clearance of a 510(k) to the FDA prior to commercial marketing; and Class III devices require submission and a PMA. Device manufacturers and PMA holders are also subject to numerous postmarketing requirements.

The FDA can require the submission of clinical data to support 510(k) clearance, *de novo* reclassification, or a PMA. Clinical studies undertaken in the United States are subject to FDA requirements applicable to investigational device exemptions, or IDEs, institutional review boards, or IRBs, review and approval, and informed consent of the study subjects.



### Clinical Trials of Devices

Clinical trials for a medical device must be conducted in accordance with FDA requirements, including informed consent from study participants, review and approval by an IRB at each institution where a trial will be conducted, financial disclosure by clinical investigators, and listing of appropriate studies on ClinicalTrials.gov. Additionally, FDA approval of an IDE application must be obtained in order to conduct a clinical trial of significant risk devices, which are devices that present a potential for serious risk to the health, safety, or welfare of a subject, including devices that are of substantial importance in diagnosing or treating disease, or preventing impairment of human health. Sponsors of clinical trials are responsible for monitoring the studies, and for recordkeeping and reporting. The FDA may prevent clinical trials from moving forward, and may suspend or terminate trials once initiated. The FDA may inspect sponsor records, clinical investigators, and clinical sites involved in clinical trials. The FDA may take enforcement action for non-compliance with any of these requirements.

### 510(k) Premarket Notification

A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a predicate device, that is legally marketed in the United States and for which a PMA was not required. A device is substantially equivalent to a predicate device if it has the same intended use and same technological characteristics as the predicate or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety or effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed predicate device.

The FDA's performance goal review time for a 510(k) notification is 90 days from the date of receipt. In practice, however, the review process often takes significantly longer. After its initial review, the FDA may require additional information, including clinical data, in order to make a decision regarding the claims of substantial equivalence. Clinical studies of IVD products are typically designed with the primary objective of obtaining analytical or clinical performance data. If the FDA believes that the device is not substantially equivalent to a predicate device, it will issue a Not Substantially Equivalent letter and designate the device as a Class III device, which will require the submission and approval of a PMA before the new device may be marketed. Under certain circumstances, the sponsor may submit a *de novo* petition to the FDA to reclassify the new device as a Class I or Class II device.

If a predicate device does not exist, the FDA may make a risk-based determination that the device is eligible for *de novo* reclassification and premarket review instead of requiring a PMA. The *de novo* process is similar to clearance of the 510(k), and typically requires the submission of clinical data to support the reclassification. A *de novo* petition can be submitted either prior to the submission of a 510(k) when no predicate device can be identified, or after the FDA determines that a new device is not substantially equivalent due to lack of an appropriate predicate device. Under the FDASIA, the FDA may decline to undertake a classification if the FDA either (1) identifies a legally marketed predicate device that would be appropriate for a 510(k), or (2) determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. The statute

directs the FDA to classify the device within 120 days following receipt of the *de novo* application.

### Premarket Approval

The PMA process is more complex, costly and time consuming than the 510(k) process. A PMA must be supported by manufacturing data, preclinical data, and more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a significant risk, the sponsor may not begin a clinical trial until it submits an application for an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial.

After the PMA is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is deemed not sufficiently complete, the FDA will issue a refuse to file determination. If the PMA is complete, the FDA will file the PMA and begin a substantive review of the application. The FDA is subject to a performance goal review time for a PMA that is 180 days from the date of filing, although in practice the total review time is longer. Questions from the FDA, requests for additional data, additional testing and submissions by the applicant, and referral to an advisory committee may delay the process considerably. Indeed, the total process may take several years and there is no guarantee that the PMA will ever be approved. Even if approved, the FDA may limit the indication for which the device may be marketed. The FDA may also request additional clinical studies or registries as a condition of approval or even after the PMA is approved. Any changes to the medical device may require a supplemental PMA to be submitted and approved. In addition, annual reports and other reports are required.

### Requirements Applicable to Marketed Devices

The FDA Quality System Regulations, or QSRs, impose requirements for design control and validation, management review, complaint handling and investigation, labeling control, servicing and recordkeeping, among others. The FDA also regulates device imports and exports. Manufacturers are required to submit medical device reports for deaths or serious injuries associated with the use of their devices, and for malfunctions that could cause or contribute to a death or serious injury. The FDA also requires reporting of certain corrections or removals of devices. Labeling and promotional activities are subject to regulation by the FDA, and certain device advertising is subject to regulation by the Federal Trade Commission.

### Laboratory Developed Tests

Although the FDA has claimed for many years that it has the statutory authority to regulate laboratory-developed tests, or LDTs, as medical devices, the agency has generally exercised enforcement discretion toward them. LDTs are tests that are developed, validated, and offered as testing services by a clinical laboratory, and these tests are regulated under the Clinical Laboratory Improvement Act, or CLIA. The FDA has stated that it will take enforcement action against any specific LDT if necessary to protect the public health. In recent years, the FDA has indicated that it is reconsidering its policy of enforcement discretion and reviewing the regulatory requirements that it will apply to LDTs.

### CLIA and State Clinical Laboratory Laws

The FDA is responsible for the complexity categorization of commercially marketed IVD tests under CLIA, placing them into one of three categories based upon the potential risk to public health in reporting erroneous results. The categories were devised on the basis of the complexity of the test, and include waived tests, tests of moderate complexity, and tests of high complexity.

The Center for Medicare and Medicaid Services, or CMS, regulates clinical laboratories under CLIA. Laboratories that perform testing on human specimens for the purpose of providing information for diagnosis, prevention or treatment of disease or assessment of health are subject to CLIA, which imposes quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results.

Laboratories performing moderate- or high-complexity testing must meet various CLIA requirements applicable to personnel, operations, establishment and verification of performance specifications, proficiency testing, patient test management, quality control, and quality assurance. CLIA certified laboratories are typically subject to survey and

inspection every two years to assess compliance with program standards. Sanctions can be applied against a laboratory that is found to be out of compliance with CLIA requirements, including, among others, suspension, limitation, or revocation of a CLIA certificate.

Laboratories may also seek accreditation by the College of American Pathologists, or CAP. CAP is an independent, non-governmental organization approved by CMS to inspect laboratories to determine compliance with CLIA requirements. The CAP Laboratory Accreditation Program is an internationally recognized program that utilizes teams of practicing laboratory professionals as inspectors, and accreditation by CAP can often be used to meet CLIA or state certification requirements.

In addition to CLIA, States also have laws that apply to clinical laboratories, including state licensing laws. Some states impose requirements that are more stringent than CLIA requirements. State laws may also require detailed review of a laboratory's technical procedures or scientific validation of laboratory tests.

***Product Development and Plan of Operations***

**Nu.Q™ Assays (Cancer and Other Conditions):**

.

***In-Vitro Diagnostics Market***

o

CE Marking (Europe): The first Nu.Q™-X biomarker assay received a CE Mark in September 2015. In April 2016 we received a CE Mark for Nu.Q™-V (variant) and Nu.Q™-T (total) assays Nu.Q™-V001 and Nu.Q™-T003, respectively. Additionally, in December 2016 we received a CE Mark on Nu.Q™ Colorectal Cancer Screening Triage Test.

o

FDA Approval (United States): FDA approval for CRC screening applications is expected to require longer large-scale prospective clinical validation studies including U.S. trials. Our FDA PMA clinical trial process is expected to commence in 2017 and be completed in 2019. When the trial is completed, the data will be submitted to the FDA for United States PMA. We estimate the cost of obtaining FDA PMA will be approximately \$5 million, with the understanding that up to \$50 million may ultimately be required depending on a multitude of factors as previously discussed. As an intermediate step we will seek 510(k) approval for use of Nu.Q™ as a symptomatic adjunct test (used in combination with other tests to identify at risk patients). This abbreviated process is expected to begin in 2017 and complete in 2018 with an estimated cost of between \$1.5 million and \$2 million.

We expect to produce a rolling pipeline of products for different types of cancers over the next one to five years.

**Nu.Q™ Clinical Diagnostic Products:**

.

***Centralized Laboratory Market***

o

*License of Nucleosomics® technology to a global diagnostics company:* We may license our Nucleosomics® technology on a non-exclusive basis to a global diagnostics company. The approximate licensing fees have not yet been determined. We have not entered into any agreements with diagnostic companies or established an anticipated timeframe for licensing our Nucleosomics® technology.

o

*Sell manual and/or semi-manual ELISA plates to centralized laboratories:* We may sell manual and/or semi-automated 96 well ELISA plates for use by centralized laboratories. The approximate manufacturing costs or sales price have not yet been determined. We are in discussions with several groups to distribute our products in multiple regions.

o

*Point-of-Care Devices:* We intend to enter the point-of-care clinical market in Europe and in the United States 18 months after launching on the manual platform. The approximate manufacturing costs or sales price per device have not yet been determined. We have not entered into any discussions or negotiations regarding the manufacture or sale of these devices.

o

*Disposable Tests for Doctor's Office or Home Use:* We intend to contract with a specialist company to adapt the Nu.Q™ tests to the doctor's office or home use system and to contract with a manufacturer for the production of these tests. The sale of these tests will initially be for professional use only (doctors) and will likely be released at a later time for non-professional home use. The approximate manufacturing costs or sales price per test have not yet been determined. We have not entered into any discussions or negotiations with a specialist company or manufacturer. We do not yet have an estimated timeframe for the manufacture or sale of these tests.

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 its research and development personnel and facilities, primarily in Belgium, and the maintenance of our patent rights. In the event of an ongoing lack of financing, we may be obliged to discontinue operations.

### ***Sales and Marketing Strategy***

Our future products will require several dynamic and evolving sales models tailored to different worldwide markets, users and products. In 2017, we intend to launch our own products to be used in combination with existing technologies, such as the FIT, to progressively grow sales volumes after CE Marking in Europe with sales to centralized governments and laboratories. We also intend to sell to the private payer market in some Asian countries.

### ***Competition***

We believe that our main competitor in the blood-based diagnostic market is Epigenomics AG. Epigenomics has European approval for its methylated DNA based PCR tests in colon cancer (Epi proColon®) and lung cancer (Epi proLung). In colon cancer, our main target market, we face potential competition from alternative procedures including flexible sigmoidoscopy, colonoscopy and virtual colonoscopy as well as traditional tests such as the guaiac and immunochemical FIT. Exact Sciences Corporation has FDA approval and reimbursement approval for its stool-based DNA screening test, Cologuard®. We anticipate facing competition primarily from healthcare, pharmaceutical and diagnostic companies such as Epigenomics AG, Applied Proteomics Inc., and Exact Sciences Corporation, as well as others such as 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 anticipated 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.

### ***Employees***

As of December 31, 2016, we (including our subsidiaries) had 18 full-time employees and 4 part-time employees.

### **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 may read and copy our reports or other filings made with the SEC at the SEC's Public Reference Room, located at 100 F Street, N.E., Washington, DC 20549 on official business days during the hours of 10:00 a.m. and 3:00 p.m. You can obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You can also access these reports and other filings electronically on the SEC's web site, [www.sec.gov](http://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 conditions 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 and have incurred losses since our formation. As of December 31, 2016, we have an accumulated total deficit of approximately \$40.9 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 we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and then maintain profitability, our business, financial condition and results of operations will be negatively affected and the market value of our common stock will decline.

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

Although we believe that we have sufficient capital to fund our operations for at least the next twelve months, we may require additional capital to fully fund our current strategic plan, which includes successfully commercializing our Nu.Q™ Colorectal Cancer Screening Triage Test and developing a pipeline of future products. If we incur delays in commencing commercialization of our Nu.Q™ Colorectal Cancer Screening Triage Test 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.***

In addition to commercializing our Nu.Q™ Colorectal Cancer Screening Triage Test, 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 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 though we have received the CE Mark on our Nu.Q™ Colorectal Cancer Screening Triage Test, 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 LDTs by the FDA, we may decide to enter the United States market through a CLIA certified laboratory in the United States. We intend to progressively grow to large volumes of tests sold to centralized laboratories and eventually reach the mass diagnostics testing market. The exact nature of the ideal sales strategy will evolve as we continue to develop our intended products and seek entry into the IVD markets. We have limited experience with direct sales and marketing and any failure to build and manage a direct sales and marketing team effectively could have a material adverse effect on our business.

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

.

identify appropriate partners;

.

negotiate beneficial partnership and distribution agreements;

.

hire qualified individuals as needed;

.  
generate sufficient leads within our targeted market for our sales force;

.  
provide adequate training for effective sales and marketing;

.  
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, 2016. 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, 2016, we had \$21.7 million in combined cash and marketable securities compared to \$5.9 million as of December 31, 2015. 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. Our Nu.Q™ Colorectal Cancer Screening Triage Test achieved CE Marking in December 2016 and is expected to be made available to the European market in the first quarter of 2017. 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.

Currently, we are heavily dependent on our Nu.Q™ Colorectal Cancer Screening Triage Test. The commercial success of our Nu.Q™ Colorectal Cancer Screening Triage Test will impact our ability to generate revenues.

Prior to commercializing the Nu.Q™ Colorectal Cancer Screening Triage Test 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 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 and other regulatory bodies in other countries where we intend to sell our future products. Before we are able to place our intended products in the clinical IVD markets in the United States and Europe, we will be required to obtain clearance or approval of our future products from the FDA and receive a CE Mark, respectively. The European Union has recently proposed regulations that would 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 MDR and IVDR, are both in the final stages of the legislative procedure and are estimated to be finished sometime in 2017. The MDR and IVDR are expected to come into effect in 2020 and 2022, respectively.

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 able to self-certify that they meet the appropriate regulatory requirements but are subject to inspection for enforcement. European national agencies, such as customs authorities and/or the Departments of Health, Industry and Labor, conduct market surveillance to ensure the applicable requirements have been met for

products marketed within the 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 U.S. 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, Applied Proteomics Inc., Roche Diagnostics, Exact Sciences Corporation, Sequenom, Inc. and several others. Most of these companies have substantially greater financial, marketing and other resources than we do. 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 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 and 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.***

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

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". As a result of the referendum, it is expected that the British government will begin negotiating the terms of the United Kingdom's future relationship with the European Union. 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 four patents related to our diagnostic tests granted in the United States; one patent granted in the European Union and four patents granted in other countries. We also hold an exclusive worldwide license to one patent which is granted in five other countries and pending in the United States. Additionally, we have patent applications in the name of our subsidiaries pending in the United States, the European Union and other countries. 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, including our first product the Nu.Q™ Colorectal Cancer Screening Triage Test, 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 10, 2017, our executive officers and directors beneficially owned, in the aggregate, approximately 21.8% 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;

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

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

.  
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 and amendments thereto authorize 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, 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 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 we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.***

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

**ITEM 1B.**

**UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2.**

**PROPERTIES**

Our principal executive office is located at 1 Scotts Road, #24-05 Shaw Centre, Singapore 228208. We have signed a one-year lease, commencing August 1, 2016, at an annual rent of \$20,389 (SGD 29,519). We believe that this facility is adequate to meet our current needs. We additionally have an office in New York, leased on a month-to-month basis, at an annual cost of approximately \$4,400.

Belgian Volition leases a laboratory and office space at 20A Rue de Séminaire, 5000, Namur, Belgium. We have signed a four-month lease, commencing December 1, 2016, at an annual rent of \$62,016 (€58,976). Additionally, Belgian Volition shall pay \$841 (€800) per month as a provision against expenses.

In October 2016, we acquired a research and development facility located at 5032 Isnes-Spy, Rue Phocas Lejeune 22, Gembloux cadastre, 8<sup>th</sup> division, Section B, n 55, Belgium. The purchase price for the property consisted of \$1.3 million (€1.2 million), exclusive of any closing costs. The property will be used to carry out clinical trials and allow the company to expand its scientific team. Belgian Volition intends to move into this facility in March 2017.

Volition Diagnostics UK Limited signed a one year lease for office space at 83 Baker Street, London, W1U 6AG, United Kingdom, commencing January 25, 2016, at an annual rent of \$68,526 (£55,548). Following the expiry of this lease, Volition Diagnostics UK signed a new two year lease for a larger office space at 93-95 Gloucester Place, London, W1U 6JQ, United Kingdom, commencing January 30, 2017, at an annual rent of \$136,193 (£110,400).

**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*

Effective February 6, 2015, shares of our common stock began trading on the NYSE MKT under the symbol VNRX. Prior to that our shares of common stock had been quoted on the OTC Bulletin Board under the symbol VNRX.OB since October 11, 2011. The following table presents quarterly information on the high and low sales prices of the common stock furnished by the NYSE MKT or the high and low bid prices for the common stock furnished by the OTC Bulletin Board, as applicable, for the fiscal years ended December 31, 2016 and 2015. The quotations on the OTC Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

| <b><u>Year Ended December 31, 2015</u></b> | <b><u>High</u></b> | <b><u>Low</u></b> |
|--|--------------------|-------------------|
| First Quarter (Jan. 1 – Mar. 31)           | \$5.30             | \$3.75            |
| Second Quarter (Apr. 1 – Jun. 30)          | \$4.30             | \$2.81            |
| Third Quarter (Jul. 1 – Sept. 30)          | \$5.25             | \$2.90            |
| Fourth Quarter (Oct. 1 – Dec. 31)          | \$4.78             | \$3.35            |
| <br>                                       |                    |                   |
| <b><u>Year Ended December 31, 2016</u></b> | <b><u>High</u></b> | <b><u>Low</u></b> |
| First Quarter (Jan. 1 – Mar. 31)           | \$4.43             | \$3.20            |
| Second Quarter (Apr. 1 – Jun. 30)          | \$4.19             | \$3.05            |
| Third Quarter (Jul. 1 – Sept. 30)          | \$5.86             | \$3.05            |
| Fourth Quarter (Oct. 1 – Dec. 31)          | \$5.39             | \$3.75            |

*Holder*s

As at March 10, 2017, an aggregate of 26,128,049 shares of our common stock were issued and outstanding and were owned by approximately 175 holders of record, based on information provided by our transfer agent.

*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***

See *Securities Authorized for Issuance Under Equity Compensation Plans* included under Part III, Item 12 of this report, which is incorporated by reference into this Item 5.

***Recent Sales of Unregistered Securities***

None.

***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*

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

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

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

We have developed thirty-nine blood-based assays to date to detect specific biomarkers that can be used individually or in combination to generate a profile which forms the basis of a product for a particular cancer or disease.

We 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 tested.

We intend to commercialize our products in the future through various channels within the European Union, the United States and throughout the rest of the world, most likely beginning with Asia.

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

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

Our first product the Nu.<sup>®</sup> Colorectal Cancer Screening Triage Test achieved the CE Mark in December 2016. We now plan to conduct pathway design studies (where appropriate) as we roll out to EU and other markets. We do not anticipate significant revenues in 2017.

### ***Liquidity and Capital Resources***

As of December 31, 2016, we had cash and cash equivalents of \$21,678,734 and prepayments and other current assets of \$332,814. As of December 31, 2016, we had current liabilities of \$2,033,496. This represents a working capital surplus of \$19,978,052.

For the year ended December 31, 2016, we used \$9,055,693 in net cash from operating activities, compared to \$8,546,274 for the year ended December 31, 2015. The increase in cash used year over year was primarily due to an increase in research and development expenditure and legal costs associated with multiple public offerings and other corporate matters. Please see *Results of Operations*, below for more detail.

Net cash used in investing activities increased year over year by \$282,896 to \$415,091 for the year ended December 31, 2016, mainly as a result of the purchase of a new building and land in Belgium. For further details, see Note 11(c) of the Consolidated Financial Statements.

