VOLITIONRX LTD
Form 10-K
March 11, 2016

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, 2015

. **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	**91-1949078**
(State or other jurisdiction of incorporation or organization)	(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:

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 X . No .

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

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

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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, 2015, the aggregate market value of the voting common stock held by non-affiliates of the registrant was $50,777,898 (based upon the $3.95 closing price for shares of the registrant s common stock as reported by the NYSE MKT, on June 30, 2015, the last trading date of the registrant s most recently completed second fiscal quarter).

As of March 11, 2016, there were approximately 18,863,272 shares of the registrant s common stock, $0.001 par value, outstanding.

Documents incorporated by reference: None

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2015, 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; statements concerning industry trends; statements regarding anticipated demand for our products, or the products of our competitors, statements relating to manufacturing forecasts, and the potential impact of our relationship with contract manufacturers and original equipment manufacturers on our business; assumptions regarding the future cost and potential benefits of our research and development efforts; 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, us and VNRX are references to VolitionRx Limited and its wholly-owned subsidiaries, Singapore Volition Pte. Ltd, Belgian Volition S.A., Hypergenomics Pte Ltd. and Volition Diagnostics UK Limited. Additionally, unless otherwise specified, all references to USD, United States Dollars or $ refer to the legal currency of the United States of America

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 SA, a Belgium registered 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 one subsidiary, Volition Diagnostics UK Limited, which it formed on November 13, 2015.

Our principal executive office is located at 1 Scotts Road, #24-05 Shaw Centre, Singapore 228208. Our telephone number is +1 (646) 650-1351. Our website is located at *www.volitionrx.com*. The information that can be accessed through our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part hereof.

BUSINESS

Description of Our Business

We are a clinical-stage life sciences company focused on developing blood-based diagnostic tests that meet the need for accurate, fast, cost effective and scalable tests for detecting and diagnosing cancer and other diseases. We have developed twenty eight 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 test for a particular cancer or disease. We intend to commercialize our products in the future through various channels within the European Union, the United States and throughout the rest of the world likely beginning with China and India.

We are developing blood-based diagnostics for the most prevalent cancers, beginning with colorectal, lung, and pancreatic cancer, using our Nucleosomics® biomarker discovery platform. The platform employs a range of simple NuQ® 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. NuQ® biomarkers can be used alone, or in combination to generate profiles related to specific conditions. The first tranche of data released from a large independent trial for colorectal cancer could, if carried through into our screening or symptomatic trials, potentially have a positive impact for broad scale, cost effective, cancer diagnostics. According to available data from the Organisation for Economic Co-operation and Development, this could be of significant benefit to the approximately 148 million 50-74 year olds in the European Union alone that the European Union recommends are screened for colorectal cancer. [1]

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 believe our blood test for colorectal cancer has the potential to have significantly higher compliance from patients compared to fecal tests and colonoscopies which are invasive and/or unpleasant.

We undertook our early trials in Europe given that our laboratories are based in Belgium and that we have strong relationships with world class collaborators. Hvidovre Hospital in Denmark has given us access to 4,800 previously collected samples from patients for our retrospective symptomatic colorectal trial and a further 14,000 samples are being collected over 24 months from August 2014, from patients for our prospective screening colorectal trial. 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, including our funding from the Walloon Region.

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[1] European guidelines for quality assurance in colorectal cancer screening and diagnosis; first Ed. Segnan N, Patnick J, von Karsa L (eds), 2010

In 2015, we decided to completely focus our efforts on the clinical in-vitro diagnostics, or IVD, market, where products are used for patient diagnosis and can only be accessed after a test has either been approved for clinical use in the United States by the United States Food and Drug Administration, or the FDA, or for risk assessment as a Laboratory Developed Test, or LDT, in the United States under a Clinical Laboratory Improvement Amendments, or CLIA, waiver. A similar system operates in China through the Chinese Food and Drug Administration, or CFDA. In the European Union, approval is obtained by 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 certification in September 2015, for a single biomarker for colorectal cancer, or CRC, and plan to certify two new biomarkers quarterly in 2016 as well as our symptomatic diagnostic panel test for CRC. We expect that we will be required to do further United States trials to achieve FDA approval for our CRC test both as an adjunct test as a 510(k) application and under a Premarket Approval, or PMA, as a screening test . We are committed to filing for FDA approval to allow patient access to our tests in the United States as soon as practicable. We intend to begin 510(k) purposed U.S. based trials in 2016 and pursue FDA clearance as an adjunct test in 2017 for CRC and for lung and pancreatic cancer in 2018. We intend to begin PMA purposed U.S. based trials in 2016 or 2017 and pursue FDA approval upon completion.

We also expect that we will be required to do trials in China to achieve CFDA approval for our lung cancer test, 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 colorectal cancer test in India for the private payer market. We plan to seek distribution partners for the major Asian markets in 2016.

Our Nucleosomics® biomarker platform is a technology that can be used for a wide variety of cancers. We are currently developing Nucleosomics® tests for a number of major cancers including colorectal, pancreatic, lung and aggressive prostate. We have one trial underway in the United States with MD Anderson Cancer Center in Texas, to establish the efficacy of Nucleosomics® in a precision medicine application to differentiate between the more aggressive anaplastic prostate cancer, and the typical, less-aggressive castration resistant prostate cancer. We are also validating the use of our tests for early diagnosis of endometriosis, a benign but often debilitating condition, and the leading cause of admissions to hospital for abdominal pain. Endometriosis affects approximately 10% of women and is a leading cause of female infertility [2]. At present, there are no non-surgical diagnostic tests for endometriosis.

The Market

Cancer is one of the leading causes of death worldwide, accounting for around 8.2 million annual deaths globally.[3] In the United States alone, there were an estimated 13.8 million cancer survivors in 2010.[4] By 2020, this figure is expected to rise to 18.1 million. The Agency for Healthcare research and Quality, or AHRQ, estimated the health economic burden for cancer relating to direct medical costs at approximately $88.7 billion for 2011.[5] The annualized cost of cancer care based on analysis of Medicare payments linked to Surveillance, Epidemiology, and End Results, or

SEER, Program data is projected to reach $157 billion at 2020.[6] These figures are mirrored across the globe and we expect will continue to grow as populations age. This is a large potential addressable market for which we believe diagnostics will be 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.[7] The Pap test has had a similar impact in improving 5-year survival rates in women with precancerous and cancerous cervical lesions.[8]

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[2] American Society for Reproductive Medicine Fact sheet: Endometriosis - A Guide for Patients [accessed 01/28/2016]

[3] Cancer - Fact sheet N°297, World Health Organization, [accessed 01/28/2016]

[4] Mariotto AB et al., Projections of the cost of cancer care in the United States: 2010-2020. Jan 19, 2011, JNCI, Vol 103, No.2 [accessed 01/28/2016]

[5] American Cancer Society, Economic Impact of Cancer, 02/06/2015 [accessed 01/28/2016]

[6] Projections of the cost of cancer care in the United States: 2010-2020 [accessed 01/28/2016]

[7] American Cancer Society, Colorectal Cancer Facts & Figures 2011-2013 [accessed 01/28/2016]

[8] National Cancer Institute Fact Sheet: Cervical Cancer Screening (PDQ®) [accessed 01/28/2016]

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 commonly used blood-screening test for 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 about 30% of healthy men as positive for cancer) but is widely used because it is the best product currently available.[9] 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.[10] 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.[11] There are currently no commonly used blood tests for screening for lung, pancreatic or colorectal cancer.

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 colorectal cancer 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.[12] 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,[13] driven by the increasing health care demands of an aging population. In the United States,[14] the IVD market is made up of:

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Immunochemistry of tissue samples (expected to grow 6.8% per annum from 2011-2018, with an expected value of $25.5 billion by 2018).[15] These are mostly used to confirm cancer diagnosis post-surgery and to determine cancer sub-type;

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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.[16] These tests are mostly used to monitor for disease progress and relapse. This market segment includes our future Nucleosomics® products, which will be blood immunoassay tests for modified histones for the diagnosis of cancer.

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[9] National Cancer Institute Fact Sheet: Prostate-Specific Antigen (PSA) Test, [24 July 2012] [accessed 01/28/2016]

[10] Wolf. A *et. al.* American Cancer Society Guideline for the Early Detection of Prostate Cancer: Update 2010, CA: A Cancer Journal for Clinicians; 3 Mar 2010:60;2:70-98 [accessed 01/28/2016]

[11] U.S. Preventative Services Task Force, Final Recommendation Statement Prostate Cancer: Screening, May 2012 [accessed 01/28/2016]

[12] American Cancer Society. Colorectal Cancer survival rates, by stage, 2014 [accessed 01/28/2016]

[13] Kalorama Report: The Worldwide Market for In Vitro Diagnostic (IVD) Tests, 9th Edition, August 13, 2014 [accessed 01/28/2016]

[14] Kalorama Report: The United States Market for In Vitro Diagnostic Tests

Mar 18, 2014 [accessed 01/28/2016]

[15] GBI Research Report: In Vitro Diagnostics Market to 2018 - Consolidation, Decentralization and Demand for Genetic Testing to Shape the Competitive Landscape, March 23, 2012 [accessed 11.12.2014]

[16] Markets and Markets Report: Immunoassay Market [Technology (Enzyme, Fluorescent, Chemiluminescence, Radioimmunoassay), Analyzers & Reagents, Applications (Infectious Diseases, Cancer, Endocrinology, Cardiology), End Users (Hospitals, Laboratory, Academics)] - Global Forecast to 2019, May, 2015 [accessed 01/28/2016]

Testing is carried out at three principal locations:[17]

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

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

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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/or CFDA approval in China). We obtained our first biomarker CE certification in September 2015 and plan to certify two to three new markers quarterly in 2016. We plan to CE Mark our CRC test panel for Europe in the second half of 2016 for the symptomatic market.

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

NuQ® Suite of Epigenetic Cancer Blood Tests

Using our Nucleosomics® technology, we have developed twenty eight epigenetic NuQ® 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 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

[17] Kalorama Report: The United States Market for In Vitro Diagnostic Tests Mar 18, 2014 [accessed 01/29/2016]

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.[18]

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 twenty eight NuQ® 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.

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NuQ®-X: We have developed two blood assays in the NuQ®-X family to detect the presence of cancer by detecting nucleosomes containing specific nucleotides.

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NuQ®-V: We have developed three blood assays in the NuQ®-V family to detect cancer by detecting 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.

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NuQ®-M: We have developed seventeen blood assays in the NuQ®-M family to detect cancer by detecting nucleosomes containing modified histones, the proteins that package and order DNA into nucleosomes.

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NuQ®-A: We have developed five blood assays in the NuQ®-A family to detect cancer by detecting nucleosome-protein adducts.

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NuQ®-T: We have developed a NuQ®-T assay to detect cancer by detecting total blood nucleosome levels.

Generally, the tests described above are being developed to work in combination, collectively called the NuQ® panel, for the IVD market. In our biggest independent clinical trial to date, we have used the NuQ® panel prototypes to test approximately 4800 samples from patients with symptoms associated with colorectal cancer (the Denmark Trial). Additionally the NuQ® panel prototypes have been used to test a small number of blood samples from lung and prostate cancer patients.

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[18] Fraga MF et al., Loss of acetylation at Lys16 and trimethylation at Lys20 of histone H4 is a common hallmark of human cancer , Nature Genetics, Vol 37 (4), p391-400, 2005

Figure 3 Example of lab instrument for running ELISA tests

NuQ® Clinical Diagnostic Products

There are three basic platforms in the clinical IVD market that we intend to adapt our future NuQ® products to in the future.

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Centralized Laboratory Market: Centralized laboratories test thousands of blood samples taken from patients everyday 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 immune responses in the body. 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 NuQ® 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. Another option that may be available to us is to sell manual and/or semi-automated 96 well ELISA plates for use by these laboratories. We do not have an anticipated timeframe for licensing our Nucleosomics® technology or selling ELISA plates to laboratories, although we are actively seeking such relationships worldwide.

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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 NuQ® 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 platform, 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. As of the date of this report, we have not entered into any discussions or negotiations regarding the manufacture or sale of these devices. 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 no products available for sale on the IVD market and there is no guarantee that any such products will be developed or commercialized on such market.

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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 no products available for sale on the IVD market and there is no guarantee that any such products will be developed or commercialized on such market.

We intend to contract with a specialist company to adapt the NuQ® 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 of 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.

NuQ® 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 and received the first samples from The University of Oxford in the first quarter of 2015 as part of a larger endometriosis study. The University of Oxford will provide serum and plasma samples from approximately 350 patients with endometriosis and 150 control patients over a period of two years. Further samples from a prospective serial collection in 20 healthy women and 20 women with confirmed endometriosis will be 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.

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. We have decided to focus on our clinical IVD Nucleosomics® products in 2015 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 patents for HyperGenomics® was filed in 2015.

We realized our first revenue of $50,000 from contract research in 2012. We will allocate resources to the HyperGenomics® research use only, or RUO, kit as soon as is practical given our focus on the Nucleosomics® clinical IVD products commencing in 2015. 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 colorectal cancer, one study in pancreatic cancer and one study in lung cancer with the results announced as set forth below.

Completed Colorectal Cancer Studies

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Results of a completed clinical study in colorectal cancer 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 colorectal cancer or were high-risk subjects. Analysis of the results revealed that a panel test of four NuQ® biomarker assays, adjusted for age, detected 91% of colorectal cancer 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.

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Results of a completed blinded retrospective clinical study in colorectal adenomas and colorectal cancer 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 colorectal cancer detection. In the study approximately 430 samples from patients with single or multiple precancerous polyp(s) (181 patients), subjects with no polyps or colorectal cancers and without other diseases (160 subjects); plus 88 early stage (I/II) colorectal cancer patients were investigated. The cohort comprised high and low risk polyps of various histologies. The samples were analyzed using 18 NuQ® assays. Use of newly developed NuQ® assays, as part of a panel of five of the Company s NuQ® biomarker blood assays, accurately detected 75% of colorectal adenomas, or polyps, that were most likely to become cancerous in an age adjusted analysis. A NuQ® panel also detected 86% of early stage I colorectal cancers in an age adjusted analysis.