Net cash provided by financing activities amounted to \$25,379,356 for the year ended December 31, 2016, compared to \$12,442,505 for the year ended December 31, 2015. In March 2016 we raised approximately \$13.1 million in net cash proceeds when approximately 4.3 million shares of common stock were issued in a public offering. In October 2016 we raised approximately \$11.8 million in net cash proceeds when approximately 2.5 million shares of common stock were issued in a public offering. We also raised approximately \$0.4 million from exercises of warrants and stock options for the year ended December 31, 2016. Repayments on a capital lease for a new building in Belgium resulted in approximately \$0.6 million of cash outflow over this period. This was offset by cash proceeds of \$0.5 million from debt financing on the aforementioned building in Belgium. This resulted in an increase of cash and cash equivalents of \$15,762,728 for the year ended December 31, 2016, compared to an increase of \$3,777,042 for the year ended December 31, 2015.

We currently lease three Tecan machines (automated liquid handling robots) under a lease classified as a capital lease. The total cost of this leased laboratory equipment is \$578,830 (€550,454). The capital lease is repayable over a five year period, ending in 2020.

On October 4, 2016, we entered into a capital lease agreement for the property located in the Créalys zoning at 5032 Isnes-Spy, Rue Phocas Lejeune 22, Gembloux cadastre, 8<sup>th</sup> division, Section B, n 55, Belgium. The lease agreement provided that we made the first lease payment of \$462,682 (€440,000), followed by quarterly lease payments of approximately \$14,143 (€13,450), based on a fixed rate of 2.62% for the term of the lease. The present value of the minimum lease payments on both capital leases is \$1,008,826 (€959,371).

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

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





**Results of Operations****Comparison of the Years Ended December 31, 2016 and December 31, 2015**

The following table sets forth our results of operations for the year ended on December 31, 2016 and the comparative period for the year ended December 31, 2015.

|   | Year<br>Ended<br>December 31,<br>2016<br>(\$) | Year<br>Ended<br>December 31,<br>2015<br>(\$) | Increase/<br>Decrease<br>(\$) | Percentage<br>Increase/<br>Decrease<br>(%) |
|---|---|---|-------------------------------|--|
| Revenues  | -   | -   | -                             | -  |
| General and administrative                                      | (741,655)                                     | (669,016)                                     | 72,639                        | 10.9%                                      |
| Professional fees   | (2,366,057)                                   | (1,606,259)                                   | 759,798                       | 47.3%                                      |
| Salaries & office administration fees                           | (2,321,376)                                   | (1,628,726)                                   | 692,650                       | 42.5%                                      |
| Research and development  | (6,837,515)                                   | (6,101,718)                                   | 735,797                       | 12.1%                                      |
| Total Operating Expenses  | (12,266,603)                                  | (10,005,719)                                  | 2,260,884                     | 22.6%                                      |
| Net Other Income  | 361,325                                       | 470,873                                       | (109,548)                     | (23.3%)                                    |
| Income Taxes  | -   | 4,604   | (4,604)                       | (100.0%)                                   |
| Net Loss  | (11,905,278)                                  | (9,530,242)                                   | 2,375,036                     | 24.9%                                      |
| Basic and Diluted Loss Per Common Share                         | (0.52)  | (0.54)  | 0.02                          | (4.3%)                                     |
| Weighted Average Basic and Diluted<br>Common Shares Outstanding | 23,049,089                                    | 17,731,809                                    | 5,317,280                     | 30.0%                                      |

**Revenues**

Our operations are still predominantly in the development stage.

**Operating Expenses**

Our total operating expenses increased by \$2,260,884, or 22.6%, in 2016 compared to 2015. Total expenses are comprised of general and administrative expenses, professional fees, salaries and administrative fees and research and development expenses.

### **General and administrative expenses**

Our general and administrative expenses increased \$72,639, or 10.9%, in 2016 compared to 2015. A large proportion of this increase is due to increased investor relations related travel and conference attendance expenses of \$27,320, alongside an increase in insurance costs of \$57,244.

### **Professional fees**

Our professional fees increased \$759,798, or 47.3%, in 2016 compared to 2015. During both years we incurred significant costs in relation to the multiple public offerings and other corporate matters. During 2016, there was (i) a decrease in legal and stock market listing fees of \$56,459, as the initial up-listing to NYSE MKT in 2015 was relatively more costly, (ii) an increase of marketing & branding services of \$369,824, to raise our profile, (iii) an increase of \$323,556 in accounting costs & consulting fees and (iv) an increase of \$71,029 for investor relations fees.

### **Salaries and office administration fees**

Our salaries and office administration fees increased \$692,650, or 42.5%, in 2016 compared to 2015. This is mainly explained by an increase in equity plan option and warrants amortization of \$184,312, alongside an increase in salaries and fees of \$395,713. There was additional compensation for our senior executives and the appointment of an additional director and additional senior officers in 2016.

### **Research and development**

Our research and development costs increased \$735,797, or 12.1%, in 2016 compared to 2015. The Hvidovre Hospital study has incurred additional costs of \$503,726, as a new CRC related study was initiated in 2016. Additional studies and research contracts increased costs by \$309,995. Antibody and sample costs decreased by \$209,384, due to the development and usage of antibodies varying year on year. An increase in equity plan option amortization costs and salaries for research and development resources of \$173,465 also contributed to the change.

### **Net other income**

We recognized net other income of \$361,325 in 2016, a decrease of 23.3%, compared to net other income of \$470,873 in 2015. In 2016, net other income consisted of \$361,325 in grant funds received from public bodies in respect of approved expenditures, where there is no obligation to repay. In 2015, net other income mainly consisted of \$146,812 in grant funds and a gain of \$339,744 on the re-measurement of a derivative liability.

### **Net Loss**

Our net loss increased \$2,375,036, or 24.9%, in 2016 compared to 2015. The change is a result of the factors described above.

### ***Going Concern***

We have not attained profitable operations and are dependent upon obtaining financing to pursue any extensive activities. For these reasons, the auditors stated in their report on the audited financial statements that they have

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

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

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

### ***Critical Accounting Policies***

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

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

### ***Contractual Obligations***

Not applicable.

*Recently Issued Accounting Pronouncements*

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

**ITEM 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, 2016 and 2015

|  |     |
|--|-----|
| Consolidated Balance Sheets                    | F-3 |
| Consolidated Statement of Operations           | F-4 |
| Consolidated Statement of Cash Flows           | F-5 |
| Consolidated Statement of Stockholders' Equity | F-7 |
| Notes to the Consolidated Financial Statements | F-8 |



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of

VolitionRx Limited

We have audited the accompanying consolidated balance sheets of VolitionRx Limited ( the Company ) as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders deficit, and cash flows for each of the years in the two year period ended December 31, 2016. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of VolitionRx Limited as of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered net losses

since inception and has accumulated a significant deficit. 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*/s/ Sadler, Gibb & Associates, LLC*

Salt Lake City, UT

March 9, 2017

**VOLITIONRX LIMITED**

## Consolidated Balance Sheets

(Expressed in United States Dollars, except share numbers)

|  | December 31,<br>2016 | December 31,<br>2015 |
|--|----------------------|----------------------|
|  | \$                   | \$                   |
| <b>ASSETS</b>                                |                      |                      |
| Cash and cash equivalents                    | 21,678,734           | 5,916,006            |
| Prepaid expenses                             | 165,927              | 152,926              |
| Other current assets                         | 166,887              | 153,723              |
| Total Current Assets                         | 22,011,548           | 6,222,655            |
| Property and equipment, net                  | 2,119,027            | 783,805              |
| Intangible assets, net                       | 602,193              | 705,381              |
| Total Assets                                 | 24,732,768           | 7,711,841            |
| <b>LIABILITIES</b>                           |                      |                      |
| Accounts payable                             | 281,179              | 323,513              |
| Accrued liabilities                          | 1,439,275            | 388,647              |
| Management and directors' fees payable       | 81,057               | 71,893               |
| Current portion of long-term debt            | 30,655               | -                    |
| Current portion of capital lease liabilities | 119,016              | 81,338               |
| Deferred grant income                        | 45,510               | 219,360              |
| Current portion of grant repayable           | 36,804               | 34,899               |
| Total Current Liabilities                    | 2,033,496            | 1,119,650            |
| Long-term debt                               | 432,027              | -                    |
| Capital lease liabilities                    | 889,810              | 299,863              |
| Grant repayable                              | 202,325              | 248,009              |
| Total Liabilities                            | 3,557,658            | 1,667,522            |
| <b>STOCKHOLDERS' EQUITY</b>                  |                      |                      |
| Common Stock                                 | 26,126               | 18,763               |

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

Edgar Filing: VOLITIONRX LTD - Form 10-K

Issued and outstanding: 26,126,049 shares and 18,763,272

shares respectively

|   |              |              |
|---|--------------|--------------|
| Additional paid-in capital                | 62,287,252   | 35,149,420   |
| Accumulated other comprehensive loss      | (193,297)    | (84,171)     |
| Accumulated Deficit                       | (40,944,971) | (29,039,693) |
| Total Stockholders Equity                 | 21,175,110   | 6,044,319    |
| Total Liabilities and Stockholders Equity | 24,732,768   | 7,711,841    |

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

F-3

---

**VOLITIONRX LIMITED**

## Consolidated Statements of Operations and Comprehensive Loss

(Expressed in United States Dollars, except share numbers)

|  | For the year ended<br>December 31,<br>2016<br>\$ | For the year ended<br>December 31,<br>2015<br>\$ |
|--|--|--|
| <b>Revenue</b>   | -  | -  |
| <b>Operating Expenses</b>                                    |  |  |
| General and administrative                                   | 741,655  | 669,016  |
| Professional fees  | 2,366,057  | 1,606,259  |
| Salaries and office administrative fees                      | 2,321,376  | 1,628,726  |
| Research and development                                     | 6,837,515  | 6,101,718  |
| <b>Total Operating Expenses</b>                              | 12,266,603                                       | 10,005,719                                       |
| <b>Net Operating Loss</b>                                    | (12,266,603)                                     | (10,005,719)                                     |
| <b>Other Income (Expenses)</b>                               |  |  |
| Grants received  | 361,325  | 146,812  |
| Other expenses   | -  | (15,683)   |
| Gain on derivative re-measurement                            | -  | 339,744  |
| <b>Net Other Income</b>                                      | 361,325  | 470,873  |
| <b>Provision for Income Taxes</b>                            | -  | 4,604  |
| <b>Net Loss</b>  | (11,905,278)                                     | (9,530,242)                                      |
| <b>Other Comprehensive (Loss) Gain</b>                       |  |  |
| Foreign currency translation adjustments                     | (109,126)  | 19,661   |
| <b>Total Other Comprehensive (Loss) Gain</b>                 | (109,126)  | 19,661   |
| <b>Net Comprehensive Loss</b>                                | (12,014,404)                                     | (9,510,581)                                      |
| <b>Net Loss per Share Basic and Diluted</b>                  | (0.52)   | (0.54)   |
| <b>Weighted Average Shares Outstanding Basic and Diluted</b> | 23,049,089                                       | 17,731,809                                       |

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

F-4

---

**VOLITIONRX LIMITED**

## Consolidated Statements of Cash Flows

(Expressed in United States Dollars)

|   | For the year ended<br>December 31,<br>2016<br>\$ | For the year ended<br>December 31,<br>2015<br>\$ |
|---|--|--|
| <b>Operating Activities</b>   |  |  |
| Net loss  | (11,905,278)                                     | (9,530,242)                                      |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |  |
| Depreciation and amortization   | 309,406  | 236,340  |
| Loss on disposal of property & equipment                                    | 3,668  | -  |
| Stock based compensation  | 1,678,748  | 1,493,334  |
| Common stock and warrants issued for services                               | 164,173  | (42,131)   |
| Non-operating income grants received  | (361,325)  | (146,812)  |
| Gain on derivative re-measurement   | -  | (339,744)  |
| Changes in operating assets and liabilities:                                |  |  |
| Prepaid expenses  | (13,168)   | (12,687)   |
| Other current assets  | (22,859)   | (108,603)  |
| Accounts payable and accrued liabilities                                    | 1,090,942  | (95,729)   |
| Net Cash Used In Operating Activities                                       | (9,055,693)                                      | (8,546,274)                                      |
| <b>Investing Activities</b>   |  |  |
| Purchases of property and equipment   | (415,091)  | (77,195)   |
| Purchase of patents   | -  | (55,000)   |
| Net Cash Used in Investing Activities                                       | (415,091)  | (132,195)  |
| <b>Financing Activities</b>   |  |  |
| Net proceeds from issuance of common shares                                 | 25,302,274                                       | 12,497,621                                       |
| Proceeds from debt payable  | 474,769  | -  |
| Grants received   | 361,325  | 146,812  |
| Grants repaid   | (36,135)   | (33,174)   |
| Deferred grant income   | (170,343)  | 48,191   |
| Payments on capital lease obligations                                       | (552,534)  | (216,945)  |
| Net Cash Provided By Financing Activities                                   | 25,379,356                                       | 12,442,505                                       |

Edgar Filing: VOLITIONRX LTD - Form 10-K

|   |            |           |
|---|------------|-----------|
| Effect of foreign exchange on cash and cash equivalents | (145,844)  | 13,006    |
| Increase in cash and cash equivalents                   | 15,762,728 | 3,777,042 |
| Cash and cash equivalents    Beginning of Period        | 5,916,006  | 2,138,964 |
| Cash and cash equivalents    End of Period              | 21,678,734 | 5,916,006 |

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

F-5

---



**VOLITIONRX LIMITED**

Consolidated Statements of Cash Flows (Continued)

(Expressed in United States Dollars)

Supplemental Disclosures of Cash Flow Information:

|                 |        |       |
|-----------------|--------|-------|
| Interest paid   | 20,378 | 7,326 |
| Income tax paid | -      | -     |

Non Cash Financing Activities:

|  |           |           |
|--|-----------|-----------|
| Common stock issued on cashless exercises of stock options | 54        | 33        |
| Reduction in derivative liability                          | -         | 1,237,896 |
| Capital lease obligation for equipment purchases           | 1,008,826 | 381,201   |

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

**VOLITIONRX LIMITED**

## Consolidated Statement of Stockholders Equity

For the Years Ended December 31, 2016 and 2015

(Expressed in United States Dollars)

|  | Common Stock |                | Additional<br>Paid-in | Other<br>Comprehensive | Accumulated     | Total       |
|--|--------------|----------------|-----------------------|------------------------|-----------------|-------------|
|  | Shares       | Amount<br>(\$) | Capital<br>(\$)       | Loss<br>(\$)           | Deficit<br>(\$) |             |
| Balance, December 31, 2014                                 | 14,691,332   | 14,691         | 19,966,771            | (103,832)              | (19,509,451)    | 368,179     |
| Common stock issued for cash, net of issuance costs        | 4,038,883    | 4,039          | 12,493,583            | -                      | -               | 12,497,622  |
| Common stock issued for cashless exercise of stock options | 33,057       | 33             | (33)                  | -                      | -               | -           |
| Employee stock options granted for services                | -            | -              | 1,493,334             | -                      | -               | 1,493,334   |
| Change in derivative liability                             | -            | -              | 1,237,896             | -                      | -               | 1,237,896   |
| Re-measurement of warrants                                 | -            | -              | (42,131)              | -                      | -               | (42,131)    |
| Other comprehensive income                                 | -            | -              | -                     | 19,661                 | -               | 19,661      |
| Net loss for the year                                      | -            | -              | -                     | -                      | (9,530,242)     | (9,530,242) |
| Balance, December 31, 2015                                 | 18,763,272   | 18,763         | 35,149,420            | (84,171)               | (29,039,693)    | 6,044,319   |
| Common stock issued for cash, net of issuance costs        | 7,309,120    | 7,309          | 25,294,965            | -                      | -               | 25,302,274  |
| Common stock issued for cashless exercise of stock options | 53,657       | 54             | (54)                  | -                      | -               | -           |
| Employee stock options granted for services                | -            | -              | 1,678,748             | -                      | -               | 1,678,748   |
| Warrants granted for services                              | -            | -              | 164,173               | -                      | -               | 164,173     |

Edgar Filing: VOLITIONRX LTD - Form 10-K

|                            |            |        |            |           |              |              |
|----------------------------|------------|--------|------------|-----------|--------------|--------------|
| Other comprehensive income | -          | -      | -          | (109,126) | -            | (109,126)    |
| Net loss for the year      | -          | -      | -          | -         | (11,905,278) | (11,905,278) |
| Balance, December 31, 2016 | 26,126,049 | 26,126 | 62,287,252 | (193,297) | (40,944,971) | 21,175,110   |

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

F-7

---

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 1 Nature of Operations**

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

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

The Company's principal business objective through its subsidiaries is to develop and bring to market simple, easy to use blood-based cancer tests to accurately diagnose a range of cancers. The tests are based on the science of Nucleosomics®, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid – an indication that disease is present. The Company has one wholly-owned subsidiary, Singapore Volition, which it acquired through a share exchange entered into on October 6, 2011. Singapore Volition has two wholly owned subsidiaries, Belgian Volition SPRL, a Belgium private limited liability company ( Belgian Volition ), which it acquired as of September 22, 2010, and Hypergenomics Pte Limited ( Hypergenomics ), which it formed as of March 7, 2011. Belgian Volition, has two wholly owned subsidiaries, Volition Diagnostics UK Limited, which it formed as of November 13, 2015 and Volition America, Inc., which it formed as of February 3, 2017 (see Note 11 to Consolidated Financial Statements). Following the acquisition of Singapore Volition the Company's fiscal year end was changed from August 31 to December 31. The financial statements are prepared on a consolidated basis.

**Note 2 - Going Concern**

The Company's financial statements are prepared using generally accepted accounting principles 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 \$40,944,971, has negative cash flows from operations, and currently no revenues, which creates substantial doubt about its ability to continue as a going concern.

The future of the Company as an operating business will depend on its ability to obtain sufficient capital contributions and/or financings as may be required to sustain its operations. Management's plan to address these needs includes: (a) continued exercise of tight cost controls to conserve cash, (b) receiving additional grant funds, and (c) obtaining additional financing through debt or equity financing.

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

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

#### Basis of Presentation

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

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ 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.

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, 2016 include the accounts of the Company and its wholly-owned subsidiaries, Singapore Volition, Belgian Volition, Hypergenomics 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, 2016 and December 31, 2015, the Company had \$21,678,734 and \$5,916,006, respectively in cash and cash equivalents. At December 31, 2016 and December 31, 2015, the Company had approximately \$17,154,377 and \$762,187 in its domestic accounts in excess of Federal Deposit Insurance Corporation insured limits, respectively. At December 31, 2016 and December 31, 2015, the Company had approximately \$2,401,894 and \$395,100 in its foreign accounts in excess of the Belgian Deposit Guarantee insured limits, respectively. At December 31, 2016 and December 31, 2015, the Company had approximately \$1,719,937 and \$4,338,088 in its foreign accounts in excess of the Singapore Deposit Insurance Scheme, respectively. At December 31, 2016 and December 31, 2015, the Company had \$nil and \$nil, 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, 2016, 2,548,666 dilutive warrants and options were excluded from the Diluted EPS calculation as their effect is anti-dilutive. As of December 31, 2015, 2,257,809 dilutive 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 or settlement of foreign currency denominated transactions or balances are included in other comprehensive loss.

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ 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 receivable, accounts payable, accrued liabilities, notes payable, 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 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.

### Comprehensive Loss

ASC 220, *Comprehensive Loss*, establishes standards for the reporting and display of comprehensive loss and its components in the financial statements. At December 31, 2016, the Company had \$193,297 of accumulated other comprehensive loss, relating to foreign currency translation.

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 3 - Summary of Significant Accounting Policies (Continued)**

Property and Equipment

Property and equipment is stated at cost and is amortized on a straight-line basis over the assets' estimated useful life, at the following rates:

|  |               |
|--|---------------|
| Computer equipment and computer software | 3 years       |
| Laboratory equipment                     | 5 years       |
| Equipment held under capital lease       | 5 years       |
| Office furniture and equipment           | 5 years       |
| Buildings                                | 30 years      |
| Land                                     | Not amortized |

At December 31, 2016, the asset held under the Buildings category had not been amortized, as the asset had not been placed into service. Occupation of the building is expected to occur in March 2017. See Note 10(c), for additional details of the purchase of the building.