Completed Pancreatic Cancer Study

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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 VolitionRx's Nucleosomics® technology platform. Analysis of the blood samples demonstrated that a panel of five NuQ® 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 Lung Cancer Study

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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 NuQ® 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 NuQ® 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 colorectal cancer and lung cancer 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 2016.

Current Colorectal Cancer Studies

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A retrospective symptomatic colorectal cancer 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 colorectal cancer, polyps or adenomas, benign bowel diseases, or other malignancies, 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 NuQ® profile for the detection of colorectal cancer 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 NuQ® assays are currently being tested on these Phase I samples. Phase II commenced using the best NuQ® assays on the blind sample cohort in 2015 with the results intended to be used to support CE Marking of specific NuQ® assays in the second half of 2016.

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A prospective Fecal Immunochemical Test, or FIT, screening colorectal cancer study with Hvidovre Hospital in Denmark with 14,000 samples being collected over 24 months from August 2014, from patients who have had a fecal occult blood test, which we refer to as the FIT Test. Patients who tested positive following the FIT Test will additionally have a colonoscopy and we have full access to these results and the patient s medical history. It is anticipated that 8,000 samples will be collected from patients who tested positive following a FIT Test and 6,000 samples from patients tested negative. The Prospective CRC Study is designed to evaluate the performance of the validated NuQ® panel from the Retrospective CRC Trial in a large non-symptomatic cohort. The samples will be analyzed in batches throughout the collection period. This study will establish the performance of NuQ® tests in relation to FIT which is the market standard in European markets. The study is in the collection and analysis phase with the first results expected in late 2016.

Current Lung Cancer Studies

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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 NuQ® 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 NuQ® 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.

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A 600 subject study conducted with Bonn University Hospital (Germany) collected from subjects with lung cancer, subjects with benign (non-cancer lung diseases) and healthy control subjects. Collection and analysis is expected to complete in 2016.

Current Prostate Cancer Studies

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A retrospective study to evaluate NuQ® 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.

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A retrospective study with Surrey Cancer Research Institute, University of Surrey, UK with 550 blood samples collected from patients attending the hospital will be analyzed using a panel of NuQ® biomarker assays. Three groups of patients will be assessed: those with aggressive prostate cancer; those with indolent or slow-growing prostate cancer; and age-matched healthy controls. The analysis of the panel of NuQ® assay data is expected to be complete in the first quarter of 2016. In addition to determining the NuQ® blood test's accuracy in detecting prostate cancer, the study will also assess the tests' ability to distinguish among the different prostate conditions and healthy samples. This study is in progress and no results have been announced to date.

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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 NuQ® 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

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A large prospective study conducted with University Hospital in Bonn, Germany on approximately 4,700 patients to evaluate the performance of our NuQ® 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 NuQ® assays. The primary objectives of this study are; (i) to identify further cancers that are highly amenable to detection by NuQ® assays; and (ii) to identify NuQ® assays suitable for the differential diagnosis between cancers. The study is expected to complete in the first half of 2017.

Research and Development Expenditures

For the years ended December 31, 2015 and 2014, our expenditures for research and development activities were $6.1 million and $4.0 million, respectively. Such research and development focused on responding to the need for early, accurate diagnostic tests through the development of our proprietary technologies and product prototypes. We intend to develop a range of products over the next five to ten years. None of these costs are borne directly by customers.

Intellectual Property

We hold or have applied for nine 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 seven are applied for in the name of our subsidiaries.

Nucleosomics® Intellectual Property

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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

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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 and China; Pending in Europe, United States, Canada, South Africa, India, Brazil

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VolitionRx s subsidiary is the applicant for the following patent application covering its total Nu assay technology:

Nucleosomics® WO2013030578: Method for Detecting Nucleosomes

Application Date: September 1, 2011

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

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VolitionRx s subsidiary is the applicant for the following patent application covering its Nu-V technology:

Nucleosomics® WO2013030579: Method for Detecting Nucleosomes containing Histone Variants

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

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VolitionRx s subsidiary is the applicant for the following patent application covering its NuQ®-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

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VolitionRx s subsidiary is the applicant for the following patent application covering a NuQ®-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

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VolitionRx s subsidiary is the applicant for the following patent application covering NuQ®-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® Patent WO2014053852: Method for detecting Histone Modifications in Nucleosomes

Application Date: February 28, 2013

Status: Pending in Europe and United States

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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

Endometriosis Intellectual Property

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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 NuQ®-X, NuQ®-V and NuQ®-A technologies.

Trademarks

We also own a number of trademarks that protect our marks including NuQ®, Nucleosomics® and HyperGenomics®

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 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. VolitionRx has 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 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 2016, allowing them to come into effect by the end of 2016, or early 2017. Some time will be required to polish the agreed text and have it translated into the official EU languages.

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 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 NuQ® 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 In-Vitro Diagnostic Medical products are:

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analytical validation of the products;

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clinical validation of the products (which can be retrospective clinical studies using biobank patient samples, i.e. blood samples from historic patients);

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implementation of regulatory compliant manufacture;

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implementation of a Quality System; and

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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 NuQ®-X assay received a CE Mark in September 2015 and our R&D, manufacturing and distribution facility, Belgian Volition SA received EN ISO 13485, 2012 certification (an internationally recognized quality system) at the start of 2016. 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 NuQ® panel. We expect to apply for CE Marking for additional NuQ®-V (variant) and NuQ®-T (total) assays NuQ®-V001 and NuQ®-T003 in the first quarter of 2016, with a further NuQ® -V002 and NuQ® -M001 (Modification) at the end of the second quarter of 2016 as well as the colorectal cancer screening test in the second half of 2016 (for European market). Sales of our clinical products can occur in Europe once CE Marking has been granted.

In Europe, IVD companies 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:

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audit commercial, industrial and storage premises;

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

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organize random checks; and

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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. Others responsible for the noncompliance of the product will be held accountable as well. Penalties, which may include imprisonment, are determined by national law.

U.S. Regulations

Food and Drug Administration

In the United States, in vitro diagnostics are regulated by the FDA as medical devices. There are two principal regulatory pathways to receive authorization to market in vitro diagnostics, a 510(k) premarket notification and a premarket approval application, or PMA. The FDA makes a risk-based determination as to which pathway a particular in vitro diagnostic 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 premarket approval. Most Class I devices are exempt from the requirement for premarket notification to the FDA; most Class II devices require the submission and clearance of a 510(k) premarket notification to the FDA prior to commercial marketing; and Class III devices require submission and approval of 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 in vitro diagnostic 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) premarket notification, 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 in vitro diagnostic, or 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

NuQ® Assays (Cancer and Other Conditions):

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In-Vitro Diagnostics Market

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CE Marking (Europe): A pilot NuQ® panel of three assays underwent external third party retrospective clinical validations during 2012 which took approximately nine months to complete. A larger NuQ® panel of assays commenced large-scale retrospective clinical validations in 2013, which will continue during the first half of 2016 in a symptomatic population. Once the retrospective validations are completed, the tests will be submitted for CE Mark approval, both for each individual biomarker assay and for the complete biomarker assay panel in a symptomatic population. The first NuQ®-X biomarker assay received a CE Mark in September 2015 and we expect the first biomarker assay panel to receive a CE Mark in the second half of 2016. We estimate that the cost of CE Marking our first biomarker panel will be approximately $500,000. We additionally expect to have the results from the prospective 14,000 patient CRC study with Hvidovre Hospital in Denmark in a European screening population in the second half of 2016 and expect to CE Mark the CRC biomarker panel for use in a screening population in 2017.