Intangible Assets

Intangible assets are stated at cost and are amortized on a straight line basis, at the following rates:

|                                   |                     |
|-----------------------------------|---------------------|
| Patents and Intellectual Property | 8 years to 20 years |
|-----------------------------------|---------------------|

Revenue Recognition

The Company recognizes revenue when all of the following have occurred (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable and (iv) the ability to collect is reasonably assured.

#### 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 \$6,837,515 and \$6,101,718 during the years ended December 31, 2016 and 2015, respectively.

#### 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 (€nil) and \$nil (€nil) were recognized during the years ended December 31, 2016 and December 31, 2015, respectively.

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 3 - Summary of Significant Accounting Policies (Continued)**

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

Recent Accounting Pronouncements

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

**Note 4 - Property and Equipment**

The Company's property and equipment consist of the following amounts as of December 31, 2016 and 2015:

|  | Cost      | Accumulated<br>Depreciation | December 31,<br>2016<br>Net Carrying<br>Value |
|--|-----------|-----------------------------|---|
|  | \$        | \$                          | \$  |
| Computer equipment and computer software | 157,002   | 68,229                      | 88,773  |
| Laboratory equipment                     | 313,655   | 151,541                     | 162,114                                       |
| Equipment held under capital lease       | 578,830   | 183,296                     | 395,534                                       |
| Office furniture and equipment           | 32,932    | 23,361                      | 9,571   |
| Buildings                                | 1,378,911 | -                           | 1,378,911                                     |
| Land                                     | 84,124    | -                           | 84,124  |
|  | 2,545,454 | 426,427                     | 2,119,027                                     |

**VOLITIONRX LIMITED****Notes to Consolidated Financial Statements (Continued)****For Years Ended December 31, 2016 and 2015****(\$ expressed in United States Dollars)****Note 4 - Property and Equipment (Continued)**

|  | Cost      | Accumulated<br>Depreciation | December 31,<br>2015<br>Net Carrying<br>Value |
|--|-----------|-----------------------------|---|
|  | \$        | \$                          | \$  |
| Computer equipment and computer software | 72,317    | 45,731                      | 26,586  |
| Laboratory equipment                     | 319,209   | 108,589                     | 210,620                                       |
| Equipment held under capital lease       | 600,325   | 70,038                      | 530,287                                       |
| Office furniture and equipment           | 34,155    | 17,843                      | 16,312  |
| Buildings                                | -         | -                           | -   |
| Land                                     | -         | -                           | -   |
|  | 1,026,006 | 242,201                     | 783,805                                       |

On April 8, 2015 the Company entered into a five year capital lease to purchase three Tecan machines (automated liquid handling robots) for a total sum of \$578,830 (€550,454).

Effective, October 25, 2016 the Company entered into a Real Estate Capital Lease Agreement to purchase real property for a total sum of \$1,177,736 (€1,120,000). See Note 10(c), for additional details of the building purchase and the capital lease.

During the years ended December 31, 2016 and 2015, the Company recognized \$222,944 and \$150,439 in depreciation expense respectively.



**VOLITIONRX LIMITED****Notes to Consolidated Financial Statements (Continued)****For Years Ended December 31, 2016 and 2015**

(\$ expressed in United States Dollars)

**Note 5 - Intangible Assets**

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

|         | Cost<br>\$ | Accumulated<br>Amortization<br>\$ | December 31,<br>2016<br>Net Carrying<br>Value<br>\$ |
|---------|------------|-----------------------------------|---|
| Patents | 1,085,133  | 482,940                           | 602,193   |
|         | 1,085,133  | 482,940                           | 602,193   |
|         | Cost<br>\$ | Accumulated<br>Amortization<br>\$ | December 31,<br>2015<br>Net Carrying<br>Value<br>\$ |
| Patents | 1,119,302  | 413,921                           | 705,381   |
|         | 1,119,302  | 413,921                           | 705,381   |

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



During the years ended December 31, 2016 and 2015, the Company recognized \$86,462 and \$85,901 in amortization expense respectively. No impairment losses were recognized during the years ended December 31, 2015 and December 31, 2016.

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

|      |           |
|------|-----------|
| 2017 | \$ 82,750 |
| 2018 | \$ 82,750 |
| 2019 | \$ 82,750 |
| 2020 | \$ 82,750 |
| 2021 | \$ 82,750 |

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, 2016. The result of this review confirmed that the fair value of the patents exceeded their carrying value as of December 31, 2016.

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 6 - Related Party Transactions**

The Company has an agreement with a related party for consultancy services for a Company subsidiary.

See Note 10 for obligations under the agreement. The Company issued shares of common stock to related parties upon the exercise of warrants and stock options. See Note 7 for details regarding such issuances.

**Note 7 - Common Stock**

On October 7, 2016, the Company held its annual meeting of stockholders. At the annual meeting, among other things, the Company's stockholders approved the Second Amended and Restated Certificate of Incorporation (the Restated Certificate), eliminating all provisions relating to preferred stock, par value \$0.001. The Restated Certificate had previously been approved by the Board of Directors of the Company on August 5, 2016, subject to the approval of the Company's stockholders. The Restated Certificate, including the elimination of all provisions relating to preferred stock, became effective upon its filing with the Secretary of State of the State of Delaware on October 7, 2016.

**2016**

On January 15, 2016, warrants to purchase 100,000 shares of common stock were exercised at a price of \$0.50 per share, for net cash proceeds to the Company of \$50,000.

On March 22, 2016, 100,000 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$50,000. As a result, a total of 100,000 shares of common stock were issued.

Edgar Filing: VOLITIONRX LTD - Form 10-K

On March 23, 2016, the Company issued 4,334,615 shares of common stock at a price of \$3.25 per share, for net cash proceeds of approximately \$13.1 million. Additionally, \$0.3 million was incurred on legal expenses and stock market listing fees, giving net proceeds of \$12.8 million.

On March 29, 2016, 100,000 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$50,000. As a result, a total of 100,000 shares of common stock were issued.

On April 20, 2016, 2,601 warrants were exercised at a price of \$2.60 per share, for net cash proceeds of \$6,763. As a result, a total of 2,601 shares of common stock were issued.

On May 20, 2016, stock options were exercised to purchase 88,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 13,419 shares of common stock.

On May 24, 2016, stock options were exercised to purchase 8,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,122 shares of common stock.

On May 25, 2016, stock options were exercised to purchase 9,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,011 shares of common stock.

On June 10, 2016, 5,484 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$2,742. As a result, a total of 5,484 shares of common stock were issued.

On June 14, 2016, 94,516 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$47,258. As a result, a total of 94,516 shares of common stock were issued.

On June 16, 2016, stock options were exercised to purchase 29,000 shares of our common stock at \$2.50 to \$3.00 per share in cashless exercises that resulted in the issuance of 5,179 shares of common stock.

On September 21, 2016, 12,500 warrants were exercised at a price of \$2.20 per share, for net cash proceeds of \$27,500. As a result, a total of 12,500 shares of common stock were issued.



**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 7 - Common Stock (Continued)**

On September 28, 2016, warrants to purchase 75,000 shares of common stock were exercised at a price of \$2.20 per share, for net cash proceeds to the Company of \$165,000. As a result, a total of 75,000 shares of common stock were issued.

On October 5, 2016, the Company issued 2,250,000 shares of common stock at a price of \$5.00 per share, for net cash proceeds of approximately \$10.7 million. Additionally, \$0.1 million was expensed on further legal expenses and stock market listing fees, giving net proceeds of approximately \$10.6 million.

On October 21, 2016, the Company issued 234,404 shares of common stock at a price of \$5.00 per share, for net cash proceeds of approximately \$1.1 million.

On November 11, 2016, stock options were exercised to purchase 4,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,209 shares of common stock.

On November 18, 2016, stock options were exercised to purchase 55,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 18,168 shares of common stock.

On November 22, 2016, stock options were exercised to purchase 5,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,551 shares of common stock.

On November 25, 2016, stock options were exercised to purchase 37,000 shares of our common stock at \$3.00 per share in cashless exercise that resulted in the issuance of 11,998 shares of common stock.

**2015**

On February 6, 2015, the Company issued 2,475,000 shares of common stock at a price of \$3.75 per share, for net cash proceeds of approximately \$8.5 million. Additionally, \$0.3 million was expensed on further legal expenses and stock market listing fees, giving net proceeds of approximately \$8.2 million.

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

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

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

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

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

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

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

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



**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 7 - Common Stock (Continued)**

On November 18, 2015, stock options were exercised to purchase 20,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 4,810 shares of common stock.

On December 1, 2015, 8,000 warrants were exercised at a price of \$2.40 per share, for net cash proceeds of \$19,200. As a result, a total of 8,000 shares of common stock were issued.

On December 2, 2015, stock options were exercised to purchase 50,000 shares of our common stock at \$3.01 per share in cashless exercises that resulted in the issuance of 14,081 shares of common stock.

On December 9, 2015, stock options were exercised to purchase 50,000 shares of our common stock at \$3.01 per share in cashless exercises that resulted in the issuance of 14,166 shares of common stock.

On December 14, 2015, 250,000 warrants were exercised at a price of \$1.05 per share, for net cash proceeds of \$262,500. As a result, a total of 250,000 shares of common stock were issued.

**Note 8 Warrants and Options**

a)

**Warrants**



**2016**

The following table summarizes the changes in warrants outstanding of the Company during the year ended December 31, 2016:

|                                | <b>Number of Warrants</b> | <b>Weighted Average<br/>Exercise Price (\$)</b> |
|--------------------------------|---------------------------|---|
| Outstanding, December 31, 2015 | 2,612,739                 | 2.07  |
| Granted                        | 40,000                    | 4.53  |
| Exercised                      | (490,101)                 | 0.81  |
| Expired                        | -                         | -   |
| Outstanding, December 31, 2016 | 2,162,638                 | 2.40  |
| Exercisable, December 31, 2016 | 2,012,638                 | 2.39  |

On January 15, 2016, warrants to purchase 100,000 shares of common stock were exercised at a price of \$0.50 per share, for net cash proceeds to the Company of \$50,000.

On March 22, 2016, 100,000 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$50,000. As a result, a total of 100,000 shares of common stock were issued.

On March 29, 2016, 100,000 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$50,000. As a result, a total of 100,000 shares of common stock were issued.

On April 20, 2016, 2,601 warrants were exercised at a price of \$2.60 per share, for net cash proceeds of \$6,763. As a result, a total of 2,601 shares of common stock were issued.

Effective May 4, 2016, the Company amended the expiry period of warrants to purchase 341,458 shares, originally granted on May 11, 2012, with an exercise price of \$2.60. The expiration period was extended from May 10, 2016 to May 10, 2017 for all 341,458 stock options.



**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 8 Warrants and Options (Continued)**

On June 10, 2016, 5,484 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$2,742. As a result, a total of 5,484 shares of common stock were issued.

On June 14, 2016, 94,516 warrants were exercised at a price of \$0.50 per share, for net cash proceeds of \$47,258. As a result, a total of 94,516 shares of common stock were issued.

Effective July 11, 2016, the Company amended the expiry period of warrants to purchase 45,000 shares, originally granted on August 7, 2013, with an exercise price of \$2.40. The expiration period was extended from August 7, 2016 to August 7, 2017 for all 45,000 stock options.

On September 21, 2016, 12,500 warrants were exercised at a price of \$2.20 per share, for net cash proceeds of \$27,500. As a result, a total of 12,500 shares of common stock were issued.

On September 28, 2016, 75,000 warrants were exercised at a price of \$0.50 per shares, for net cash proceeds of \$165,000. As a result, a total of 75,000 shares of common stock were issued.

On November 14, 2016, the Company granted warrants to purchase 40,000 shares of common stock at an exercise price of \$4.53 per share. These warrants vested on the date of grant and expire four years from the date of vesting. The Company has calculated the estimated fair market value of these warrants at \$101,830, using the Black-Scholes Option Pricing model and the following assumptions: term: four years, stock price: \$4.28, exercise price: \$4.53, 82.9% volatility, 1.7% risk free rate.

**2015**

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

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

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

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

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

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

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

On December 1, 2015, 8,000 warrants were exercised at a price of \$2.40 per share, for net cash proceeds of \$19,200. As a result, a total of 8,000 shares of common stock were issued.

On December 14, 2015, 250,000 warrants were exercised at a price of \$1.05 per share, for net cash proceeds of \$262,500. As a result, a total of 250,000 shares of common stock were issued.

## VOLITIONRX LIMITED

## Notes to Consolidated Financial Statements (Continued)

For Years Ended December 31, 2016 and 2015

(\$ expressed in United States Dollars)

## Note 8 Warrants and Options (Continued)

Below is a table summarizing the warrants issued and outstanding as of December 31, 2016, which have a weighted average exercise price of \$2.40 per share and a weighted average remaining contractual life of 1.90 years.

| Date     | Number           | Number           | Exercise   | Contractual  | Weighted<br>Average<br>Remaining<br>Contractual<br>Life | Expiration              | Proceeds to<br>Company if |
|----------|------------------|------------------|------------|--------------|---|-------------------------|---------------------------|
| Issued   | Outstanding      | Exercisable      | Price (\$) | Life (Years) | (Years)   | Date                    | Exercised (\$)            |
| 05/11/12 | 341,458          | 341,458          | 2.60       | 5.0          | 0.06  | 05/10/17                | 887,791                   |
| 03/20/13 | 150,000          | -                | 2.47       | 3.0 to 6.5   | 0.28  | 03/20/16<br>to 12/20/19 | 370,500                   |
| 06/10/13 | 29,750           | 29,750           | 2.00       | 5.0          | 0.02  | 06/10/18                | 59,500                    |
| 08/07/13 | 45,000           | 45,000           | 2.40       | 4.0          | 0.01  | 08/07/17                | 108,000                   |
| 11/25/13 | 456,063          | 456,063          | 2.40       | 5.0          | 0.40  | 11/25/18                | 1,094,551                 |
| 12/31/13 | 64,392           | 64,392           | 2.40       | 5.0          | 0.06  | 12/31/18                | 154,541                   |
| 01/28/14 | 2,000            | 2,000            | 2.40       | 3.0          | 0.00  | 01/28/17                | 4,800                     |
| 02/26/14 | 980,975          | 980,975          | 2.20       | 5.0          | 0.98  | 02/26/19                | 2,158,145                 |
| 09/05/14 | 10,000           | 10,000           | 2.40       | 3.0          | 0.00  | 09/05/17                | 24,000                    |
| 09/26/14 | 24,000           | 24,000           | 3.00       | 3.0          | 0.01  | 09/26/17                | 72,000                    |
| 11/17/14 | 19,000           | 19,000           | 3.75       | 3.0          | 0.01  | 11/17/17                | 71,250                    |
| 11/14/16 | 40,000           | 40,000           | 4.53       | 4.0          | 0.07  | 11/14/20                | 181,200                   |
|          | <b>2,162,638</b> | <b>2,012,638</b> |            |              | <b>1.90</b>   |                         | <b>5,186,278</b>          |



**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ 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 Stock Incentive Plan (as amended, the 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. 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, 2016:

| <b>Number of Options</b> | <b>Weighted Average</b> |
|--------------------------|-------------------------|
|--------------------------|-------------------------|

|                                |           | <b>Exercise Price (\$)</b> |
|--------------------------------|-----------|----------------------------|
| Outstanding, December 31, 2015 | 1,830,300 | 3.53                       |
| Granted                        | 825,000   | 4.03                       |
| Exercised                      | (235,000) | 2.97                       |
| Expired                        | (36,000)  | 4.31                       |
| Outstanding, December 31, 2016 | 2,384,300 | 3.75                       |
| Exercisable, December 31, 2016 | 1,565,133 | 3.60                       |

## 2016

On March 1, 2016, stock options to purchase 5,000 shares of common stock expired unexercised.

On April 15, 2016, the Company granted options to purchase 775,000 shares, at an exercise price of \$4.00 per share, pursuant to the 2015 Stock Incentive Plan ( 2015 Plan ). These options vest in full twelve months from the date of grant and expire five years from the date of vesting. The Company has calculated the estimated fair market value of these options at \$2,035,060, using the Black-Scholes Option Pricing model and the following assumptions: term 6 years, stock price \$3.75, exercise price \$4.00, 84.4% volatility, 1.22% risk free rate.

On May 20, 2016, stock options were exercised to purchase 88,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 13,419 shares of common stock.

On May 24, 2016, stock options were exercised to purchase 8,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,122 shares of common stock.

On May 25, 2016, stock options were exercised to purchase 9,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,011 shares of common stock.

On June 16, 2016, stock options were exercised to purchase 29,000 shares of our common stock at \$2.50 to \$3.00 per share in cashless exercises that resulted in the issuance of 5,179 shares of common stock.



**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 8 Warrants and Options (Continued)**

On June 23, 2016, the Company granted options to purchase 15,000 shares, at an exercise price of \$4.00 per share, pursuant to the 2015 Plan. The options will vest in full twelve months from the date of grant and will expire five years from the date of vesting. The Company has calculated the estimated fair market value of these options at \$33,938, using the Black-Scholes Option Pricing model and the following assumptions: term 6 years, stock price \$3.35, exercise price \$4.00, 83.11% volatility, 1.25% risk free rate.

Effective June 27, 2016, the Company amended the expiry period of 37,000 options, originally granted pursuant to Stock Option Agreements dated March 20, 2013, with an exercise price of \$2.35 to \$4.35 per share. The expiration period was extended from three to four years from the date of vesting for all 37,000 stock options. The result was deemed to be immaterially different to the original calculation and the financial statements were not adjusted.

Effective June 27, 2016, the Company amended the expiry period of 16,300 options, originally granted on pursuant to Stock Option Agreements dated September 2, 2013, with an exercise price of \$2.35 to \$4.35 per share. The expiration period was extended from three to four years from the date of vesting for all 16,300 stock options. The result was deemed to be immaterially different to the original calculation and the financial statements were not adjusted.

On June 30, 2016, stock options to purchase 26,000 shares of common stock expired unexercised.

On September 1, 2016, stock options to purchase 5,000 shares of common stock expired unexercised.

On September 13, 2016, the Company granted options to purchase 25,000 shares, at an exercise price of \$4.65 per share, pursuant to the 2015 Plan. The options will vest in full twelve months from the date of grant and will expire five years from the date of vesting. The Company has calculated the estimated fair market value of these options at \$81,274, using the Black-Scholes Option Pricing model and the following assumptions: term 6 years, stock price \$4.65, exercise price \$4.65, 81.94% volatility, 1.56% risk free rate.

On October 7, 2016, the 2015 Plan was amended to increase the number of shares available for issuance under such plan by 750,000 shares, to an aggregate of 1,750,000 shares.

On November 11, 2016, the Company granted options to purchase 10,000 shares. These options vest immediately and expire six years after the vesting date, with an exercise price of \$5.00 per share. The Company has calculated the estimated fair market value of these options at \$29,019, using the Black-Scholes Option Pricing model and the following assumptions: term 6.0 years, stock price \$4.30, exercise price \$5.00, 81.3% volatility, 1.92% risk free rate.

On November 11, 2016, stock options were exercised to purchase 4,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,209 shares of common stock.

On November 18, 2016, stock options were exercised to purchase 55,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 18,168 shares of common stock.

On November 22, 2016, stock options were exercised to purchase 5,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 1,551 shares of common stock.

On November 25, 2016, stock options were exercised to purchase 37,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 11,998 shares of common stock.

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 8 Warrants and Options (Continued)**

**2015**

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

On May 18, 2015, the Company amended the expiry period of 630,000 stock options, originally granted on November 25, 2011. The expiration period was extended from three to four years for all 630,000 stock options. As a result, an additional \$20,796 of stock option amortization was realized in 2015.