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FDA Approval (United States): FDA approval for colorectal 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 2016 and be completed in 2018. 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 NuQ® as a symptomatic adjunct test (used in combination with other tests to identify at risk patients). This abbreviated process is expected to begin in 2016 and complete in 2017 with an estimated cost of between $1million and $1.5 million.

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

NuQ® Clinical Diagnostic Products:

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Centralized Laboratory Market

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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.

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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.

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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.

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Disposable Tests for Doctor s Office or Home Use: We intend to contract with a specialist company to adapt the NuQ® 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. Pending completion of our review of the regulatory environment in the United States, including the effect of the Draft Guidance, we will combine a licensing and sales strategy focused on the IVD products through 2016. In 2017 we intend to license NuQ® tests for LDT use in the United States and/or launch our own products as an adjunct product to progressively grow sales volumes after CE Marking in Europe and FDA approval in the United States, with sales to centralized laboratories and eventually reach the mass diagnostics testing market. The sales strategy will evolve as we continue to develop our intended products and seek entry into the IVD markets.

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 Tests. Exact Sciences Corporation has recently received FDA approval and reimbursement approval for its stool-based DNA screening test. We anticipate facing competition primarily from large healthcare, pharmaceutical and diagnostic companies such 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, Roche Diagnostics and Sequenom, Inc.

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 will 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, 2015, we (including our subsidiaries) had 13 full-time employees and 2 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.

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

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

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

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

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

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

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

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

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The demand for our intended products;

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Our ability to obtain any necessary financing;

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Our ability to market and sell our future products;

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Market acceptance of our future products and technology;

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Performance of any future strategic business partners;

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Our ability to obtain regulatory clearances or approvals;

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

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Competition with other cancer diagnostics companies; and

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Adverse changes in the healthcare industry.

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

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

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

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

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

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

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

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

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Identify appropriate partners;

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Negotiate beneficial partnership and distribution agreements;

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Hire qualified individuals as needed;

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

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Provide adequate training for effective sales and marketing;

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Retain and motivate our direct sales and marketing professionals; and

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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.

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

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

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:

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

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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

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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, 2015. See *Item 9A*, *Controls and Procedures* of our Annual Report on Form 10-K for the year ended December

31, 2015 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.

Risks Associated with our Business

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

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

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

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

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

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

We are subject to regulation and supervision by the FDA in the United States, the Conformité Européenne in Europe and other regulatory bodies in other countries where we intend to sell our future products. Before we are able to place our intended products in the clinical IVD markets in the United States and Europe, we will be required to obtain approval of our future products from the FDA and receive a CE Mark, respectively. The European Union has recently proposed terms that would impose additional requirements to obtain a CE Mark, which could result in delays and further expense, 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 finished sometime in 2016, allowing them to come into effect by the end of 2016, or early 2017. Some time will be required to polish the agreed text and have it translated into the official EU languages. Delays in obtaining approvals and clearances could have material adverse effects on us and our ability to fully carry out our plan of operations.

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

Recent announcements from the FDA may impose additional regulatory obligations and costs upon our business.

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

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

If the FDA requires us to seek clearance or approval for any of our products, (as opposed to simply licensing our technology to a CLIA lab), we may not be able to obtain such approvals on a timely basis, or at all. The cost of conducting clinical trials and otherwise developing data and information to support any applications may be significant. Failure to comply with applicable regulatory requirements of the FDA could result in enforcement action, including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

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

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

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

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

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

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

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Significantly greater name recognition;

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Established relationships with healthcare professionals, companies and consumers;

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

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Established supply and distribution networks; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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:

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

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

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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

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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 two patents related to our diagnostic tests granted in the United States; one patent granted in the European Union and three patents granted in other countries. We also hold an exclusive worldwide license to a patent granted in four other countries. Additionally, we have patent applications in the name of our subsidiaries pending in the United States, the European Union and other countries. We cannot assure you that any of the pending patent applications will result in patents being issued. In addition, due to technological changes that may affect our future products or judicial interpretation of the scope of our patents, our intended products might not, now or in the future, be adequately covered by our patents.

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

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

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

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

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

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

Risks Associated with our Common Stock

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

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

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competition;

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additions or departures of key personnel;

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our ability to execute our business plan;

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operating results that fall below expectations;

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loss of any strategic relationship;

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industry developments;

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economic and other external factors; and

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period-to-period fluctuations in our financial results.

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

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

As of March 11, 2016, our executive officers and directors owned, in the aggregate, approximately 28.6% of our outstanding shares. As a result, if the officers and directors were to oppose a third party s acquisition proposal for, or a change in control of, the Company, the officers and directors may have sufficient voting power to be able to block or at least delay such an acquisition or change in control from taking place, even if other stockholders would support such a sale or change of control.

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

Our Board of Directors, or Board, has the power, under our articles of incorporation, to issue additional shares of common stock and create and authorize the sale of one or more series of preferred stock without having to obtain stockholder approval for such action. As a result, our Board could authorize the issuance of shares of a series of preferred stock to implement a stockholders rights plan (often referred to as a poison pill) or could sell and issue preferred shares with special voting rights or conversion rights, which could deter or delay attempts by our

stockholders to remove or replace management, and attempts of third parties either to engage in proxy contests or to acquire control of the Company. In addition, our charter documents:

.

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

.

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

.

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

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

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

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

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

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

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

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

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

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

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

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

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

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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, 2015, at an annual rent of $20,861. We believe that this facility is adequate to meet our current needs. We additionally have an office in New York at an annual cost of approximately $4,000.

Belgian Volition leases a laboratory and office space at 20A Rue de Séminaire, 5000, Namur, Belgium. We have signed a two-year lease, commencing December 1, 2014, at an annual rent of $60,201. Additionally, Belgian Volition shall pay $872 per month as a provision against expenses. Belgian Volition intends to move into a larger facility in the latter part of 2016, as our research and development activities have expanded over recent years.

Volition Diagnostics UK Limited signed a one year lease for office space at 83 Baker Street, London, W1U 6AN, United Kingdom, commencing January 25, 2016, at an annual rent of $82,222. We believe this is adequate to meet our current needs.

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, 2015 and 2014. 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.