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

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

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

On August 17, 2015, stock options to purchase 40,000 shares of common stock expired unexercised.

On October 30, 2015, the Company adopted and approved the 2015 Plan for the directors, officers, employees and consultants to the Company. Pursuant to the Plan, the Company is authorized to issue 1,000,000 shares of the Company's common stock. All options granted after December 31, 2015 were from the 2015 Stock Incentive Plan.

On November 18, 2015, stock options were exercised to purchase 20,000 shares of our common stock at \$3.00 per share in cashless exercises that resulted in the issuance of 4,810 shares of common stock.

**VOLITIONRX LIMITED****Notes to Consolidated Financial Statements (Continued)****For Years Ended December 31, 2016 and 2015****(\$ expressed in United States Dollars)****Note 8 Warrants and Options (Continued)**

On December 2, 2015, stock options were exercised to purchase 50,000 shares of our common stock at \$3.01 per share in cashless exercises that resulted in the issuance of 14,081 shares of common stock to a related party.

On December 9, 2015, stock options were exercised to purchase 50,000 shares of our common stock at \$3.01 per share in cashless exercises that resulted in the issuance of 14,166 shares of common stock to a related party.

Below is a table summarizing the options issued and outstanding as of December 31, 2016, all of which were issued pursuant to the 2011 Equity Incentive Plan ( 2011 Plan ) (for option issuances prior to 2016) or the 2015 Plan (for option issuances commencing in 2016) which have a weighted average exercise price of \$3.75 per share and a weighted average remaining contractual life of 3.37 years.

| Date     | Number      | Number      | Exercise   | Contractual | Weighted     | Expiration        | Proceeds to    |
|----------|-------------|-------------|------------|-------------|--------------|-------------------|----------------|
| Issued   | Outstanding | Exercisable | Price (\$) | Life        | Average      | Date              | Company if     |
|          |             |             |            | (Years)     | Remaining    |                   | Exercised (\$) |
|          |             |             |            |             | Contractual  |                   |                |
|          |             |             |            |             | Life (Years) |                   |                |
| 11/25/11 | 404,000     | 404,000     | 4.00-5.00  | 5.5-7.0     | 0.19         | 05/25/17-11/25/18 | 1,818,000      |
| 09/01/12 | 20,000      | 20,000      | 5.31-6.31  | 4.5-6.0     | 0.01         | 03/01/17-09/01/18 | 116,200        |
| 03/20/13 | 37,000      | 37,000      | 2.35-4.35  | 4.5-7.0     | 0.03         | 09/20/17-03/20/20 | 123,950        |
| 09/02/13 | 16,300      | 16,300      | 2.35-4.35  | 4.5-7.0     | 0.02         | 03/02/18-09/02/20 | 54,605         |
| 05/16/14 | 25,000      | 20,833      | 3.00-5.00  | 3.5-6.0     | 0.02         | 11/16/17-05/16/20 | 100,000        |
|          |             |             | 2.50 and   |             |              |                   |                |
| 08/18/14 | 645,000     | 645,000     | 3.00       | 4.5 and 5.5 | 0.72         | 02/18/19-02/18/20 | 1,773,750      |
| 05/18/15 | 20,000      | 20,000      | 3.80       | 4.5         | 0.02         | 11/18/19          | 76,000         |
| 07/23/15 | 317,000     | 317,000     | 4.00       | 4.5         | 0.42         | 01/23/20          | 1,268,000      |

Edgar Filing: VOLITIONRX LTD - Form 10-K

|          |                  |                  |      |     |             |          |                  |
|----------|------------------|------------------|------|-----|-------------|----------|------------------|
| 08/17/15 | 75,000           | 75,000           | 3.75 | 5.0 | 0.11        | 08/17/20 | 281,250          |
| 04/15/16 | 775,000          | -                | 4.00 | 6.0 | 1.72        | 04/15/22 | 3,100,000        |
| 06/23/16 | 15,000           | -                | 4.00 | 6.0 | 0.03        | 06/23/22 | 60,000           |
| 09/13/16 | 25,000           | -                | 4.65 | 6.0 | 0.06        | 09/13/22 | 116,250          |
| 11/11/16 | 10,000           | 10,000           | 5.00 | 6.0 | 0.02        | 11/11/22 | 50,000           |
|          | <b>2,384,300</b> | <b>1,565,133</b> |      |     | <b>3.37</b> |          | <b>8,938,005</b> |

Stock option expense of \$1,678,748 and \$1,493,334 was recorded in the years ended December 31, 2016 and December 31, 2015, respectively. Total remaining unrecognized compensation cost related to unvested stock options is approximately \$659,639 and is expected to be recognized over a period of 0.75 years.

**VOLITIONRX LIMITED****Notes to Consolidated Financial Statements (Continued)****For Years Ended December 31, 2016 and 2015**

(\$ expressed in United States Dollars)

**Note 9 - Income Taxes**

The Company has estimated net operating losses for the years ended December 31, 2016 and 2015 of \$11,000,471 and \$8,774,691, respectively, available to offset taxable income in future years.

The Company is subject to Singapore income taxes at a rate of 17 percent, Belgium income taxes at a rate of 34 percent, UK taxes at a rate of 20 percent and U.S. taxes at a rate of 35 percent, for a weighted average of 28 and 26 percent, respectively. The reconciliation of the provision for income taxes at the weighted average rate compared to the Company's income tax expense as reported is as follows:

|                                       | 2016         | 2015        |
|---------------------------------------|--------------|-------------|
|                                       | \$           | \$          |
| Net loss                              | (11,905,278) | (9,530,242) |
| Tax adjustments                       | 904,807      | 755,551     |
| Estimated net operating losses        | (11,000,471) | (8,774,691) |
| Tax rate                              | 28%          | 26%         |
| Income tax recovery at statutory rate | (3,061,493)  | (2,306,549) |
| Valuation allowance                   | 3,061,493    | 2,306,549   |
| Refund received re previous tax year  | -            | (4,604)     |
| Provision for income taxes            | -            | 4,604       |

The significant components of deferred income taxes and assets as at December 31, 2016 are as follows:

| 2016 | 2015 |
|------|------|
| \$   | \$   |

|                                      |             |             |
|--------------------------------------|-------------|-------------|
| Net operating losses carried forward | 8,806,016   | 5,792,392   |
| Valuation allowance                  | (8,806,016) | (5,792,392) |
| Net deferred income tax asset        | -           | -           |

## Note 10 Commitments and Contingencies

a)

### Walloon Region Grant

On March 16, 2010, the Company entered into an agreement with the Walloon Region government in Belgium wherein the Walloon Region would fund up to a maximum of \$1,102,045 (€1,048,020) to help fund the research endeavors of the Company in the area of CRC. The Company had received the entirety of these funds in respect of approved expenditures as of March 31, 2014. Under the terms of the agreement, the Company is due to repay \$330,614 (€314,406) of this amount by installments over the period June 30, 2014 to June 30, 2023. The Company has recorded the balance of \$771,432 (€733,614) to other income as there is no obligation to repay this amount. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 6 percent royalty on such revenue to the Walloon Region. The maximum amount payable to the Walloon Region, in respect of the aggregate of the amount repayable of \$330,614 (€314,406) and the 6 percent royalty on revenue, is twice the amount of funding received. As at December 31, 2016, \$239,129 (€227,406) was outstanding to be repaid to the Walloon Region under this agreement.



**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 10 Commitments and Contingencies (Continued)**

b)

Consulting Agreement

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

c)

Lease Obligations Payable

The Company leases three Tecan machines (automated liquid handling robots) under a lease classified as a capital lease. The total cost of this leased laboratory equipment is \$578,830 (€550,454). The leased equipment is amortized on a straight line basis over five years. Total accumulated depreciation related to the leased equipment is \$183,296 (€174,310) for the year ended December 31, 2016 and \$70,038 (€64,220) for the year ended December 31, 2015.

On October 4, 2016, and effective on October 25, 2016, Belgian Volition entered into a Real Estate Capital Lease Agreement (the Capital Lease Agreement ) with ING Asset Finance Belgium S.A. ( ING ). The Capital Lease Agreement became a contractual obligation of Belgian Volition upon the execution of the Deed of Sale to acquire the Company's new research and development facility described below. Pursuant to the Capital Lease Agreement, ING paid \$1.18 million (€1.12 million) in return for Belgian Volition granting to ING a right of emphyteusis (a form of leasehold) on the property located in the Belgian Créalys zoning at 5032 Isnes-Spy, Rue Phocas Lejeune 22,

Gembloux cadastre, 8th division, Section B, n 55 (the Property ) for a period of 27 years, extendable to the authorized maximum legal term of 99 years. In addition, the Capital Lease Agreement provides that ING shall grant Belgian Volition a 15-year lease over the Property with an option for Belgian Volition to purchase the Property outright upon payment of \$35,332 (€33,600) at the end of the lease. The Capital Lease Agreement provides that Belgian Volition shall make the first lease payment of \$462,682 (€440,000) following the execution of the Capital Lease Agreement, and then quarterly lease payments of approximately \$14,143 (€13,450), based on a fixed rate of 2.62% for the term of the lease. On October 25, 2016, Belgian Volition acquired the Property by entering into a Deed of Sale to the Sale Agreement with Gerard Dekoninck S.A. The purchase price for the Property consisted of \$1.3 million (€1.2 million), exclusive of any closing costs (the “Purchase Price”). The Purchase Price was funded by Belgian Volition with cash on hand and the monies received under the Capital Lease Agreement. At December 31, 2016, the Property had not been amortized, as the asset had not been placed into service. Occupation of the Property is expected to occur in March 2017.

On October 25, 2016, Belgian Volition entered into an additional Capital Lease agreement with ING for an amount up to a maximum of \$283,919 (€270,000) to fund building improvements of the above Property. This additional Capital Lease provides for a 15-year term, with payments commencing on March 31, 2017, a fixed interest rate to be determined on March 31, 2017, with quarterly instalments, payable in advance and interest only payments on the amount drawn until March 31, 2017. The liability will take effect, upon receipt by ING of the first invoice for building improvements and will be drawn down in increments of at least \$31,547 (€30,000). At December 31, 2016, the liability had not yet taken effect.

**VOLITIONRX LIMITED****Notes to Consolidated Financial Statements (Continued)****For Years Ended December 31, 2016 and 2015****(\$ expressed in United States Dollars)****Note 10 – Commitments and Contingencies (Continued)**

The following is a schedule showing the future minimum lease payments under capital leases by years and the present value of the minimum payments as of December 31, 2016.

|  |           |                  |
|--|-----------|------------------|
| 2017   | \$        | 143,157          |
| 2018   | \$        | 143,156          |
| 2019   | \$        | 143,157          |
| 2020   | \$        | 98,429           |
| 2021   | \$        | 56,560           |
| Greater than 5 years                           | \$        | 586,786          |
| Total minimum lease payments                   | \$        | 1,171,245        |
| Less: Amount representing interest             | \$        | 162,419          |
| <b>Present value of minimum lease payments</b> | <b>\$</b> | <b>1,008,826</b> |

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

|              |           |                |
|--------------|-----------|----------------|
| 2017         | \$        | 189,610        |
| 2018         | \$        | 161,049        |
| Thereafter   | \$        | 61,088         |
| <b>Total</b> | <b>\$</b> | <b>411,747</b> |

d)

Bonn University Agreement

On July 11, 2012, the Company entered into a collaborative research agreement with Bonn University, Germany, relating to a program of samples testing. The agreement was for a period of two years from June 1, 2012 to May 31, 2014. The total payments made by the Company in accordance with the agreement were \$410,105 (€390,000). On April 16, 2014, the Company entered into a two-year extension of this agreement through May 31, 2016. The total payments made by the Company in accordance with the extension of the agreement were \$410,105 (€390,000). On May 25, 2016, the Company entered into a further extension to the agreement through May 31, 2017. The total payments to be made by the Company in accordance with the extension of the agreement are \$220,826 (€210,000).

e)

#### Hvidovre Hospital, Denmark Agreements

On August 8, 2014, the Company entered into an agreement with Hvidovre Hospital, University of Copenhagen in Denmark, relating to a program of samples testing associated with CRC. It will run for a period of two years to August 8, 2016. Total payments (inclusive of local taxes) to be made under the agreement are \$1,448,336 (DKR 10,245,000). On April 15, 2015, the Company amended the aforementioned collaborative research agreement with an additional commitment for samples costing \$50,000, to be provided over a two year period, expiring on April 15, 2017.

On November 2, 2016, the Company entered into a clinical research agreement with Hvidovre Hospital, University of Copenhagen in Denmark, relating to a program of samples testing associated with CRC and other diseases. The first phase of the agreement will expire on September 30, 2018 and the Company may participate in additional phases upon its election (and payment of required amounts). Total payments (inclusive of local taxes) to be made by the Company under the agreement for the first phase are \$2,120,550 (DKR 15,000,000).

**VOLITIONRX LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**For Years Ended December 31, 2016 and 2015**

**(\$ expressed in United States Dollars)**

**Note 10 Commitments and Contingencies (Continued)**

f)

Long Term Debt: Preface S.A. Loan Agreement

On September 16, 2016, Belgian Volition SPRL ( Belgian Volition ) entered into an unsecured loan agreement with Namur Invest or Preface S.A. for the amount of \$478,700 (€440,000) (the “Loan Agreement”). The proceeds from the Loan Agreement were received by Belgian Volition on October 20, 2016. The Loan Agreement provides for an approximate 7-year term, a fixed interest rate at 4.85%, and interest only payments between the receipt of proceeds and June 30, 2017. The proceeds from this Loan Agreement were used for the first payment on the Real Estate Capital Lease Agreement. See Note 10(c) for additional details.

g)

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

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

On February 3, 2017, Belgian Volition SPRL created a wholly owned subsidiary, Volition America, Inc., organized in the state of Delaware, United States of America.

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

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

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

## 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, 2016, 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 generally accepted in the United States of America.



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, 2016, 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, 2016, 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; and

2.

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

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, 2016, based on criteria established in *Internal Control - Integrated Framework* issued by COSO.



***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, 2016, we did not maintain sufficient internal controls over financial reporting:

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

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

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, 2016 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 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 IT and Human Resources have been recruited to recommend and implement relevant policy and processes to strengthen IT and Human Resources internal controls associated with financial reporting.

## **ITEM 9B.**

### **OTHER INFORMATION**

On March 7, 2017, Cameron Reynolds entered into an Employment Agreement with Volition Diagnostics UK Limited, or the Reynolds Employment Agreement, which shall take effect on April 1, 2017 and replaces both the Reynolds Executive Employment Agreement and the Reynolds Consultancy Agreement (as such terms are defined in *Item 11. Executive Compensation – Employment and Consulting Agreements*). Pursuant to the terms of the Reynolds Employment Agreement, Mr. Reynolds shall serve as Chief Executive Officer of Volition Diagnostics UK. Volition Diagnostics UK will also make available the services of Mr. Reynolds, as Chief Executive Officer, to VolitionRx and its other subsidiaries, pursuant to services agreements entered into by and between Volition Diagnostics UK and VolitionRx or its subsidiaries. The Reynolds Employment Agreement continues until terminated by either party providing not less than six months notice. In exchange for his services, Mr. Reynolds shall receive, among other things (i) £24,500 GBP per month (approximately \$30,224) from Volition Diagnostics UK; and (ii) a lump sum severance payment if terminated by Volition Diagnostics UK without cause (as per the agreement) equal to the salary that he would have received between the date of termination and the completion of a six month notice period. The foregoing description of the Reynolds Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.27.



On March 7, 2017, Dr. Jacob Micallef entered into an Employment Agreement with Volition Diagnostics UK, or the Micallef Employment Agreement, which shall take effect on April 1, 2017 and replaces the 2015 Micallef Agreement (as such term is defined in *Item 11. Executive Compensation – Employment and Consulting Agreements*). Volition Diagnostics UK will make available the services of Dr. Micallef, as Chief Scientific Officer, to VolitionRx and its other subsidiaries, pursuant to services agreements entered into by and between Volition Diagnostics UK and VolitionRx or its subsidiaries. The Micallef Employment Agreement continues until terminated by either party providing not less than three months' notice. In exchange for his services, Dr. Micallef shall receive, among other things (i) £12,000 GBP per month (approximately \$14,804) from Volition Diagnostics UK; and (ii) a lump sum severance payment if terminated by Volition Diagnostics UK without cause (as per the agreement) equal to the salary that he would have received between the date of termination and the completion of a three month notice period. The foregoing description of the Micallef Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.28.

On March 7, 2017, Rodney Rootsart entered into an Employment Agreement with Volition Diagnostics UK, or the Rootsart UK Employment Agreement, which shall take effect on April 1, 2017 and replaces the Rootsart Employment Agreement (as such term is defined in *Item 11. Executive Compensation – Employment and Consulting Agreements*). Volition Diagnostics UK will make available to VolitionRx the services of Mr. Rootsart as Corporate Secretary of VolitionRx, pursuant to a services agreement entered into by and between Volition Diagnostics UK and VolitionRx. The Rootsart UK Employment Agreement continues until terminated by either party providing not less than three months' notice. In exchange for his services, Mr. Rootsart shall receive, among other things (i) £10,000 GBP per month (approximately \$12,336) from Volition Diagnostics UK; and (ii) a lump sum severance payment if terminated by Volition Diagnostics UK without cause (as per the agreement) equal to the salary that he would have received between the date of termination and the completion of a three month notice period. The foregoing description of the Rootsart UK Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.29.

On March 7, 2017, Dr. Martin Faulkes entered into an Employment Agreement with Volition Diagnostics UK Limited, or the Faulkes Employment Agreement, which shall take effect on April 1, 2017 and replaces the Executive Chairman Agreement (as such term is defined in *Item 11. Executive Compensation – Employment and Consulting Agreements*). Volition Diagnostics UK will make available to VolitionRx the services of Dr. Faulkes as Executive Chairman of the Board of VolitionRx, pursuant to a services agreement entered into by and between Volition Diagnostics UK and VolitionRx and subject to any necessary approval by the Company's stockholders as required by applicable law and VolitionRx's governing documents. The Faulkes Employment Agreement continues until terminated by either party providing not less than three months' notice. In exchange for his services, Dr. Faulkes shall receive, among other things (i) £12,000 GBP per month (approximately \$14,804) from Volition Diagnostics UK; and (ii) a lump sum severance payment if terminated by Volition Diagnostics UK without cause (as per the agreement) equal to the salary that he would have received between the date of termination and the completion of a three month notice period. The foregoing description of the Faulkes Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.30.



**PART III****ITEM 10.****DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***Identification of Directors*

The following table sets forth the names and ages of the Company's Directors as of December 31, 2016.

| <b>Name</b>                                | <b>Age</b> | <b>Position with the Company</b> | <b>Officer/Director Since</b> |
|--|------------|----------------------------------|-------------------------------|
| Cameron Reynolds                           | 45         | President                        | October 6, 2011               |
|  |            | Chief Executive Officer          | October 6, 2011               |
|  |            | Director                         | October 6, 2011               |
| Dr. Martin Faulkes                         | 72         | Director                         | October 6, 2011               |
|  |            | Executive Chairman               | October 6, 2011               |
| Guy Innes <sup>(1) (2) (3)</sup>           | 60         | Director                         | October 6, 2011               |
| Dr. Alan Colman <sup>(1)</sup>             | 68         | Director                         | October 6, 2011               |
| Dr. Habib Skaff <sup>(1) (2) (3)</sup>     | 39         | Director                         | June 1, 2014                  |
| Dr. Edward Fletcher <sup>(1) (2) (3)</sup> | 62         | Director                         | June 23, 2016                 |

(1)

Member of the Audit Committee

(2)

Member of the Compensation Committee

(3)

Member of the Nominations and Governance Committee

*Term of Office*

Each Director serves for a term of one year and until his or her successor is elected at the Annual Stockholders Meeting and is qualified, subject to removal by the stockholders.



***Background and Business Experience of Directors***

The business experience during the past five years of the directors is as follows:

**CAMERON REYNOLDS** serves as our President, Chief Executive Officer and Director. Prior to completion of the transactions under the Share Exchange Agreement, he was Chief Executive Officer and Director of Singapore Volition, a position he held since August 5, 2010. He is also a Director of Belgian Volition since October 27, 2010, serving as Managing Director between January 18, 2012 and July 24, 2015, a Director and Chief Executive Officer of Hypergenomics since March 7, 2011, was appointed Director and Chief Executive Officer of Volition Diagnostics UK Limited, on November 13, 2015, and was appointed Director of Volition America, Inc. on February 3, 2017. Since February 2017, Mr. Reynolds has concurrently served as a non-executive director of Ucuroo Pty Ltd. From 2004 until 2011, Mr. Reynolds founded and served as Managing Director and Director of Mining House, where he was responsible for identifying potential mining projects, coordinating the preliminary evaluations and securing the financing with a view to listing the companies on the AIM, the TSX and the U.S. OTC. Mr. Reynolds furthered his education between 2002 and 2003 as he undertook an MBA. From 1998 until 2001, Mr. Reynolds served as the commercialization director for Probio, Inc., a company that commercialized intellectual property in the animal biotechnology fields including transgenesis and cloning research from the University of Hawaii. Mr. Reynolds' main responsibilities were managing all legal and contract issues with the University of Hawaii; implementing patenting strategy; managing all stockholder issues including the merger and its legal and contractual documentation; head office management; budgetary control; team building and recruitment. Furthermore, Mr. Reynolds held a junior management position in 1996 at Integrated Coffee Technologies, a genetically modified coffee company where he was responsible for business plan creation, office management, recruitment, and business development. Starting in 1994, Mr. Reynolds was working for Southern China Group, where as regional manager he set up operations in Hong Kong and Yunnan. Between 2005 and 2011, Mr. Reynolds held a number of board directorships including Atlantic Mining PLC; Carbon Mining PLC, Magellan Copper and Gold (Carbon Mining and MCG both became part of Solfotara Mining and Copper Development Corp.); KAL Energy Inc. (OTC: KALG), Iofina Natural Gas PLC (AIM: IOF); Canyon Copper Corp. (TSX-V: CNC, OTCBB: CNYC), and Hunter Bay Resources (TSX-V: HBY). The Board of Directors believes Mr. Reynolds brings to the Company strong experience in management, structuring and strategic planning of start-up companies based on his over 20 years of entrepreneurial executive experience in the mining and biotechnology sectors.

**DR. MARTIN FAULKES** serves as Executive Chairman of the Board of Directors. Prior to completion of the transactions under the Share Exchange Agreement, Dr. Faulkes served as a Director of Singapore Volition from August 18, 2010 to December 15, 2015 and as Executive Chairman of the Board of Directors of Singapore Volition from March 22, 2011 until December 15, 2015. Dr. Faulkes also served as a Director of Belgian Volition between August 10, 2011 and March 31, 2016. From 1998 until the present day, Dr. Faulkes has focused on charitable activities, as the founder and sole benefactor of Dill Faulkes Educational Trust, a U.K. registered charity, where he is Chairman. He also sits on the board of the Cambridge 800th Anniversary Campaign in the U.K. Prior to Dr. Faulkes charitable activities he founded Triad Plc., a computer software development company that provides systems and consultants to the business community, where he was a Director from 1987 to 1998, and responsible for controlling the company financially. From 1985 to 1987, he became Managing Director of System Programming Ltd., a company that provides computer programming for systems in businesses such as airlines, utility companies, banks, and insurance companies, where he was responsible for all aspects of the business. Prior to System Programming Ltd., Dr. Faulkes served from 1979 to 1984 as founder, President and Chief Executive Officer for Logica Inc., a company providing bespoke software to all industries but mainly banks and communications companies. Dr. Faulkes was responsible for all aspects of the business, including sales, finance, recruitment, staff management and project control. Dr. Faulkes has over 30 years of entrepreneurial and managerial experience as the founder and Chief Executive Officer of several software companies within the United Kingdom and the United States. The Board of Directors believes that Dr. Faulkes is qualified to serve as a director of the Company based on his extensive experience in business development and management.

**GUY INNES** serves as a Director. Prior to completion of the transactions under the Share Exchange Agreement, Mr. Innes served as a Director of Singapore Volition, a position he held from August 18, 2010 to December 15, 2015. Mr. Innes has served as a non-executive Director on the board of companies such as Carbon Mining Plc. from 2007 to 2010, Magellan Copper & Gold Plc. from 2007 to 2010, and ProBio Inc. from 2000 to 2006. As a non-executive Director, Mr. Innes was responsible for the development of corporate strategy and the implementation of financial controls and risk management systems. Mr. Innes had a long career in banking and private equity, including advisory roles with Quartz Capital Partners Limited from 1997 to 2000, where Mr. Innes served as Head of Corporate Finance and was responsible for managing the corporate finance department and leading the transactions undertaken by Quartz including IPOs, private placements and mergers and acquisitions; Baring Private Equity Partners Limited in London and Singapore from 1995 to 1997, where he was involved in the setting up, recruiting of managers and capital raising for an Asian media and communications private equity fund; and Baring Brothers & Co. Limited in London and Paris from 1984 to 1995, where he was involved in executing and advising on national and international mergers and acquisitions, but also IPOs and capital raising. Mr. Innes is a Chartered Accountant and a member of the Institute of Chartered Accountants in England and Wales. Mr. Innes has extensive experience in financing and managing technology companies. Our Board of Directors believes Mr. Innes' technical, financial and managerial background would be beneficial to our growth.

**DR. ALAN COLMAN** serves as a Director. Prior to completion of the transactions under the Share Exchange Agreement, Dr. Colman served as a Director of Singapore Volition from April 1, 2011 to December 15, 2015 and currently serves as Chairman of the Scientific Advisory Board of Singapore Volition, a position he has held since April 5, 2011. Dr. Colman received a BA (1971), MA (1975) and Ph.D. (1975) from Oxford University. Dr. Colman is currently a Visiting Scholar at the Harvard University Department of Stem Cell and Regenerative Biology. He also currently serves on the Scientific Advisory Board of Semma Therapeutics, Inc., a stem cell therapy company based in Cambridge, Massachusetts, a position he has held since December 2014. From 2007 to 2013, Dr. Colman served as the Executive Director of the Singapore Stem Cell Consortium. Concurrently, Dr. Colman was Professor of

Regenerative Medicine at King's College, London, U.K., from 2008 to 2009. Prior to joining the A\*STAR Singapore Stem Cell Consortium, Dr. Colman was Chief Scientific Officer and then Chief Executive Officer for the Singaporean human embryonic stem cell company, ES Cell International from 2002 to 2007. Dr. Colman was the research director at PPL Therapeutics in Edinburgh, U.K., from the late 1980s until 2002, where he was responsible for leading PPL's research program strategy, also playing a role in PPL's financing rounds, culminating in its listing on the London Stock Exchange in 1996. PPL attracted considerable media attention because of its participation in the technique of somatic nuclear transfer that led to the world's first sheep cloned from an adult cell, Dolly, in 1996. Dr. Colman had a successful university career in the Universities of Oxford, Warwick, Birmingham (where he was Professor of Biochemistry) and London (as mentioned above). None of the above companies or organizations is a parent, subsidiary or other affiliate of the Company. Dr. Colman's current interest is the development of human disease models using induced pluripotent stem cells. He has extensive experience in the molecular biology field where he has worked in the production of transgenic livestock, somatic nuclear transfer, and human disease models. The Board of Directors appointed Dr. Colman a Director of the Company and a member of the Scientific Advisory Board based on his extensive experience in biochemistry, stem cell research and pathology.

**DR. HABIB SKAFF** serves as a Director. Prior to completion of the transactions under the Share Exchange Agreement, Dr. Skaff served as a Scientific Advisory Board Member of Singapore Volition between April 4, 2011 and May 31, 2014. Dr. Skaff currently serves as Managing Partner of Cedar Capital Holdings, LLC, where he heads operations as well as acquisitions of companies in fields varying from wound care to recycling. Dr. Skaff co-founded Intezyne Technologies in 2004 and served as its Chief Executive Officer until 2016. At Intezyne, Dr. Skaff was responsible for establishing and implementing strategic planning for the future, working closely with the Chief Scientific Officer to develop and implement Intezyne's intellectual property strategy as well as establishing alliances with potential partners. As Chief Executive Officer, Dr. Skaff led Intezyne's fundraising through debt and equity financing and worked closely with the Chief Financial Officer in this capacity. In addition, since 2001, Dr. Skaff has co-authored 11 peer-reviewed scientific papers and is a co-inventor on 34 pending or issued patents in the fields of chemistry, nanotechnology and biotechnology. Dr. Skaff works as a synthetic chemist specializing in the area of nanotechnology; his doctoral studies focused on the design of organic and polymeric ligands for the encapsulation of semiconductor nanoparticles and modification of the physical, optical, electronic, and assembly properties of the nanoparticles. Due to his extensive scholarly work and inventions in the fields of chemistry and biotechnology, the Board of Directors feels that Dr. Skaff is a valuable asset to the Company.

**DR. EDWARD FUTCHER** serves as a Director. Dr. Futcher holds a B.Sc. in Physics and a Ph.D. in Physics from the University of London and has extensive experience in engineering and management in high technology companies. Since 1997, Dr. Futcher has held non-executive directorships with a variety of private companies. He co-founded Azima, Inc. in 2003, a company that provides advanced machine diagnosis to large industrial facilities and, from 2003 to 2008, served as its Vice President of Engineering with responsibility for the engineering, information technology and customer support groups. Prior to that, from 1997 to 2003, Dr. Futcher served as Vice President of Technology of interWAVE Communications International, Ltd., a company providing GSM and CDMA cellular infrastructure equipment, where he was responsible for operational management of acquisitions and interim management of the worldwide research and development organization. From 1997 to 1999, Dr. Futcher also served as Vice President of Engineering of interWAVE Communications. From 1994 to 1997, Dr. Futcher was Director of Engineering at Tellabs, Inc., a telecommunications equipment supplier. The Board of Directors believes that Dr. Futcher is qualified to serve as a Director of the Company based on his extensive commercial and management experience in dynamic and fast growing companies.

### *Identification of Executive Officers*

The following table sets forth the names and ages of the Company's executive officers as of December 31, 2016.

| <b>Name</b>                     | <b>Age</b> | <b>Position with the Company</b> | <b>Officer/Director Since</b> |
|---------------------------------|------------|----------------------------------|-------------------------------|
| Cameron Reynolds                | 45         | President                        | October 6, 2011               |
|                                 |            | Chief Executive Officer          | October 6, 2011               |
|                                 |            | Director                         | October 6, 2011               |
| David Kratochvil <sup>(1)</sup> | 51         | Chief Financial Officer          | August 17, 2015               |
|                                 |            | Treasurer                        | August 17, 2015               |
| Rodney Rootsart                 | 45         | Secretary                        | October 6, 2011               |

|                    |    |                          |                 |
|--------------------|----|--------------------------|-----------------|
| Dr. Jason Terrell  | 36 | Chief Medical Officer    | March 20, 2013  |
|                    |    | Head of U.S. Operations  |                 |
| Dr. Jacob Micallef | 60 | Chief Scientific Officer | January 1, 2015 |

(1)

Mr. Kratochvil provided notice of resignation on November 30, 2016. The resignation will become effective May 31, 2017.

### *Term of Office*

Each officer serves for such term as determined by their employment agreement as approved by the Board of Directors or Compensation Committee. For current officers, unless disclosed above, the terms range from one to three years.

### *Background and Business Experience of Executive Officers*

The business experience during the past five years of the executive officers is as follows:

**CAMERON REYNOLDS** serves as our President and Chief Executive Officer and is a Director of the Company. Additional information regarding Mr. Reynolds is provided under *Item 10 Directors, Executive Officers and Corporate Governance - Background and Business Experience of Directors* of this report.

**DAVID KRATOCHVIL** serves as our Chief Financial Officer and Treasurer. Mr. Kratochvil has over twenty years of successful investment experience ranging from developed and emerging market equity, fixed income, and currency investing to commodity and private equity investing. At Euro Pacific Capital, Mr. Kratochvil was Managing Director in the Corporate Finance department overseeing the firm's investment banking efforts across a variety of sectors. Additionally, he was an international portfolio manager at the multi-billion-dollar hedge fund Omega Advisors where he invested in international equities, emerging market debt, currencies, and commodities. Prior to joining Omega, he was a Director at Merrill Lynch Asset Management in London where he was responsible for emerging market investing. Mr. Kratochvil also ran his own advisory firm, Vista Capital Advisors, and worked as an equity analyst in New York, as a private equity investor in Prague, and as a business tax consultant in New York. Mr. Kratochvil holds an MBA in finance and international business from the University of Chicago's Booth School of Business and a B.S. in Economics with a double concentration in finance and accounting from The Wharton School at the University of Pennsylvania. Mr. Kratochvil holds FINRA 7, 24, 63, 79, 86 and 87 registrations. The Board of Directors believes that Mr. Kratochvil brings value to the Company with his extensive financial and accounting knowledge.

**RODNEY ROOTSAERT** serves as our Secretary. Prior to the completion of the transactions under the Share Exchange Agreement, he was the Administration and Legal Officer of Singapore Volition, a position he held since August 6, 2010. Mr. Rootsart became a Director of Singapore Volition and Hypergenomics on December 15, 2015. He has been a Director and Secretary of Belgian Volition since October 4, 2010 and was appointed Director of Volition Diagnostics UK Limited, on November 13, 2015. Mr. Rootsart concurrently serves as director and corporate secretary of Mining House Ltd., positions he has had since 2007. His responsibilities include ensuring compliance with all relevant statutory and regulatory requirements. From 2007 until 2011, Mr. Rootsart served as corporate secretary for Magellan Copper and Gold Plc., where his duties included maintaining and preparing company documents, accounts and contracts. Due to Mr. Rootsart's ten years of experience in providing corporate, legal and administrative services and prior roles as corporate secretary for small public companies, the Board of Directors believes that he is a valuable addition to our team.

**DR. JASON TERRELL** serves as our Chief Medical Officer and Head of U.S. Operations. Effective January 1, 2016, Dr. Terrell was appointed to the position of Chief Medical Officer and Head of U.S. Operations on a full-time basis, having previously served in a part-time capacity as the Company's Chief Medical Officer and Head of U.S. Operations since March 2013. On February 3, 2017, Dr. Terrell was appointed Director of Volition America, Inc. Since February 2017, Dr. Terrell has also concurrently served as both a director and Chief Medical Diagnostics Officer of Genex Biotechnology Corporation (OTCMKTS : GNBT), a publicly-held biopharmaceutical company focused on developing or acquiring technologies that help pharmaceutical companies discover and develop medicines, and additionally as the non-executive chairman of the board of directors of Kiromic BioPharma, Inc. (a private company). Between January 2013 and October 2015, Dr. Terrell served on the board of directors of CDEX Inc., a publicly-held company developing drug validation technology, and between January 2012 and October 2015, as Medical Director of CDEX Inc. In addition, over the last six years, Dr. Terrell has built and sold multiple private diagnostic laboratories and currently serves as a National Franchise Corporate Medical Director for Any Lab Test Now, giving him oversight of over 70 franchises in 14 states. Dr. Terrell is a Texas-based doctor educated at the University of Texas and its affiliate MD Anderson Cancer Center, with expertise in both clinical medicine and the laboratory diagnostics business. He has a strong grounding in diagnostics and product commercialization and has both executive and board directorship experience with publicly traded companies in the biotechnology and pharmaceutical industries. Our Board of Directors has concluded that Dr. Terrell brings value to the Company with his strong grounding in both medicine and more specifically in diagnostics.

**DR. JACOB MICALLEF** serves as the Company's Chief Scientific Officer. Dr. Micallef also served as a Director of Belgian Volition between August 10, 2011 and March 31, 2016. Prior to the Share Exchange Agreement, he served as a Science Executive Officer of Belgian Volition since October 11, 2010, but was not otherwise involved with Singapore Volition. Dr. Micallef joined Cronos Therapeutics Limited, or Cronos, in 2004 and, in 2006, Cronos was listed in the U.K. on the AIM, becoming Valirx plc, or Valirx. Dr. Micallef continued to work as Technical Officer for Valirx, where he in-licensed the HyperGenomics® and Nucleosomics® technologies and co-founded ValiBio SA, which is now Belgian Volition. From 2004 to 2007, he taught science and enterprise to science research workers from four universities at CASS Business School before joining Cronos. In 2001, Dr. Micallef co-founded Gene Expression Technologies, after getting his MBA in 1999, where he successfully led the development of the chemistry of the GeneICE technology and implemented the manufacture of GeneICE molecules. He also played a major role in business development and procured a GeneICE contract with Bayer AG. Over a 15-year period, starting in 1985, Dr. Micallef worked for the World Health Organization, or WHO. While working for the WHO, Dr. Micallef developed new diagnostic products in the areas of reproductive health and cancer. In 1990, he commenced development of a new diagnostic technology platform for WHO which was launched in 1992 and supported 13 tests. Dr. Micallef also initiated and implemented in-house manufacture (previously outsourced to Abbott Diagnostics Inc.) and world-wide distribution of these products for WHO. Also in 1990, he started a not-for-profit WHO company, Immunometrics Ltd., which marketed and distributed those diagnostic products worldwide. Dr. Micallef has 20 years of experience in research and development and in the management of early stage biotechnical companies, including the manufacture of biotechnology products and the establishment of manufacturing operations. The Board of Directors believes that Dr. Micallef's prior work with Belgian Volition in the development of diagnostic products would continue to be an asset to us in his role as Chief Scientific Officer of both our subsidiary, Belgian Volition, and the Company.

## CORPORATE GOVERNANCE

### Family Relationship

We currently do not have any officers or directors of our Company who are related to each other.

### Involvement in Certain Legal Proceedings

During the past ten years no director, executive officer, promoter or control person of Volition or its subsidiaries, has been involved in any legal proceedings required to be disclosed pursuant to Item 401(f) of Regulation S-K.

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who beneficially own more than ten percent of a registered class of our equity securities to file with the SEC initial reports of ownership and reports of change in ownership of our common stock and other equity securities. Officers, directors and greater than ten percent stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely upon a review of Forms 3, 4, and 5 and amendments thereto furnished to us under Rule 16a-3(e) during the year ended December 31, 2016, and the representations made by the reporting persons to us, we believe that during the year ended December 31, 2016, our executive officers and directors and all persons who own more than ten percent of a registered class of our equity securities have complied with all Section 16(a) filing requirements, except as set forth below:

·  
Two Form 4 s filed by Mr. Reynolds to report beneficial ownership of spouse; and

·  
Form 4 filed by Dr. Micallef to report the grant of an option and subsequent transfer to a consulting firm for which Dr. Micallef reports indirect ownership since he has voting and dispositive control over the securities held by Borlaug Limited, or Borlaug.



### *Code of Ethics*

We have adopted a Code of Ethics, or the Code, that applies to our directors, officers and employees, including our Chief Executive Officer and Chief Financial Officer. A copy of the Code is available on our Company website at <http://ir.volitionrx.com/governance-documents>. Amendments to the Code that apply to our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, if any, will be posted on our website at <http://ir.volitionrx.com/governance-documents>. We will disclose any waivers of provisions of our Code that apply to such persons by disclosing such information on a Current Report on Form 8-K.

### **Committees of the Board of Directors**

Our Board of Directors has established an audit committee, a compensation committee, and a nominations and governance committee. The committees operate pursuant to written charters adopted by the Board of Directors, copies of which are available on our website <http://ir.volitionrx.com/committee-charters>. In addition, from time to time, the Board of Directors may establish special committees when necessary to address specific issues.