Year Ended December 31, 2014	**High**	**Low**
First Quarter (Jan. 1 Mar. 31)	$3.25	$2.05
Second Quarter (Apr. 1 Jun. 30)	$2.75	$1.30
Third Quarter (Jul. 1 Sept. 30)	$9.28	$1.45
Fourth Quarter (Oct. 1 Dec. 31)	$4.32	$3.25

Year Ended December 31, 2015	**High**	**Low**
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

Holders

As at March 11 2016, an aggregate of 18,863,272 shares of our common stock were issued and outstanding and were owned by approximately 186 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 II, Item 12 of this report, which is incorporated by reference into this Item 5.

Recent Sales of Unregistered Securities

On or about November 18, 2015, 20,000 options under the Company s 2011 Equity Incentive Plan, or the 2011 Plan, were exercised at $3.00 per shares in a cashless exercise that resulted in the issuance of 4,810 shares of common stock to one non-U.S. investor.

On or about December 1, 2015, 8,000 warrants were exercised for total proceeds of $19,200. As a result, an aggregate total of 8,000 shares of common stock were issued at a price of $2.40 per share to one U.S. accredited investor.*

On or about December 2, 2015, 50,000 options under the Company s 2011 Plan were exercised at $3.01 per shares in a cashless exercise that resulted in the issuance of 14,081 shares of common stock to one non-U.S. investor.

On or about December 9, 2015, 50,000 options under the Company s 2011 Plan were exercised at $3.01 per shares in a cashless exercise that resulted in the issuance of 14,166 shares of common stock to one non-U.S. investor.

On or about December 14, 2015, 250,000 warrants were exercised at a price of $1.05 per share, giving cash proceeds to the registrant of $262,500. As a result, a total of 250,000 unregistered shares of common stock were issued to one non-U.S. investor.

No underwriters were used in connection with any of the foregoing transactions. These issuances were deemed to be exempt from registration under the Securities Act in reliance on (i) Section 4(2) of the Securities Act, including in some cases, Regulation D and Rule 506 promulgated thereunder (as noted by *), and (ii) Rule 903 of Regulation S of the Securities Act, as transactions by an issuer not involving a public offering or sales completed in an offshore transaction as defined in Rule 902(h) of Regulation S, as we did not engage in any directed selling efforts in the United States in connection with the sale of the shares and each investor represented to us that the investor was not a U.S. person as defined in Regulation S (as noted by).

On December 11, 2015 a registration statement on Form S-8 was filed registering all of the shares under the 2011 Plan.

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

This Annual Report on Form 10-K contains forward-looking statements. These forward-looking statements are not historical facts but rather are based on current expectations, estimates and projections. We may use words such as anticipate, expect, intend, plan, believe, foresee, estimate and variations of these words and similar expressions to identify forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and other factors, some of which are beyond our control, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted. You should read this report completely and with the understanding that actual future results may be materially different from what we expect. The forward-looking statements included in this report are made as of the date of this report and should be evaluated with consideration of any changes occurring after the date of this report. We will not update forward-looking statements even though our situation may change in the future and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and other financial information included elsewhere in this report.

Overview

We are a clinical-stage life sciences company focused on developing blood based diagnostic tests that meet the need for accurate, fast, cost effective and scalable tests for detecting and diagnosing cancer and other diseases. We have developed twenty eight 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 test for a particular cancer or disease. We intend to commercialize our products in the future through various channels within the European Union, the United States and throughout the rest of the world likely beginning with China and India.

We are developing blood-based diagnostics for the most prevalent cancers, beginning with colorectal, lung and pancreatic cancer, using our Nucleosomics® biomarker discovery platform. The platform employs a range of simple NuQ® immunoassays on an industry standard ELISA format, which allow 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. NuQ® biomarkers can be used alone, or in combination to generate profiles related to specific conditions. The first tranche of data released from a large independent trial for colorectal cancer could, if carried through into our screening or symptomatic trials, potentially have a positive impact for broad scale, cost effective, cancer diagnostics.

Management has identified the specific processes and resources required to achieve the near and medium term objectives of the Company s 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.

Liquidity and Capital Resources

As of December 31, 2015, the Company had cash of $5,916,006 and prepayments and other current assets of $306,649. The Company had current liabilities of $1,119,650. This represents a working capital surplus of $5,103,005.

The Company used $8,766,323 in net cash for the year ended December 31, 2015, compared to $4,140,825 for the year ended December 31, 2014. The increase in cash used year over year was primarily due to an increase in research and development expenditure and legal costs associated with our up-listing onto the NYSE MKT. Please see Results of Operations, below for more detail.

Net cash used in investing activities increased year over year by $49,254 to $352,243 in the 2015 period, mainly as a result of the purchase of the Nucleosomics® WO2005019826: Detection of Histone Modifications in Cell-Free Nucleosomes patent (i.e. the patent that underlies the NuQ®-M tests) from Chroma Therapeutics Limited for $55,000.

Net cash provided by financing activities amounted to $12,882,602 for the year ended December 31, 2015, compared to $5,737,766 for the year ended December 31, 2014. The Company raised approximately $9.7 million in net proceeds in February 2015, when approximately 2.8 million shares of common stock were issued in a public offering at the time of our up-listing to the NYSE MKT. We also raised another $1.5 million from further issuances in a private placement during the first quarter of 2015 and approximately $1.3 million from exercises of warrants and stock options in 2015. A capital lease for three Tecan machines resulted in an additional $223,152 being raised over this period. This resulted in an increase of cash of $3,777,042 for the year ended December 31, 2015, compared to an increase of $1,250,260 for the year ended December 31, 2014.

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 $600,325. The capital lease is repayable over a five year period, ending in 2020. The present value of the minimum lease payments is $352,889. The Company additionally owns one Tecan machine which it purchased with cash in 2014.

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

In the event that additional financing is delayed, the Company will prioritize the maintenance of its research and development personnel and facilities, primarily in Belgium, and the maintenance of its patent rights. However the completion of clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market would be delayed. In the event of an ongoing lack of financing, 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, 2015 and December 31, 2014

The following table sets forth the Company s results of operations for the year ended on December 31, 2015 and the comparative period for the year ended December 31, 2014.

	Year Ended December 31, 2015 ($)	Year Ended December 31, 2014 ($)	Increase/ Decrease ($)	Percentage Increase/ Decrease (%)
Revenues	-	-	-	-
General and administrative	(669,016)	(299,051)	(369,965)	124%
Professional fees	(1,606,259)	(533,716)	(1,072,543)	201%
Salaries & office administration fees	(1,628,726)	(1,075,410)	(553,316)	51%
Research and development	(6,101,718)	(4,044,023)	(2,057,695)	51%
Total Operating Expenses	(10,005,719)	(5,952,200)	(4,053,519)	68%
Net Other Income/(Net Other Expenses)	470,873	(2,261,329)	2,732,202	-121%
Income Taxes	4,604	-	4,604	-
Net Loss	(9,530,242)	(8,213,529)	(1,316,713)	16%
Basic and Diluted Loss Per Common Share	(0.54)	(0.61)	0.07	-11%
Weighted Average Basic and Diluted Common Shares Outstanding	17,731,809	13,435,253	4,296,556	32%

Revenues

The Company s operations are still predominantly in the development stage.