### *Audit Committee*

Our audit committee consists of four members, Mr. Innes (Chair), and Drs. Skaff, Colman and Futcher, each of whom has been determined to be an independent director under applicable SEC rules and the applicable rules of the NYSE MKT. The audit committee shall at all times be composed exclusively of directors who are, in the opinion of our Board of Directors, free from any relationship which would interfere with the exercise of independent judgment as a committee member and who possess an understanding of financial statements and generally accepted accounting principles.

The audit committee is responsible for, among other things:

.

appointing, terminating, compensating and overseeing the work of any independent auditor engaged to prepare or issue an audit report or other audit, review or attest services;

.

reviewing all audit and non-audit services to be performed by the independent auditor, taking into consideration whether the independent auditor's provision of non-audit services to us is compatible with maintaining the independent auditor's independence;

.

reviewing and discussing the adequacy and effectiveness of our accounting and financial reporting processes and internal controls and the audits of our financial statements;

.

establishing and overseeing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, including procedures for the confidential, anonymous submission by our employees regarding questionable accounting or auditing matters;

.

investigating any matter brought to its attention within the scope of its duties and engaging independent counsel and other advisors as the audit committee deems necessary;

.

determining compensation of the independent auditors and of advisors hired by the audit committee and ordinary administrative expenses;

.

reviewing and discussing with management and the independent auditor the annual and quarterly financial statements prior to their release;

.

monitoring and evaluating the independent auditor's qualifications, performance and independence on an ongoing basis;

.

reviewing reports to management prepared by the internal audit function, as well as management's response;

reviewing and assessing the adequacy of the formal written charter on an annual basis; and

reviewing and approving related party transactions for potential conflict of interest situations on an ongoing basis; and overseeing such other matters that are specifically delegated to the audit committee by our Board of Directors from time to time.

The Board of Directors has affirmatively determined that Mr. Innes is designated as an audit committee financial expert.

### *Compensation Committee*

Our compensation committee consists of three members, Mr. Innes (Chair) and Drs. Skaff and Futcher, each of whom has been determined to be an independent director under the applicable rules of the NYSE MKT.

The compensation committee is responsible for, among other things:

developing, reviewing, and approving our overall compensation programs, and regularly reporting to the full Board of Directors regarding the adoption of such programs;

developing, reviewing and approving our cash and equity incentive plans, including approving individual grants or awards thereunder;

reviewing and approving individual and company performance goals and objectives that may be relevant to the compensation of executive officers and other key employees;

reviewing and discussing with management the tables and narrative discussion regarding executive officer and director compensation to be included in the annual proxy statement;

reviewing and assessing, on an annual basis, the adequacy of the formal written charter; and

.

overseeing such other matters that are specifically delegated to the compensation committee by our Board of Directors from time to time.

In fulfilling its responsibilities, the compensation committee has the authority to delegate any or all of its responsibilities to a subcommittee of the compensation committee.

### *Nominations and Governance Committee*

Our nominations and governance committee consists of three members, Mr. Innes (Chair) and Drs. Skaff and Fletcher, each of whom has been determined to be an independent director under the applicable rules of the NYSE MKT.

The nominations and governance committee is responsible for, among other things:

.  
identifying and screening candidates for our Board of Directors, and recommending nominees for election as directors;

.  
assessing, on an annual basis, the performance of the Board of Directors and any committee thereof;

.  
reviewing the structure of the Board of Director s committees and recommending to the board for its approval directors to serve as members of each committee, including each committee s respective chair, if applicable;

.  
reviewing and assessing, on an annual basis, the adequacy of its formal written charter; and

.  
generally advising our board of directors on corporate governance and related matters.

### ***Nominating Procedures***

The nominations and governance committee does not have a formal policy regarding the consideration of any director nominee, but will consider candidates for the Board of Directors from any reasonable source, including stockholder recommendations. The committee will not evaluate candidates differently based on who has made the proposal. The committee has the authority under its charter to hire and pay a fee to consultants or search firms to assist in the process of identifying and evaluating candidates. No such consultants or search firms have been used to date and, accordingly, no fees have been paid to consultants or search firms in the past fiscal year. The nominations and governance committee, and our Board of Directors, believe that directors should possess the highest personal and professional ethics, integrity and values, and to be committed to representing the long-term interests of the Company s stockholders. Each director must also be able to dedicate the time and resources sufficient to ensure the diligent performance of his or her duties. Further, our Board of Directors is intended to encompass a range of talents, experience, skills, backgrounds, and expertise sufficient to provide sound and prudent guidance with respect to the operations and interests of the Company and its stockholders. The Company values diversity and seeks to achieve a diversity of professional experiences and personal backgrounds on our board of directors, but no specific policy regarding board diversity has been adopted.

Stockholders who wish to suggest qualified candidates should write to the chair of the nominations and governance committee at Centre Technologique, Rue du Séminaire, 20A, BE - 5000 Namur, Belgium, specifying the name of the candidates and stating in detail the qualifications of such persons for consideration by the committee. A written statement from the candidate consenting to be named as a candidate and, if nominated and elected, to serve as a director should accompany any such recommendation.

## ITEM 11.

## EXECUTIVE COMPENSATION

## Summary Compensation Table

The following table sets forth the principal positions of our named executive officers at VolitionRx and its subsidiaries and the compensation paid to such persons for the fiscal years ended December 31, 2016 and 2015. Unless otherwise specified, the term of each named executive officer is as set forth under that section entitled, Directors, Executive Officers and Corporate Governance- Term of Office .

| Name and<br>Principal<br>Position   | Year<br>Ended<br>December 31, | Nonqualified |        |              |                        |                             |                       |                        |          |
|---|-------------------------------|--------------|--------|--------------|------------------------|-----------------------------|-----------------------|------------------------|----------|
|   |                               | Non-Equity   |        |              |                        |                             | Deferred              |                        |          |
|   |                               | Salary       | Bonus  | Stock Awards | Option Awards          | Incentive Plan Compensation | Compensation Earnings | All Other Compensation | Total    |
|   |                               | (\$)         | (\$)   | (\$)         | (\$) <sup>(1)(7)</sup> | (\$)                        | (\$)                  | (\$)                   | (\$)     |
| <b>C a m e r o n Reynolds<sup>(2)</sup></b><br>President, CEO<br>and Director | 2016                          | 25,000       | -0-    | -0-          | 257,717                | -0-                         | -0-                   | 285,168                | 567,885  |
|   | 2015                          | 121,672      | -0-    | -0-          | 199,287                | -0-                         | -0-                   | 145,340                | 466,299  |
| <b>D r J a c o b Micallef<sup>(3)</sup></b><br>Chief Scientific<br>Officer    | 2016                          | -0-          | -0-    | -0-          | 260,178                | -0-                         | -0-                   | 151,551                | 411,729  |
|   | 2015                          | -0-          | 46,760 | -0-          | 224,905                | -0-                         | -0-                   | 147,209                | 418,874  |
| <b>R o d n e y Rootsart<sup>(4)</sup></b><br>Secretary                        | 2016                          | 126,227      | -0-    | -0-          | 136,497                | -0-                         | -0-                   | -0-                    | 262,724  |
|   | 2015                          | 118,351      | -0-    | -0-          | 123,174                | -0-                         | -0-                   | 4,128                  | 245,653  |
| <b>D r . J a s o n Terrell<sup>(5)</sup></b><br>Chief Medical<br>Officer      | 2016                          | 120,000      | -0-    | -0-          | 48,813                 | 62,343                      | -0-                   | -0-                    | 231,156  |
|   | 2015                          | -0-          | -0-    | -0-          | 21,348                 | (42,131)                    | -0-                   | -0-                    | (20,783) |
| <b>D a v i d Kratochvil<sup>(6)</sup></b><br>C F O<br>and<br>Treasurer        | 2016                          | 223,333      | -0-    | -0-          | 24,271                 | -0-                         | -0-                   | 9,700                  | 257,304  |
|   | 2015                          | 82,500       | -0-    | -0-          | 165,572                | -0-                         | -0-                   | 32,864                 | 280,936  |

(1)

All option and warrant award amounts have been calculated based upon the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in footnote <sup>(7)</sup> below.

(2)

Mr. Reynolds' salary for the years ended December 31, 2016 and 2015 was determined pursuant to the Reynolds Executive Employment Agreement (as described below). On April 15, 2016, Mr. Reynolds was granted an option to purchase 125,000 shares of common stock of VolitionRx under the 2015 Stock Incentive Plan, or 2015 Plan, vesting in full on the twelve month anniversary of the date of grant. The other compensation consists of consultancy fees received by Mr. Reynolds pursuant to the Reynolds Consultancy Agreement (as described below).

(3)

Dr. Micallef does not receive compensation directly from the Company. On April 15, 2016, Dr. Micallef was granted an option to purchase 125,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant. This option has been subsequently transferred to Borlaug for no value. The other compensation consists of fees received under the 2015 Micallef Agreement, as amended (as described below). Effective May 4, 2016, the warrant to purchase 5,000 shares of common stock granted to Borlaug on May 11, 2012, was amended to extend the original exercise period by one year from May 10, 2016 to May 10, 2017.

(4)

Mr. Rootsart's salary for the years ended December 31, 2016 and 2015 was determined pursuant to the Rootsart Employment Agreement (as described below). On April 15, 2016, Mr. Rootsart was granted an option to purchase 65,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant. In 2015, other compensation consists of fees paid by the Company to Mining House Limited, or Mining House. Mining House ceased to charge the Company fees in 2016. Mr. Rootsart is a director of Mining House and is deemed to have received one-half of all fees paid by the Company to Mining House.

(5)

Dr. Terrell's salary for the year ended December 31, 2016 was determined pursuant to the 2016 Terrell Employment Agreement (as described below). On April 15, 2016, Dr. Terrell was granted an option to purchase 25,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant. Dr. Terrell was also granted warrants to purchase 200,000 shares of common stock on March 20, 2013. Of the 200,000 warrants, 25,000 vested at the date of grant and the remaining 175,000 have variable vesting dates linked to business objectives. In October 2014, 25,000 of the warrants vested. In 2015, the warrant agreement was amended with respect to the remaining 150,000 warrants resulting in a gain of \$42,131. In 2016, the warrant agreement was further amended with respect to the remaining 150,000 warrants when Dr. Terrell became an employee of the Company, resulting in a loss of \$62,343.





(6)

Mr. Kratochvil's salary for the years ended December 31, 2016 and 2015 was determined pursuant to the Kratochvil Employment Agreement (as described below). On September 13, 2016, Mr. Kratochvil was granted an option to purchase 25,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant. The other compensation includes medical premiums for 2015 and 2016 and consultancy fees for 2015.

(7)

November 25, 2011 Grants: Under the terms of the 2011 Plan, each of the options granted on November 25, 2011 vest in six equal installments according to the following schedule: (i) on May 25, 2012 and November 25, 2012 at an exercise price of \$3.00 per share, (ii) on May 25, 2013 and November 25, 2013 at an exercise price of \$4.00 per share and (iii) on May 25, 2014 and November 25, 2014 at an exercise price of \$5.00 per share. On May 18, 2015, the Company amended the expiry period of 630,000 stock options, originally granted on November 25, 2011. The expiration period was extended from three to four years from vesting for all 630,000 stock options.

We have calculated the estimated fair market value of the options granted on November 25, 2011 using the Black-Scholes Option Pricing model and the following assumptions: stock price at valuation of \$1.20; expected term of 3.5 to 7 years; exercise price of \$3.00 to \$5.00; a risk free interest rate of 0.41% for the options which vest on May 25, 2012 and November 25, 2012 and a risk free interest rate of 0.93% for the options which vest between May 25, 2013 and November 25, 2014; a dividend yield of 0% and volatility of 174%. On May 18, 2015, the expiry period of these options was extended from three (3) to four (4) years and the Black Scholes Option Pricing model was used to estimate a revised market value.

December 3, 2012 Grants: Under the terms of the 2011 Plan, each of the options granted on December 3, 2012 vested immediately on December 3, 2012 at an exercise price of \$3.01 per share. The options shall expire three (3) years after they vest.

We have calculated the estimated fair market value of the options granted on December 3, 2012 using the Black-Scholes Option Pricing model and the following assumptions: stock price at valuation of \$3.15; expected term of 3 years; exercise price of \$3.01; a risk free interest rate of 0.34%, a dividend yield of 0% and volatility of 251%.

August 18, 2014 Grants: Under the terms of the 2011 Plan, these options vest in two equal tranches, the first tranche vests on February 18, 2015. The second tranche vests on February 18, 2016. All the options expire four years after their vesting dates. The exercise prices are \$2.50 for options vesting in the first year and \$3.00 for options vesting in the second year.

We have calculated the estimated fair market value of these options granted on August 18, 2014 using the Black-Scholes Option Pricing model and the following assumptions: term 4.5 to 5.5 years, stock price \$1.85, exercise prices \$2.50-\$3.00, 237% volatility, 1.58% risk free rate.

July 23, 2015 Grants: Under the terms of the 2011 Plan, each of the options granted on July 23, 2015 vest 6 months after grant on January 23, 2016, at an exercise price of \$4.00 per share. The options shall expire four (4) years after they vest.

We have calculated the estimated fair market value of the options granted on July 23, 2015 using the Black-Scholes Option Pricing model and the following assumptions: stock price at valuation of \$3.55; expected term of 4.5 years; exercise price of \$4.00; a risk free interest rate of 1.65%, a dividend yield of 0% and volatility of 88%.

August 17, 2015 Grant to David Kratochvil: Under the terms of the 2011 Plan, the options granted on August 17, 2015 vested immediately on August 17, 2015 at an exercise price of \$3.75 per share. The options shall expire five (5) years after they vest.

We have calculated the estimated fair market value of the options granted on August 17, 2015 using the Black-Scholes Option Pricing model and the following assumptions: stock price at valuation of \$3.31; expected term of 5 years; exercise price of \$3.75; a risk free interest rate of 1.58%, a dividend yield of 0% and volatility of 88%.

April 15, 2016 Grants: Under the terms of the 2015 Plan, these options vest in full on the first anniversary of the grant date. All the options expire six years after their vesting dates. The exercise price is \$4.00.

We have calculated the estimated fair market value of these options granted on April 15, 2016 using the Black-Scholes Option Pricing model and the following assumptions: term 6 years, stock price \$3.75, exercise price \$4.00, 84.4% volatility, 1.22% risk free rate.

September 13, 2016 Grant to David Kratochvil, these options vest in full on the first anniversary of the grant date. The option expires five years after the vesting date and has an exercise price of \$4.65.

We have calculated the estimated fair market value of these options granted on September 13, 2016 using the Black-Scholes Option Pricing model and the following assumptions: term 6 years, stock price \$4.65, exercise price \$4.65, 81.94% volatility, 1.56% risk free rate.

## **Employment and Consulting Agreements**

### *Cameron Reynolds*

On May 11, 2016, Singapore Volition entered into a consultancy agreement with PB Commodities Pte Limited, or PB Commodities for the services of Cameron Reynolds, or the 2016 PB Commodities Consultancy Agreement (as further described in *Item 13*).

On January 1, 2015, Mr. Reynolds entered into a consultancy agreement with PB Commodities, or the Reynolds Consultancy Agreement. Mr. Reynolds receives compensation from PB Commodities under the Reynolds Consultancy Agreement in exchange for serving as a consultant for PB Commodities and performing consultancy services on its behalf (including for services provided to Singapore Volition). The Reynolds Consultancy Agreement continues until terminated by either party providing not less than two months' notice. In exchange for these services Mr. Reynolds received \$6,500 per month from PB Commodities, which increased on March 1, 2015 to \$8,000 per month following the up-listing of the Company to the NYSE MKT. On September 1, 2015 this amount increased to an average of \$21,085 per month. The foregoing description of the Reynolds Consultancy Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.12.

On January 1, 2015, Mr. Reynolds entered into an Executive Employment Agreement with VolitionRx, or the Reynolds Executive Employment Agreement, in exchange for serving as the Chief Executive Officer of VolitionRx. The term of the Reynolds Executive Employment Agreement is three (3) years, which shall be automatically extended for successive periods of two (2) years. In exchange for his services, Mr. Reynolds shall receive £4,500.00 GBP per month from VolitionRx. Commencing March 1, 2015, following the up-listing of the Company to the NYSE MKT, this amount increased to £10,000 GBP per month. On September 1, 2015 this amount was amended to \$2,803 per month. Mr. Reynolds is also entitled to the use of a residential apartment in Namur, Belgium, as leased by the Company. The foregoing description of the Reynolds Executive Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.13.

### *Dr. Jacob Micallef*

On January 1, 2015, VolitionRx and Borlaug entered into consultancy agreement, or the 2015 Micallef Agreement. Under the terms of the 2015 Micallef Agreement, Borlaug will make available to VolitionRx the services of Dr. Micallef to (i) manage VolitionRx's intellectual property portfolio and file new patents as required by VolitionRx; (ii) provide project management for VolitionRx's diagnostic development programs; and (iii) identify and pursue business development opportunities for VolitionRx. The 2015 Micallef Agreement continues until terminated in accordance with its terms. In exchange for such services, VolitionRx pays Borlaug a monthly fee of £6,014 GBP (approximately \$7,419), which increased on March 1, 2015 to £8,333 GBP per month (approximately \$10,280) following the up-listing of the Company to the NYSE MKT. The foregoing description of the 2015 Micallef Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.14. On May 11, 2016, VolitionRx entered into an amendment of the 2015 Micallef Agreement. Pursuant to the amendment, Borlaug shall receive £10,000 GBP per month (approximately \$12,336) in exchange for the services of Dr. Micallef. The foregoing description of the amendment to the 2015 Micallef Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.15.

*Rodney Rootsart*

On January 1, 2015, Mr. Rootsart entered into an employment agreement with VolitionRx, or the Rootsart Employment Agreement, in exchange for serving as the Corporate Secretary of VolitionRx. The term of the Rootsart Employment Agreement is three (3) years, which shall be automatically extended for successive periods of two (2) years. In exchange for his services, Mr. Rootsart received £4,500 GBP per month (approximately \$5,551) from VolitionRx which increased on March 1, 2015 to £6,666 GBP per month (approximately \$8,223) following the up-listing of the Company to the NYSE MKT and increased further on May 11, 2016 to £8,333 GBP per month (approximately \$10,280). The foregoing description of the 2015 Rootsart Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.16.

*Dr. Jason Terrell*

On January 1, 2016, Dr. Terrell entered into an employment agreement with VolitionRx, or the 2016 Terrell Employment Agreement, in exchange for serving as the Chief Medical Officer and Head of U.S. Operations of VolitionRx. The term of the 2016 Terrell Employment Agreement is one (1) year, which shall be automatically extended for successive periods of one (1) year, unless either party gives 30 day notice of intent to terminate. In exchange for his services, Dr. Terrell shall receive \$10,000 per month from VolitionRx. The foregoing description of the 2016 Terrell Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.17.

*David Kratochvil*

On August 17, 2015, Mr. Kratochvil entered into an employment agreement with VolitionRx, or the Kratochvil Employment Agreement, in exchange for serving as the CFO and Treasurer of VolitionRx. The term of the Kratochvil Employment Agreement is one (1) year, which shall be automatically extended for successive periods of one (1) year. In exchange for his services, Mr. Kratochvil shall receive \$18,333 per month, plus reimbursement of certain health and medical insurance premiums from VolitionRx. The foregoing description of the Kratochvil Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.18. Mr. Kratochvil's salary was increased further on September 1, 2016 to \$19,167 per month.

**Additional Narrative Disclosure**

Pursuant to the Reynolds Executive Employment Agreement, the Rootsart Employment Agreement and the Kratochvil Employment Agreement, if such individual is terminated by the Company without cause (as defined in his employment agreement) upon less than 6 months' prior notice, he shall be entitled to a lump sum severance payment equal to the base salary that he would have received between the date of termination and the completion of a six (6) month prior notice period.