Operating Expenses

The Company s total operating expenses increased $4,053,519, or 68%, in 2015 compared to 2014. Total expenses are comprised of general and administrative expenses, professional fees, salaries and administrative fees and research and development expenses.

General and administrative expenses

The Company s general and administrative expenses increased $369,965, or 124%, in 2015 compared to 2014. A large proportion of this increase is due to increased investor relations related travel and conference attendance expenses of $131,795, alongside an increase in insurance costs of $134,840.

Professional fees

The Company s professional fees increased $1,072,543, or 201%, in 2015 compared to 2014. The Company incurred significant costs in relation to the up-listing to the NYSE MKT in February 2015. During 2015, there were increases in (i) legal fees of $567,734 in 2015 as a result of legal activity associated with the up-list to the NYSE MKT, capital raising activities and other contractual matters, (ii) investor relations services of $210,346, to raise the profile of the Company and (iii) NYSE MKT listing fees of $107,083 as compared to 2014.

Salaries and office administration fees

The Company s salaries and office administration fees increased $553,316, or 51%, in 2015 compared to 2014. This is mainly explained by an increase in equity plan option amortization of $468,085, alongside an increase in salaries and fees of $402,085. There was additional compensation for senior executives of the Company and an additional director appointed in June 2014. A saving of $282,746 has been made due to a decrease in consultant warrants amortization.

Research and development

The Company s research and development costs increased $2,057,695, or 51%, in 2015 compared to 2014. The Hvidovre Hospital study has incurred additional costs of $422,617. Antibody and sample costs increased by $1,398,460, due to the development and usage of new and increased amounts of antibodies. An increase in equity plan option amortization costs for research and development resources of $195,138 also contributed to the change.

Net other income/net other expenses

The Company recognized net other income of $470,873 in 2015, as compared to net other expenses of $2,261,329 in 2014. Net other income mainly consisted of $146,812 in grant funds received from public bodies in respect of approved expenditures, where there is no obligation to repay, as well as $339,744 recorded as a result of a gain on re-measurement of a derivative liability. For 2014, net other expenses mainly consisted of $143,987 in grant funds and a loss of $2,420,101 on the re-measurement of a derivative liability.

Net Loss

The Company s net loss increased $1,316,713, or 16%, in 2015 compared to 2014. The change is a result of the factors described above.

Going Concern

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

Not applicable.

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, 2015 and 2014

Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

VolitionRx Limited

We have audited the accompanying consolidated balance sheets of VolitionRx Limited as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders deficit, and cash flows for each of the years in the two year period ended December 31, 2015. VolitionRx Limited s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

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 audits 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 audits 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, 2015 and 2014, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2015, 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 11, 2016

VOLITIONRX LIMITED

Consolidated Balance Sheets

(Expressed in U.S. dollars)

	December 31, 2015	December 31, 2014
	$	$
ASSETS		
Cash	5,916,006	2,138,964
Prepaid expenses	152,926	144,095
Other current assets	153,723	52,659
Total Current Assets	6,222,655	2,335,718
Property and equipment, net	783,805	288,585
Intangible assets, net	705,381	808,726
Total Assets	7,711,841	3,433,029
LIABILITIES		
Accounts payable and accrued liabilities	712,160	797,909
Management and directors fees payable	71,893	146,016
Derivative Liability	-	1,577,640
Capital lease liabilities	81,338	-
Deferred grant income	219,360	191,512
Grant repayable	34,899	-
Total Current Liabilities	1,119,650	2,713,077
Capital lease liabilities	299,863	-
Grant repayable	248,009	351,773
Total Liabilities	1,667,522	3,064,850
STOCKHOLDERS EQUITY		
	-	-
Preferred Stock		
Authorized: 1,000,000 shares, at $0.001 par value		

Issued and outstanding: Nil shares and Nil shares respectively		
Common Stock		
Authorized: 100,000,000 shares, at $0.001 par value		
Issued and outstanding: 18,763,272 shares and 14,691,332		
shares respectively	18,763	14,691
Additional paid-in capital	35,149,420	19,966,771
Accumulated other comprehensive loss	(84,171)	(103,832)
Accumulated Deficit	(29,039,693)	(19,509,451)
Total Stockholders Equity	6,044,319	368,179
Total Liabilities and Stockholders Equity	7,711,841	3,433,029

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

VOLITIONRX LIMITED

Consolidated Statements of Operations and Comprehensive Loss

(Expressed in U.S. dollars)

	For the year ended December 31, 2015	For the year ended December 31, 2014
	$	$
Revenue	-	-
Expenses		
General and administrative	669,016	299,051
Professional fees	1,606,259	533,716
Salaries and office administrative fees	1,628,726	1,075,410
Research and development	6,101,718	4,044,023
Total Operating Expenses	10,005,719	5,952,200
Net Operating Loss	(10,005,719)	(5,952,200)
Other Income/(Expenses)		
Grants received	146,812	143,987
(Other Expenses)/Other Income	(15,683)	14,785
Gain/(Loss) on derivative liabilities	339,744	(2,420,101)
Net Other Income/(Expenses)	470,873	(2,261,329)
Provision for Income Taxes	4,604	-
Net Loss	(9,530,242)	(8,213,529)
Other Comprehensive Gain/(Loss)		
Foreign currency translation adjustments	19,661	(44,037)
Total Other Comprehensive Gain/(Loss)	19,661	(44,037)
Net Comprehensive Loss	(9,510,581)	(8,257,566)
Net Loss per Share Basic and Diluted	(0.54)	(0.61)
	17,731,809	13,435,253

Weighted Average Shares Outstanding Basic and Diluted	

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

VOLITIONRX LIMITED

Consolidated Statements of Cash Flows

(Expressed in U.S. dollars)

	For the year ended December 31, 2015 $	For the year ended December 31, 2014 $
Operating Activities		
Net loss	(9,530,242)	(8,213,529)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	236,340	142,131
Stock based compensation	1,493,334	767,483
Common stock and warrants issued for services (recapture)	(42,131)	708,182
Non-operating income grants received	(146,812)	(143,987)
(Gain) / Loss on derivative re-measurement	(339,744)	1,424,554
Derivative expense	-	995,547
Changes in operating assets and liabilities:		
Prepaid expenses	(12,687)	(78,335)
Other current assets	(108,603)	(24,731)
Accounts payable and accrued liabilities	(315,778)	281,860
Net Cash Used In Operating Activities	(8,766,323)	(4,140,825)
Investing Activities		
Purchases of property and equipment	(297,243)	(302,989)
Purchase of patents	(55,000)	-
Net Cash Used in Investing Activities	(352,243)	(302,989)
Financing Activities		
Net proceeds from issuance of common shares	12,497,621	5,626,945
Grants received	146,812	143,987
Grants repaid	(33,174)	(33,166)
Deferred grant income	48,191	-
Capital lease funding	223,152	-

Net Cash Provided By Financing Activities	12,882,602	5,737,766
Effect of foreign exchange on cash	13,006	(43,692)
Increase in Cash	3,777,042	1,250,260
Cash Beginning of Period	2,138,964	888,704
Cash End of Period	5,916,006	2,138,964