Pursuant to the 2015 Micallef Agreement, if the agreement is terminated by the Company without cause upon less than 6 months' prior notice, Borlaug shall receive the fees that would have been payable between the date of termination and the completion of the 6 month prior notice period.

Pursuant to the 2016 Terrell Employment Agreement, if Dr. Terrell is terminated by the Company without cause (as defined in his employment agreement) upon less than three (3) months' prior notice, he shall be entitled to a lump sum severance payment equal to the base salary that Dr. Terrell would have received between the date of termination and

the completion of a three (3) month prior notice period.

**Outstanding Equity Awards**

The following table sets forth the outstanding equity awards for the executive officers of VolitionRx and its subsidiaries as of the fiscal year ended December 31, 2016.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

| Name             | Grant Date                       | Number of Securities Underlying Unexercised Options (#) exercisable | Number of Securities Underlying Unexercised Options (#) un-exercisable | Equity Incentive Plan Awards:                           |   | Option Exercise Price (\$) | Option Expiration Date | Number of Shares or Units of Stock that have not Vested (#) | Market Value of Shares or Units of Stock that have not Vested (\$) | Number of Shares, Units or Rights that have not Vested (#) | Unearned Share Value (\$) |
|------------------|----------------------------------|---|--|---|---|----------------------------|------------------------|---|--|--|---------------------------|
|                  |                                  |   |  | Number of Securities Underlying Unexercised Options (#) | Number of Securities Underlying Unexercised Options (#) |                            |                        |   |  |  |                           |
| Cameron Reynolds | November 25, 2011 <sup>(1)</sup> | 80,000  | -0-  | -0-   | (2)   | (3)                        | -0-                    | -0-   | -0-  | -0-  | -0-                       |
|                  | August 18, 2014 <sup>(4)</sup>   | 100,000   | -0-  | -0-   | (5)   | (6)                        | -0-                    | -0-   | -0-  | -0-  | -0-                       |



Edgar Filing: VOLITIONRX LTD - Form 10-K

|                    |                                      |         |     |         |        |                     |     |     |     |     |
|--------------------|--------------------------------------|---------|-----|---------|--------|---------------------|-----|-----|-----|-----|
|                    | July 23,<br>2015 <sup>(7)</sup>      | 55,000  | -0- | -0-     | \$4.00 | January 23,<br>2020 | -0- | -0- | -0- | -0- |
|                    | April 15,<br>2016 <sup>(8)</sup>     | -0-     | -0- | 125,000 | \$4.00 | April 15,<br>2022   | -0- | -0- | -0- | -0- |
| Dr. Jacob Micallef | November 25,<br>2011 <sup>(9)</sup>  | 80,000  | -0- | -0-     | (2)    | (3)                 | -0- | -0- | -0- | -0- |
|                    | August 18,<br>2014 <sup>(10)</sup>   | 130,000 | -0- | -0-     | (5)    | (6)                 | -0- | -0- | -0- | -0- |
|                    | July 23,<br>2015 <sup>(11)</sup>     | 55,000  | -0- | -0-     | \$4.00 | January 23,<br>2020 | -0- | -0- | -0- | -0- |
|                    | April 15,<br>2016 <sup>(12)</sup>    | -0-     | -0- | 125,000 | \$4.00 | April 15,<br>2022   | -0- | -0- | -0- | -0- |
| Rodney Rootsart    | November 25,<br>2011 <sup>(13)</sup> | 40,000  | -0- | -0-     | (2)    | (14)                | -0- | -0- | -0- | -0- |
|                    | August 18,<br>2014 <sup>(15)</sup>   | 60,000  | -0- | -0-     | (5)    | (16)                | -0- | -0- | -0- | -0- |
|                    | July 23,<br>2015 <sup>(17)</sup>     | 35,000  | -0- | -0-     | \$4.00 | January 23,<br>2020 | -0- | -0- | -0- | -0- |
|                    | April 15,<br>2016 <sup>(18)</sup>    | -0-     | -0- | 65,000  | \$4.00 | April 15,<br>2022   | -0- | -0- | -0- | -0- |
| Jason Terrell      | August 18,<br>2014 <sup>(19)</sup>   | 25,000  | -0- | -0-     | (5)    | (20)                | -0- | -0- | -0- | -0- |
|                    | April 15,<br>2016 <sup>(21)</sup>    | -0-     | -0- | 25,000  | \$4.00 | April 15,<br>2022   | -0- | -0- | -0- | -0- |
| David Kratochvil   | August 17,                           | 75,000  | -0- | -0-     | \$3.75 | August 17,          | -0- | -0- | -0- | -0- |

Edgar Filing: VOLITIONRX LTD - Form 10-K

| 2015 <sup>(22)</sup> |     |     |        |        | 2020          |     |     |     |     |
|----------------------|-----|-----|--------|--------|---------------|-----|-----|-----|-----|
| September 13,        | -0- | -0- | 25,000 | \$4.65 | September 13, | -0- | -0- | -0- | -0- |
| 2016 <sup>(23)</sup> |     |     |        |        | 2022          |     |     |     |     |

(1)

On November 25, 2011, Mr. Reynolds was granted an option to purchase 120,000 shares of common stock of VolitionRx under the 2011 Equity Incentive Plan, or 2011 Plan, vesting one-sixth (20,000 shares) every 6 months from the date of grant. As of the date of this report, options to purchase 40,000 shares have been exercised.

(2)

Pursuant to the applicable option agreement, as amended, the exercise price of the options is (a) \$4.00 per share for those vesting on May 25, 2013 and November 25, 2013, and (b) \$5.00 per share for those vesting on May 25, 2014 and November 25, 2014.

(3)

Pursuant to the applicable option agreement, as amended, the expiration date of the options is four years from the date of vesting, such that options to purchase 20,000 shares expire on each of May 25, 2017, November 25, 2017, May 25, 2018 and November 25, 2018.

(4)

On August 18, 2014, Mr. Reynolds was granted an option to purchase 100,000 shares of common stock of VolitionRx under the 2011 Plan, vesting one-half (50,000 shares) on the six month anniversary of the date of grant and vesting one-half (50,000 shares) on the eighteen month anniversary of the date of grant.

(5)

Pursuant to the applicable option agreement, the exercise price of the options is (a) \$2.50 per share for those vesting on February 18, 2015 and (b) \$3.00 per share for those vesting on February 18, 2016.

(6)

Pursuant to the applicable option agreement, the expiration date of the options is four years from the date of vesting, such that options to purchase 50,000 shares expire on each of February 18, 2019 and February 18, 2020.

(7)

On July 23, 2015, Mr. Reynolds was granted an option to purchase 55,000 shares of common stock of VolitionRx under the 2011 Plan, vesting in full on the six month anniversary of the date of grant.

(8)

On April 15, 2016, Mr. Reynolds was granted an option to purchase 125,000 shares of common stock of VolitionRx under the 2015 Stock Incentive Plan, or 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

(9)

On November 25, 2011, Dr. Micallef was granted an option to purchase 120,000 shares of common stock of VolitionRx under the 2011 Plan, vesting one-sixth (20,000 shares) every 6 months from the date of grant. This option has been subsequently transferred to Borlaug for no value. As of the date of this report, options to purchase 40,000 shares have been exercised.

(10)

On August 18, 2014, Borlaug was granted an option to purchase 130,000 shares of common stock of VolitionRx under the 2011 Plan, vesting one-half (65,000 shares) on the six month anniversary of the date of grant and vesting one-half (65,000 shares) on the eighteen month anniversary of the date of grant. This option has been granted to Borlaug for the services of Dr. Micallef.

(11)

On July 23, 2015, Borlaug was granted an option to purchase 55,000 shares of common stock of VolitionRx under the 2011 Plan, vesting in full on the six month anniversary of the date of grant. This option has been granted to Borlaug for the services of Dr. Micallef.

(12)

On April 15, 2016, Dr. Micallef was granted an option to purchase 125,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant. This option has been subsequently transferred to Borlaug Limited for no value.

(13)

On November 25, 2011, Mr. Rootsart was granted an option to purchase 60,000 shares of common stock of VolitionRx under the 2011 Plan, vesting one-sixth (10,000 shares) every 6 months from the date of grant. As of the date of this report, options to purchase 20,000 shares have been exercised.

(14)

Pursuant to the applicable option agreement, the expiration date of the options is four years from the date of vesting, such that options to purchase 10,000 shares expire on each of May 25, 2017, November 25, 2017, May 25, 2018 and November 25, 2018.

(15)

On August 18, 2014, Mr. Rootsart was granted an option to purchase 60,000 shares of common stock of VolitionRx under the 2011 Plan, vesting one-half (30,000 shares) on the six month anniversary of the date of grant and vesting one-half (30,000 shares) on the eighteen month anniversary of the date of grant.

(16)

Pursuant to the applicable option agreement, the expiration date of the options is four years from the date of vesting, such that options to purchase 30,000 shares expire on each of February 18, 2019 and February 18, 2020.

(17)

On July 23, 2015, Mr. Rootsart was granted an option to purchase 35,000 shares of common stock of VolitionRx under the 2011 Plan, vesting in full on the six month anniversary of the date of grant.

(18)

On April 15, 2016, Mr. Rootsart was granted an option to purchase 65,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

(19)

On August 18, 2014, Dr. Terrell was granted an option to purchase 25,000 shares of common stock of VolitionRx under the 2011 Plan, vesting one-half (12,500 shares) on the six month anniversary of the date of grant and vesting one-half (12,500 shares) on the eighteen month anniversary of the date of grant.

(20)

Pursuant to the applicable option agreement, the expiration date of the options is four years from the date of vesting, such that options to purchase 12,500 shares expire on each of February 18, 2019 and February 18, 2020.

(21)

On April 15, 2016, Dr. Terrell was granted an option to purchase 25,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

(22)

On August 17, 2015, Mr. Kratochvil was granted an option to purchase 75,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the date of grant.

(23)

On September 13, 2016, Mr. Kratochvil was granted an option to purchase 25,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

### Long-Term Incentive Plans

As at December 31, 2016 and 2015, there were no arrangements or plans in which VolitionRx, Singapore Volition or its subsidiaries provided pension, retirement or similar benefits for directors or executive officers.

### Compensation of Directors

The following table sets forth the compensation paid to the non-employee directors of VolitionRx for the fiscal year ended December 31, 2016. No executive officer is paid compensation for his role as a director. There are no employment agreements by and between the Company and the non-employee directors. See the sections entitled *Executive Compensation Summary Compensation Table* for additional information on the compensation paid to executive officers who were also directors.

#### Director Compensation Table

| Name                              | Fees                   | Stock Awards | Option Awards <sup>(1)</sup> | Non-Equity Incentive Plan Compensation | Nonqualified Deferred Compensation Earnings | All Other Compensation | Total   |
|-----------------------------------|------------------------|--------------|------------------------------|--|---|------------------------|---------|
|                                   | Earned or Paid in Cash |              |                              |  |   |                        |         |
|                                   | (\$)                   | (\$)         | (\$)                         | (\$)                                   | (\$)  | (\$)                   | (\$)    |
| Guy Innes <sup>(2)</sup>          | 40,000                 | -0-          | 62,858                       | -0-                                    | -0-   | -0-                    | 102,858 |
| Dr. Martin Faulkes <sup>(3)</sup> | 151,831                | -0-          | 137,924                      | -0-                                    | -0-   | -0-                    | 289,755 |
| Dr. Alan Colman <sup>(4)</sup>    | 60,000                 | -0-          | 40,265                       | -0-                                    | -0-   | -0-                    | 100,265 |
| Dr. Habib Skaff <sup>(5)</sup>    | 40,000                 | -0-          | 32,963                       | -0-                                    | -0-   | -0-                    | 72,963  |
| Dr. Edward Futcher <sup>(6)</sup> | 20,000                 | -0-          | 17,759                       | -0-                                    | -0-   | -0-                    | 37,759  |

(1)

All option awards have been calculated based upon the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in note <sup>(6)</sup> below for Dr. Futcher and in *Item 11*, note <sup>(7)</sup> to the Summary Compensation Table for all other directors.





(2)

On March 31, 2015 Mr. Innes entered into an Independent Director Agreement with VolitionRx, or the Innes Independent Director Agreement, pursuant to which Mr. Innes will continue to serve as a member of the Board of VolitionRx subject to any necessary approval by the Company's stock holders as required by applicable law and VolitionRx's governing documents. In exchange for his services Mr Innes shall receive \$10,000 per calendar quarter commencing March 1, 2015. The foregoing description of the Innes Independent Director Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.23.

On April 15, 2016, Mr. Innes was granted an option to purchase 30,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

Effective May 4, 2016, the warrant to purchase 74,821 shares of common stock granted to Mr. Innes on May 11, 2012, was amended to extend the original exercise period by one year from May 10, 2016 to May 10, 2017.

(3)

On March 31, 2015, Dr. Faulkes entered into an Executive Chairman Agreement with VolitionRx, or the Faulkes Executive Chairman Agreement, pursuant to which Dr. Faulkes will continue to serve as a member of the Board and as Executive Chairman of the Board of VolitionRx subject to any necessary approval by the Company's stockholders as required by applicable law and VolitionRx's governing documents. In exchange for his services Dr. Faulkes shall receive £8,333 GBP per month (approximately \$10,280) commencing March 1, 2015. The foregoing description of the Faulkes Executive Chairman Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.21. On May 11, 2016, the Compensation Committee approved an amendment to the Faulkes Executive Chairman Agreement, or Amended Faulkes Executive Chairman Agreement. The Amended Faulkes Executive Chairman Agreement provides that Dr. Faulkes shall receive £10,000 GBP per month (approximately \$12,336) in exchange for his services. The foregoing description of the Amended Faulkes Executive Chairman Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.22.

On April 15, 2016, Dr. Faulkes was granted an option to purchase 65,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

Effective May 4, 2016, the warrant to purchase 58,034 shares of common stock granted to Dr. Faulkes on May 11, 2012, was amended to extend the original exercise period by one year from May 10, 2016 to May 10, 2017.

(4)

On March 31, 2015, Dr. Colman entered into an Independent Director Agreement with VolitionRx, or the Colman Independent Director Agreement, pursuant to which Dr. Colman will continue to serve as a member of the Board of VolitionRx subject to any necessary approval by the Company's stock holders as required by applicable law and VolitionRx's governing documents. In exchange for his services Dr. Colman shall receive \$15,000 per calendar quarter commencing March 1, 2015. The foregoing description of the Colman Independent Director Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.23.

On April 15, 2016, Dr. Colman was granted an option to purchase 20,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

Effective May 4, 2016, the warrant to purchase 13,000 shares of common stock granted to Dr. Colman on May 11, 2012, was amended to extend the original exercise period by one year from May 10, 2016 to May 10, 2017.

(5)

On March 31, 2015, Dr. Skaff entered into an Independent Director Agreement with VolitionRx, or the Skaff Independent Director Agreement, pursuant to which Dr. Skaff will continue to serve as a member of the Board of VolitionRx subject to any necessary approval by the Company's stock holders as required by applicable law and VolitionRx's governing documents. In exchange for his services Dr. Skaff shall receive \$10,000 per calendar quarter commencing March 1, 2015. The foregoing description of the Skaff Independent Director Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.23.

On April 15, 2016, Dr. Skaff was granted an option to purchase 15,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant.

Effective May 4, 2016, the warrant to purchase 3,143 shares of common stock granted to Dr. Skaff on May 11, 2012, was amended to extend the original exercise period by one year from May 10, 2016 to May 10, 2017.

(6)

On June 23, 2016 Dr. Futcher entered into an Independent Director Agreement with VolitionRx, or the Futcher Independent Director Agreement, pursuant to which Dr. Futcher will continue to serve as a member of the Board of VolitionRx subject to any necessary approval by the Company's stock holders as required by applicable law and VolitionRx's governing documents. In exchange for his services Dr. Futcher shall receive \$10,000 per calendar quarter commencing June 23, 2016. The foregoing description of the Futcher Independent Director Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.23.

On June 23, 2016, Dr. Futcher was granted an option to purchase 15,000 shares of common stock of VolitionRx under the 2015 Plan, vesting in full on the twelve month anniversary of the date of grant. The option expires five years after the vesting date and has an exercise price of \$4.00.

The Company has calculated the estimated fair market value of these options granted on June 23, 2016 using the Black-Scholes Option Pricing model and the following assumptions: term 6 years, stock price \$3.35, exercise price \$4.00, 83.11% volatility, 1.25% risk free rate.

#### **Security Holders Recommendations to Board of Directors**

Stockholders can direct communications to our Secretary, Rodney Rootsart, at our executive offices. However, while we appreciate all comments from stockholders, we may not be able to individually respond to all communications. We attempt to address stockholder questions and concerns in our press releases and documents filed with the SEC so that all stockholders have access to information about us at the same time. Mr. Rootsart collects and evaluates all stockholder communications. All communications addressed to our directors and executive officers will be reviewed by those parties unless the communication is clearly frivolous.

**ITEM 12.****SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***Security Ownership of Management*

The following table sets forth certain information concerning the number of shares of our common stock owned beneficially as of March 10, 2017, by: (i) each of our directors and director nominees; (ii) each of our named executive officers; (iii) all of our directors, director nominees and executive officers as a group; and (iv) each person or group known by us to beneficially own more than 5% of our outstanding shares of common stock.

We have determined beneficial ownership in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under the rules of the SEC, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of such security, or investment power, which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which the person has a right to acquire beneficial ownership within sixty (60) days. Under these rules more than one person may be deemed a beneficial owner of the same securities and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest.

Unless otherwise indicated below, to the best of our knowledge (i) each beneficial owner named in the table has the sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable, and (ii) the address of such beneficial owner is 1 Scotts Road, #24-05 Shaw Centre, Singapore, 228208.

| <b>Name and Address of Beneficial Owner</b>    | <b>Amount and Nature Of</b> | <b>Percent of Class</b> |
|--|-----------------------------|-------------------------|
|  | <b>Beneficial Ownership</b> | <b>(1)</b>              |
|  | <b>(#)</b>                  | <b>(%)</b>              |
| <b>Directors and Named Executive Officers:</b> |                             |                         |
| Dr. Alan Colman <sup>(2)</sup>                 | 219,699                     | *                       |
| Dr. Martin Faulkes <sup>(3)</sup>              | 1,892,284                   | 7.2%                    |
| Dr. Edward Futcher <sup>(4)</sup>              | 383,000                     | 1.5%                    |
| Guy Innes <sup>(5)</sup>                       | 1,581,947                   | 6.0%                    |
| David Kratochvil <sup>(6)</sup>                | 85,000                      | *                       |
| Dr. Jacob Micallef <sup>(7)</sup>              | 555,569                     | 2.1%                    |

Edgar Filing: VOLITIONRX LTD - Form 10-K

|  |           |       |
|--|-----------|-------|
| Cameron Reynolds <sup>(8)</sup>  | 2,512,837 | 7.2%  |
| Rodney Rootsart <sup>(9)</sup>   | 1,208,916 | 4.6%  |
| Habib Skaff <sup>(10)</sup>  | 85,542    | *     |
| Jason Terrell <sup>(11)</sup>  | 111,364   | *     |
| Other Executive Officers <sup>(12)</sup>                                     | 991,765   | 3.7%  |
| All Executive Officers and Directors as a Group (18 Persons) <sup>(13)</sup> | 8,267,386 | 28.8% |
| <b>5% Stockholders:</b>  |           |       |
| Cotterford Company Limited <sup>(14)</sup>                                   | 1,447,616 | 5.5%  |
| Hever Investments Limited  |           |       |
| Alma House, 7 Circular Road, Douglas   |           |       |
| Isle of Man, IM1 1AF   |           |       |
| United Kingdom   |           |       |
| Richard Bayles <sup>(15)</sup>   | 3,074,406 | 11.8% |
| Fatina Dickey  |           |       |
| Youngdawn Ha   |           |       |
| Lagoda Investment Management, L.P.   |           |       |
| 3 Columbus Circle  |           |       |
| New York, New York   |           |       |

(1)

For purposes of the table, the percent of class is based upon 26,128,049 shares of our common stock issued and outstanding as of March 10, 2017. Shares of common stock subject to stock purchase options or warrants currently exercisable, or exercisable within 60 days of March 10, 2017, are deemed beneficially owned and outstanding for computing the percentage of the person or entity holding such securities, but are not considered outstanding for computing the percentage of any other person or entity.