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

Supplemental Disclosures of Cash Flow Information		
Interest paid	7,326	10,541
Income tax paid		
Non Cash Financing Activities::		
Common stock issued on cashless exercises of stock options	33	
Change in derivative liability	1,237,896	3,924,967
Capital lease obligation for equipment purchases	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, 2015 and 2014

(Expressed in U.S. dollars)

	Common Stock				Deficit Accumulated	
			Additional	Other	During the	
		Amount	Paid-in	Comprehensive	Development	
	Shares	($)	Capital	Loss	Stage	Total
			$	$	$	$
Balance, December 31, 2013	11,679,757	11,680	12,024,711	(59,795)	(11,295,922)	680,674
Common stock issued for cash	2,834,916	2,835	3,257,497	-	-	3,260,332
Common stock issued for debt	77,481	77	167,477	-	-	167,554
Direct offering costs	-	-	(457,472)	-	-	(457,472)
Employee stock options granted for services	-	-	767,483	-	-	767,483
Common stock issued under deferred contingency rights	99,178	99	(99)	-	-	-
Warrants formerly derivative liability	-	-	3,924,967	-	-	3,924,967
Warrants granted for services	-	-	282,207	-	-	282,207
Other comprehensive loss	-	-	-	(44,037)	-	(44,037)
Net loss for the year	-	-	-	-	(8,213,529)	(8,213,529)
Balance, December 31, 2014	14,691,332	14,691	19,966,771	(103,832)	(19,509,451)	368,179
Common stock issued for cash	4,038,883	4,039	13,414,097	-	-	13,418,136
Common stock issued for cashless exercise of stock options	33,057	33	(33)	-	-	-

Direct offering costs	-	-	(920,514)	-	-	(920,514)
Employee stock options granted for services	-	-	1,493,334	-	-	1,493,334
Change in derivative liability	-	-	1,237,896	-	-	1,237,896
Warrants granted for services	-	-	(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

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

VOLITIONRX LIMITED

Notes to Consolidated Financial Statements

For Years Ended December 31, 2015 and 2014

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 Ltd., a Singapore corporation, 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 Pte Ltd. 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 Pte Ltd., 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 Pte Ltd.

The Company s principal business objective through its subsidiaries is to develop and bring to market diagnostic tests for cancer and other diseases. The tests are based on the science of Nucleosomics®, which is the practice of identifying and measuring nucleosomes in the bloodstream or other biofluids an indication that disease is present. The Company has one wholly-owned subsidiary, Singapore Volition Pte Ltd., which it acquired through a share exchange entered into on October 6, 2011. Singapore Volition Pte Ltd. has two wholly owned subsidiaries, Belgian Volition SA, which it acquired as of September 22, 2010, and Hypergenomics Pte Ltd., which it formed as of March 7, 2011. Belgian Volition SA, has one wholly owned subsidiary, Volition Diagnostics UK Limited, which it formed as of November 13, 2015. Following the acquisition of Singapore Volition Pte Ltd. 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 $29,039,693, 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.

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.

Note 3 - Summary of Significant Accounting Policies (Continued)

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, 2015 include the accounts of the Company and its wholly-owned subsidiaries, Singapore Volition Pte Ltd., Belgian Volition SA, Hypergenomics Pte. Ltd. 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, 2015 and December 31, 2014, the Company had $5,916,006 and $2,138,964, respectively in cash and cash equivalents. At December 31, 2015 and December 31, 2014 the Company had approximately $762,187 and $nil in its domestic accounts in excess of Federal Deposit Insurance Corporation insured limits, respectively. At December 31, 2015 and December 31, 2014 the Company had approximately $395,100 and $233,727 in its foreign accounts in excess of the Belgian Deposit Guarantee insured limits, respectively. At December 31, 2015 and December 31, 2014 the Company had approximately $4,338,088 and $1,879,840 in its foreign accounts in excess of the Singapore Deposit Insurance Scheme, respectively.

Basic and Diluted Net Loss Per Share

The Company computes net loss per share in accordance with ASC 260, Earnings Per Share, which requires presentation of both basic and diluted earnings per share (EPS) on the face of the income statement. Basic EPS is computed by dividing net loss available to common shareholders (numerator) by the weighted average number of shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method and convertible preferred stock using the if-converted method. In computing Diluted EPS, the average stock price for the period is used in determining the number of shares

assumed to be purchased from the exercise of stock options or warrants. As of December 31, 2015, 2,257,809 dilutive warrants and options were excluded from the Diluted EPS calculation as their effect is anti-dilutive. As of December 31, 2014, 1,857,761 dilutive warrants and options were excluded from the Diluted EPS calculation as their effect is anti-dilutive.

Foreign Currency Translation

The Company s functional currency is the Euro and its reporting currency is the United States dollar. Management has adopted ASC 830-20, Foreign Currency Matters Foreign Currency Transactions . All assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the balance sheet date. For revenues and expenses, the weighted average exchange rate for the period is used. Gains and losses arising on translation or settlement of foreign currency denominated transactions or balances are included in other comprehensive loss.

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, 2015, the Company had $84,171 of accumulated other comprehensive loss, relating to foreign currency translation.

Property and Equipment

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

Computer hardware	3 years
Laboratory equipment	5 years
Equipment held under capital lease	5 years
Office furniture and equipment	5 years

Note 3 - Summary of Significant Accounting Policies (Continued)

Intangible Assets

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

Patents and Intellectual Property	13 years and 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 $6,101,718 and $4,044,023 during the years ended December 31, 2015 and 2014, 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. No impairment losses were recognized during the years ended December 31, 2015 and December 31, 2014.

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.

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Note 4 - Property and Equipment

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

	Cost	Accumulated Depreciation	December 31, 2015 Net Carrying Value
	$	$	$
Computer hardware	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
	1,026,006	242,201	783,805

	Cost	Accumulated Depreciation	December 31, 2014 Net Carrying Value
	$	$	$
Computer hardware	48,331	39,293	9,039
Laboratory equipment	313,285	53,080	260,205
Equipment held under capital lease	-	-	-
Office furniture and equipment	31,745	12,403	19,341
	393,361	104,776	288,585

On April 8, 2015 the Company entered into a five year capital lease to purchase three Tecan machines (automated liquid handling robots) for a total sum of $600,325 (€550,454).

During the years ended December 31, 2015 and 2014, the Company recognized $150,439 and $47,095 in depreciation expense respectively.

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 their remaining lives, which range from 8 to 16 years.

	Cost $	Accumulated Amortization $	December 31, 2015 Net Carrying Value $
Patents	1,119,302	413,921	705,381
	1,119,302	413,921	705,381

	Cost $	Accumulated Amortization $	December 31, 2014 Net Carrying Value $
Patents	1,173,593	364,867	808,726
	1,173,593	364,867	808,726

Note 5 - Intangible Assets (Continued)

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

During the years ended December 31, 2015 and 2014, the Company recognized $85,901 and $95,037 in amortization expense respectively. No impairment losses were recognized during the years ended December 31, 2014 and December 31, 2015.