(2)

Dr. Colman's beneficial ownership includes direct ownership of (i) 156,699 shares of common stock; (ii) options to purchase 50,000 shares of common stock that are exercisable within 60 days; and (iii) warrants to purchase 13,000 shares of common stock that are exercisable within 60 days.

(3)

Dr. Faulkes' s beneficial ownership includes direct ownership of (i) 1,293,250 shares of common stock; (ii) options to purchase 185,000 shares of common stock that are exercisable within 60 days; and (iii) warrants to purchase 58,034 shares of common stock that are exercisable within 60 days. Dr. Faulkes' s beneficial ownership also includes indirect ownership of 356,000 shares of common stock held directly by The Dill Faulkes Educational Trust Limited, or DFET. Dr. Faulkes serves as the chairman, director and trustee of the DFET and shares voting and dispositive control over such shares. On December 8, 2015, Dr. Faulkes pledged 12,500 shares to secure a loan.

(4)

Dr. Futcher' s beneficial ownership includes direct ownership of 27,000 shares of common stock. Dr. Futcher' s beneficial ownership also includes indirect ownership of 356,000 shares of common stock held directly by DFET. Dr. Futcher serves as a director and a trustee of DFET and shares voting and dispositive control over such shares.

(5)

Mr. Innes' s beneficial ownership includes direct ownership of (i) 1,230,154 shares of common stock; (ii) options to purchase 95,000 shares of common stock that are exercisable within 60 days; and (iii) warrants to purchase 207,067 shares of Company common stock that are exercisable within 60 days. Mr. Innes' s beneficial ownership also includes indirect ownership of (x) 47,940 shares of Company common stock and (y) warrants to purchase 1,786 shares of Company common stock that are exercisable within 60 days, each held in a bare trust, which is not a separate legal entity, of which Mr. Innes is the trustee, for the benefit of certain minors.

(6)

Mr. Kratochvil' s beneficial ownership includes direct ownership of (i) 10,000 shares of common stock and (ii) options to purchase 75,000 shares of common stock that are exercisable within 60 days.

(7)

Dr. Micallef' s beneficial ownership includes direct ownership of (i) 86,166 shares of common stock and (ii) warrants to purchase 10,000 shares of common stock that are exercisable within 60 days. Dr. Micallef' s beneficial ownership also includes indirect ownership of (v) 11,000 shares of common stock held directly by Dr. Micallef' s wife, (w) 38,113 shares of common stock held directly by Borlaug, which Dr. Micallef shares voting and dispositive control over, (x) warrants held directly by Dr. Micallef' s wife to purchase 11,000 shares of common stock that are exercisable within 60 days, (y) warrants held directly by Borlaug to purchase 9,290 shares of common stock that are exercisable within 60 days, and (z) options held directly by Borlaug to purchase 390,000 shares of common stock that are exercisable within 60 days.

(8)

Mr. Reynolds' s beneficial ownership includes direct ownership of (i) 1,114,673 shares of common stock and (ii) options to purchase 360,000 shares of common stock that are exercisable within 60 days. Mr. Reynolds' s beneficial ownership also includes indirect ownership of (x) 34,076 shares of common stock held directly by Mr. Reynolds' s spouse and (y) 1,004,088 shares of common stock held directly by Concord International, Inc., of which Mr. Reynolds' s is the majority shareholder and shares voting and dispositive control over such shares.

(9)

Mr. Rootsart's beneficial ownership includes direct ownership of (i) 4,828 shares of common stock and (ii) options to purchase 200,000 shares of common stock that are exercisable within 60 days. Mr. Rootsart's beneficial ownership also includes indirect ownership of 1,004,088 shares of common stock beneficially owned by Concord International, Inc., for which Mr. Rootsart serves as a controlling director and shares voting and dispositive control over such shares.

(10)

Dr. Skaff's beneficial ownership includes direct ownership of (i) 16,399 shares of common stock; (ii) options to purchase 66,000 shares of common stock that are exercisable within 60 days; and (iii) warrants to purchase 3,143 shares of common stock that are exercisable within 60 days.

(11)

Dr. Terrell's beneficial ownership includes direct ownership of (i) 61,364 shares of common stock and (ii) options to purchase 50,000 shares of common stock that are exercisable within 60 days.

(12)

The other executive officers of the Company have beneficial ownership of 211,722 shares of common stock, 774,634 shares issuable upon the exercise of stock purchase options, and 5,409 shares issuable upon the exercise of stock purchase warrants.

(13)

The amount beneficially owned by the executive officers, directors and director nominees as a group consists of an aggregate of 5,703,023 shares of common stock, 2,225,634 shares issuable upon the exercise of stock purchase options, and 338,729 shares issuable upon the exercise of stock purchase warrants.

(14)

Cotterford Company Limited and Hever Investments Limited together beneficially own 1,143,463 shares of common stock, and 304,153 shares issuable upon the exercise of stock purchase warrants. Jack Murphy holds dispositive and voting control over the shares of common stock beneficially owned by both Cotterford Company Limited and Hever Investments Limited.

(15)

This information has been derived from Schedules 13G and 13G/A filed with the SEC on January 24, 2017. Based on the information contained in the filing, Lagoda Investment Management, L.P. serves as the investment manager to certain managed accounts, and Richard Bayles, Fatima Dickey and Youngdawn Daniel Ha, as the managing principals of Lagoda Investment Management, LLC, the General Partner of Lagoda Investment Management, L.P. possess sole voting and dispositive power with respect to the common stock.

### ***Changes in Control***

There are no present arrangements or pledges of the Company's securities which may result in a change in control of the Company, other than as previously disclosed.





*Securities Authorized for Issuance Under Equity Compensation Plans*

Under the 2015 Plan, we may grant incentive awards, including options, restricted stock, stock bonuses, stock appreciation rights, restricted stock units or performance awards, to any qualified employee, officer, director, consultant or other service provider that provides services to us or any of our affiliates. An aggregate of 1,750,000 shares of our common stock are reserved for issuance under the 2015 Plan. The purpose of the 2015 Plan is to provide additional incentives to eligible participants to devote their utmost effort and skill to the advancement and betterment of the registrant, by providing them an opportunity to participate in the ownership of the registrant and thereby have an interest in the success and increased value of the Company. The 2015 Plan replaces the 2011 Plan which was also approved by the stockholders. No further grants will be made under the 2011 Plan.

| <b>Plan category</b>                                       | <b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b> | <b>Weighted-average price of outstanding options, warrants and rights</b> | <b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</b> |
|--|--|---|--|
| <b>(a)</b>   | <b>(b)</b>   |   | <b>(a)</b>   |
| Equity compensation plans approved by security holders:    |  |   |  |
| - 2011 Equity Incentive Plan                               | 1,554,300  | \$3.59  | -0-  |
| - 2015 Stock Incentive Plan                                | 900,000  | \$4.10  | 850,000  |
| Equity compensation plans not approved by security holders | -0-  | -0-   | -0-  |
| Total  | 2,454,300  | \$3.78  | 850,000  |



**ITEM 13.**

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

See *Item 9B. Other Information* of this report.

On May 11, 2016, Singapore Volition entered into a consultancy agreement with PB Commodities Pte Limited, or PB Commodities for the services of Cameron Reynolds, or the 2016 PB Commodities Consultancy Agreement. Under the terms of the 2016 PB Commodities Consulting Agreement, PB Commodities shall receive \$25,925 per month for the services provided to Singapore Volition by Mr. Reynolds on its behalf. The foregoing description of the 2016 PB Commodities Consultancy Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.5 filed herewith. The 2016 PB Commodities Consultancy Agreement replaced the PB Commodities Consulting Agreement, dated August 6, 2010, as amended, or Prior PB Commodities Consultancy Agreement. The foregoing description of the Prior PB Commodities Consulting Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.4.

On May 2, 2014, VolitionRx entered into a consultancy agreement with Isosceles Finance Limited, or Isosceles, a consulting services company founded by VolitionRx's then-current Chief Financial Officer Mike O'Connell, for the provision of accountancy and financial control services, or the Isosceles Consultancy Agreement. The initial term of the Isosceles Consultancy Agreement was for twelve (12) months, with automatic extensions for successive twelve (12) month periods until terminated as provided in the Agreement. While Mr. O'Connell ceased serving as VolitionRx's Chief Financial Officer in August 2015, the Isosceles Consultancy Agreement continues in place. The services are provided on a time and materials basis. For the years ended December 31, 2015 and 2016, Isosceles received £155,287 GBP (\$239,429) and £203,788 GBP (\$273,507), respectively, pursuant to the Isosceles Consultancy Agreement. The foregoing description of the Isosceles Consultancy Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.26.

As part of the engagement letters with each of our directors, certain indemnification provisions may require us, among other things, to indemnify our directors and executive officers for expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers.

Other than the foregoing, none of the directors or executive officers of the Company, nor any person who owned of record or was known to own beneficially more than 5% of the Company's outstanding shares of its Common Stock, nor any associate or affiliate of such persons or companies, has any material interest, direct or indirect, in any transaction that has occurred during the past two fiscal years, or in any proposed transaction, which has materially affected or will affect the Company.

## **Director Independence**

For purposes of determining director independence, the Board of Directors reviews a summary of the relationships of each director with the Company and other facts relevant to the analysis of whether the directors qualify as independent directors under the NYSE MKT Company Guide §803(A)(2). No director qualifies as independent unless the Board of Directors affirmatively determines that the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In addition, the NYSE MKT Company Guide provides a non-exclusive list of persons who may not be considered independent.

The Board of Directors has affirmatively determined that each of Drs. Colman, Fatcher and Skaff, as well as Mr. Innes, is an independent director under the rules of the NYSE MKT. In addition, the members of the Audit Committee are independent directors pursuant to the heightened independence criteria for members of Audit Committees set forth in SEC rules.

## **Policy on the Review, Approval or Ratification of Transactions with Related Persons**

The Company has not adopted a separate written policy for the approval or ratification of all transactions with related parties that are required to be reported under Item 404(a) of Regulation S-K. Rather, at this time and pursuant to its existing charter, and unless otherwise provided by the Board of Directors, the Audit Committee of the Board of Directors reviews the material facts of all such transactions and either ratifies, approves or disapproves of the entry into the transaction.

No director is allowed to participate in the approval of a transaction for which he or she is a related party and the director has to provide all material information concerning the transaction to the Audit Committee.

**ITEM 14.****PRINCIPAL ACCOUNTANT FEES AND SERVICES**

|                    | <b>Year Ended</b>        |               | <b>Year Ended</b>        |               |
|--------------------|--------------------------|---------------|--------------------------|---------------|
|                    | <b>December 31, 2016</b> |               | <b>December 31, 2015</b> |               |
| Audit fees         | \$                       | 39,000        | \$                       | 37,660        |
| Audit-Related fees | \$                       | 1,240         | \$                       | 6,700         |
| Tax fees           | \$                       | 4,250         | \$                       | 8,886         |
| All other fees     | \$                       | -0-           | \$                       | -0-           |
| <b>Total</b>       | <b>\$</b>                | <b>44,490</b> | <b>\$</b>                | <b>53,246</b> |

***Audit Fees***

Represents the aggregate fees billed to us for each of the last two fiscal years for professional services rendered by the principal accountant for the audit of our annual financial statements and review of financial statements included in our Form 10-Q or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagement for those fiscal years.

***Audit-Related Fees***

Represents the aggregate fees billed to us in each of the last two fiscal years for assurance and related services by the principal accountants that are reasonably related to the performance of the audit or review of our financial statements that are not already reported in Audit Fees. These services include accounting consultations and attestation services that are not required by statute.

***Tax Fees***

Represents the aggregate fees billed to us in each of the last two fiscal years for professional services rendered by the principal account for tax compliance, tax advice, and tax planning.

*All Other Fees*

Represents the aggregate fees billed in each of the last two fiscal years for products and services provided by the principal accountant to us, excluding those enumerated above.

**Policy on Audit Committee Pre-approval of Audit and Permissible Non-audit Services of Independent Auditor**

All audit and non-audit services by our independent registered public accounting firm are pre-approved by our audit committee. For audit services, the independent accountant provides the Audit Committee with an audit plan, including proposed fees in advance of the annual audit. The audit committee approves the plan and fees for the audit.

Pursuant to its charter, the audit committee may establish pre-approval policies and procedures, subject to SEC and NYSE MKT rules and regulations, to approve audit and non-audit services; however, it has not yet done so.

**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.*

| <b>Exhibit<br/>Number</b> | <b>Exhibit Description</b>   | <b>Form</b> | <b>Incorporated by Reference</b> |                |                        | <b>Filed<br/>Herewith</b> |
|---------------------------|--|-------------|----------------------------------|----------------|------------------------|---------------------------|
|                           |  |             | <b>File No.</b>                  | <b>Exhibit</b> | <b>Filing<br/>Date</b> |                           |
| 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                |                           |

Edgar Filing: VOLITIONRX LTD - Form 10-K

|       |   |       |            |       |          |
|-------|---|-------|------------|-------|----------|
| 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 its Shareholders dated September 27, 2011.  | 8-K/A | 000-30402  | 10.28 | 4/5/12   |
| 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 Nucleosomic <sup>TM</sup> 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# | Agreement by and between Singapore Volition and PB Commodities dated August 6, 2010.  | 8-K/A | 000-30402  | 10.07 | 1/11/12  |
| 10.5# | Consultancy Agreement by and between Singapore Volition and PB Commodities, dated May 11, 2016.   | 10-Q  | 001-36833  | 10.2  | 5/13/16  |





| Exhibit Number | Exhibit Description   | Incorporated by Reference |            |         | Filing Date | Filed Herewith |
|----------------|---|---------------------------|------------|---------|-------------|----------------|
|                |   | Form                      | File No.   | Exhibit |             |                |
| 10.6           | 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     |                |
| 10.7           | 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     |                |
| 10.8           | 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     |                |
| 10.9#          | Agreement by and between HyperGenomics and PB Commodities dated October 1, 2011.                                      | 8-K/A                     | 000-30402  | 10.27   | 2/24/12     |                |
| 10.10          | 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     |                |
| 10.11          | 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     |                |
| 10.12#         | Consultancy Agreement by and between PB Commodities and Cameron Reynolds effective as of January 1, 2015.             | S-1/A                     | 333-200628 | 10.25   | 1/8/15      |                |
| 10.13#         | Executive Employment Agreement by and between VolitionRx and Cameron Reynolds effective as of January 1, 2015.        | S-1/A                     | 333-200628 | 10.26   | 1/23/15     |                |

Edgar Filing: VOLITIONRX LTD - Form 10-K

|           |   |       |            |       |          |
|-----------|---|-------|------------|-------|----------|
| 10.14#    | Consultancy Agreement by and between VolitionRx and Borlaug dated as of January 1, 2015.            | S-1/A | 333-200628 | 10.27 | 1/23/15  |
| 10.15#    | First Amendment to Consultancy Agreement by and between VolitionRx and Borlaug, dated May 11, 2016. | 10-Q  | 001-36833  | 10.3  | 5/13/16  |
| 10.16#    | Employment Agreement by and between VolitionRx and Rodney Rootsart effective as of January 1, 2015. | S-1/A | 333-200628 | 10.28 | 1/23/15  |
| 10.17#    | Employment Agreement by and between VolitionRx and Jason Terrell MD, dated December 29, 2015.       | 10-K  | 001-36833  | 10.24 | 3/11/16  |
| 10.18#    | Employment Agreement by and between VolitionRx and David Kratochvil dated August 11, 2015.          | 10-K  | 001-36833  | 10.25 | 3/11/16  |
| 10.19#    | 2011 Equity Incentive Plan dated November 17, 2011.   | 8-K   | 000-30402  | 4.01  | 11/18/11 |
| 10.19(a)# | Form Stock Option Agreement.  | 8-K   | 000-30402  | 4.02  | 11/18/11 |
| 10.19(b)# | Form Stock Award Agreement for Restricted Stock.  | 8-K   | 000-30402  | 4.03  | 11/18/11 |

| Exhibit Number | Exhibit Description  | Incorporated by Reference |            |         | Filing Date | Filed Herewith |
|----------------|--|---------------------------|------------|---------|-------------|----------------|
|                |  | Form                      | File No.   | Exhibit |             |                |
| 10.20#         | 2015 Stock Incentive Plan, as amended.   | S-8                       | 333-214118 | 10.1    | 10/14/16    |                |
| 10.20(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    |                |
| 10.20(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    |                |
| 10.20(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    |                |
| 10.20(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    |                |
| 10.20(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    |                |
| 10.20(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    |                |
| 10.21#         | Faulkes Executive Chairman Agreement with VolitionRx dated March 31, 2015.   | 10-Q                      | 001-36833  | 10.32   | 5/12/15     |                |

Edgar Filing: VOLITIONRX LTD - Form 10-K

|        |   |       |            |       |          |   |
|--------|---|-------|------------|-------|----------|---|
| 10.22# | First Amendment to Executive Chairman's Agreement between VolitionRx and Dr. Faulkes, dated May 11, 2016.   | 10-Q  | 001-36833  | 10.1  | 5/13/16  |   |
| 10.23# | Independent Director Agreement.   | 10-Q  | 001-36833  | 10.33 | 5/12/15  |   |
| 10.24  | 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 |   |
| 10.25  | 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 |   |
| 10.26  | Agreement by and between VolitionRx and Isosceles dated May 2, 2014.  | S-1/A | 333-200628 | 10.30 | 1/23/15  |   |
| 10.27# | Employment Agreement by and between Volition Diagnostics UK Limited and Cameron Reynolds, dated March 7, 2017.  |       |            |       |          | X |
| 10.28# | Employment Agreement by and between Volition Diagnostics UK Limited and Jacob Micallef, dated March 7, 2017.  |       |            |       |          | X |

| Exhibit<br>Number | Exhibit Description  | Form | Incorporated by Reference |         |                | Filed<br>Herewith |
|-------------------|--|------|---------------------------|---------|----------------|-------------------|
|                   |  |      | File<br>No.               | Exhibit | Filing<br>Date |                   |
| 10.29#            | Employment Agreement by and between Volition Diagnostics UK Limited and Rodney Rootsart, dated March 7, 2017.  |      |                           |         |                | X                 |
| 10.30#            | Employment Agreement by and between Volition Diagnostics UK Limited and Martin Faulkes, dated March 7, 2017.   |      |                           |         |                | X                 |
| 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   |      |                           |         |                | X                 |

18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

|         |   |   |
|---------|---|---|
| 101.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.

## 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 10, 2017

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 Rootsart, 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.

| <u>Signature</u>              | <u>Title</u>                                    | <u>Date</u>    |
|-------------------------------|---|----------------|
| <u>/s/ Cameron Reynolds</u>   | President, Chief Executive Officer and Director | March 10, 2017 |
| Cameron Reynolds              | (Principal Executive Officer)                   |                |
| <u>/s/ David Kratochvil</u>   | Chief Financial Officer and Treasurer           | March 10, 2017 |
| David Kratochvil              | (Principal Financial and Accounting Officer)    |                |
| <u>/s/ Dr. Martin Faulkes</u> | Director  | March 10, 2017 |



Dr. Martin Faulkes

/s/ Guy Innes

Director

March 10, 2017

Guy Innes

/s/ Dr. Alan Colman

Director

March 10, 2017

Dr. Alan Colman

/s/ Dr. Habib Skaff

Director

March 10, 2017

Dr. Habib Skaff

/s/ Dr. Edward Futcher

Director

March 10, 2017

Dr. Edward Futcher