The Company amortizes the long-lived assets on a straight line basis with terms of 13 and 20 years. The annual estimated amortization schedule over the next five years is as follows:

2016	$ 85,378
2017	$ 85,378
2018	$ 85,378
2019	$ 85,378
2020	$ 85,378

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, 2015. The result of this review confirmed that the fair value of the patents exceeded their carrying value as of December 31, 2015.

Note 6 - Related Party Transactions

The Company has had agreements with a related party to rent office space, be provided with office support staff, and have consultancy services provided on behalf of the Company. See Note 12 for obligations under the agreements.

Note 7 - 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.

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.

Note 7 - Common Stock (Continued)

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 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.

2014

On February 26, 2014, the Company issued 1,500,000 shares of common stock for a total of $3,000,000 at a price of $2.00 per share. Attached to these share issuances were 1,500,000 warrants, immediately exercisable for a period of five years at $2.20 per share. The warrants were valued at $3,955,546 using the Black-Scholes Option Pricing model using the following assumptions: Five year term, $2.68 stock price, $2.20 exercise price, 239% volatility, 1.50% risk free rate. Agents received 30,975 warrants, exercisable on the same terms as the warrants issued for cash subscriptions, and valued at $82,507 on the same basis as above. Due to a ratchet provision in the warrant agreement effective for the twelve months to February 26, 2015, all the foregoing warrants have been treated as a derivative liability in accordance with ASC 815. Other fees and expenses directly attributable to agents in respect of these issuances were $147,186 in cash, and $25,900 settled by the issue of shares of common stock. Legal expenses directly attributable to the issuances amounted to $84,879.

On February 26, 2014, the Company issued 16,667 shares of common stock to settle liabilities for services valued at $35,000, at a price of $2.10 per share.

On March 25, 2014, the Company issued 12,334 shares of common stock to settle liabilities for services valued at $25,900, at a price of $2.10 per share.

On March 26, 2014, the Company issued 99,178 shares of common stock to the subscribers for the 297,500 shares of common stock issued on June 10, 2013. These additional shares were issued for no additional consideration under the terms of the Private Placement Memorandum because certain subsequent fundraising targets had not been met.

On June 5, 2014, the Company issued 160,228 shares of common stock for cash of $352,500, at a price of $2.20 per share.

On September 24, 2014, the Company issued 21,250 shares of common stock at a price of $2.20 per share to settle liabilities for services valued at $46,748. In addition, on that date, the Company issued 492,316 shares of common stock at a price of $2.20 for net cash proceeds of $1,083,094 and 27,230 shares of common stock at a price of $2.20 to an agent in settlement of their debt of $59,906.

On September 26, 2014, the Company issued 300,000 shares of common stock at a price of $2.50 per share for net cash proceeds of $688,970. The amount received was the net proceeds, after fees of $60,000 had been paid to an agent and $1,030 paid in other fees and bank charges.

Note 7 - Common Stock (Continued)

In addition, on that date, the Company issued 24,000 warrants to the same agent, immediately exercisable over a period of three years at $3 per share. The warrants were valued at $103,223 using the Black-Scholes Option Pricing model using the following assumptions: Three year term, $4.45 stock price, $3 exercise price, 235% volatility, 1.08% risk free rate.

On October 3, 2014, 50,000 warrants were exercised at a price of $2.47 per share, for net cash proceeds of $123,500. As a result, a total of 50,000 shares of common stock were issued.

On October 9, 2014, the Company issued 91,757 shares of common stock at a price of $2.50 per share for net cash proceeds of $229,393.

On November 17, 2014, the Company issued 237,500 shares of common stock at a price of $3.00 per share for net cash proceeds of $654,464. $57,000 had been paid in fees to an agent and $1,036 was paid in escrow fees and charges.

In addition, on November 17, 2014, the Company issued 19,000 warrants to the same agent, immediately exercisable over a period of three years at $3.75 per share. The warrants were valued at $72,694 using the Black-Scholes Option Pricing model using the following assumptions: Three year term, $3.99 stock price, $3.75 exercise price, 234% volatility, 0.96% risk free rate.

On November 21, 2014, the Company issued 3,115 shares of common stock at a price of $3.00 per share for net cash proceeds of $9,345.

Note 8 Warrants and Options

a)

Warrants

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, a related party exercised 250,000 warrants 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 (Continued)

2014

On January 28, 2014, the Company issued 10,000 warrants to a consultant for services at an exercise price of $2.40, exercisable immediately for three years. The warrants were valued at $21,500 using the Black-Scholes Option Pricing model using the following assumptions: Three-year term, $2.26 stock price, $2.40 exercise price, 229% volatility, 0.75% risk free rate.

On February 26, 2014, the Company issued 1,500,000 warrants attached to the issue of 1,500,000 shares for cash totaling $3,000,000. The Company has valued these warrants at $3,995,547 and treated this amount as a derivative liability, in accordance with ASC 815. The warrants are exercisable immediately for five years at an exercise price of $2.20.

On February 26, 2014, the Company issued 30,975 warrants to agents as part remuneration in respect of the issuance of 1,500,000 shares for cash totaling $3,000,000. The warrants were valued at $82,507 using the Black-Scholes Option Pricing model using the following assumptions: Five-year term, $2.68 stock price, $2.20 exercise price, 241% volatility, 1.5% risk free rate. The Company has treated this amount as a derivative liability, in accordance with ASC 815. Each warrant is exercisable immediately for five years at an exercise price of $2.20 per share.

On September 5, 2014, the Company issued 10,000 warrants to a consultant for services. These warrants were valued at $20,092 using the Black-Scholes Option Pricing model using the following assumptions: Three year term, $2.10 stock price, $2.40 exercise price, 236% volatility, 0.99% risk free rate. Each warrant is exercisable immediately for three years at an exercise price of $2.40 per share.

On September 26, 2014, the Company issued 24,000 warrants to an agent as part remuneration in respect of the issuance of 300,000 shares for net proceeds of $688,970. These warrants were valued at $103,223 using the Black-Scholes Option Pricing model using the following assumptions: Three year term, $4.45 stock price, $3 exercise price, 235% volatility, 1.08% risk free rate. Each warrant is exercisable immediately for three years at an exercise price of $3 per share.

On October 1, 2014, 25,000 of the remaining 175,000 warrants with variable vesting dates, issued March 20, 2013, vested. The 25,000 warrants were valued at $104,281 using the Black-Scholes Option Pricing model using the following assumptions: Three-year term, $4.21 stock price, $2.47 exercise price, 235% volatility, 1.0 % risk free rate. The Company carried out a re-measurement of the valuation of the unvested warrants as at December 31, 2014, in

accordance with ASC 505. The Company estimated that vesting of the unvested warrants will take place over the three years to December 31, 2017. The unvested warrants were re-measured at $583,829 using the Black-Scholes Option Pricing model using the following assumptions: Three-year term, $3.90 stock price, $2.47 exercise price, 233% volatility, 1.1% risk free rate. As of December 31, 2014, $439,175 of the $745,156 value of vested and unvested warrants has been expensed.

On November 17, 2014, the Company issued 19,000 warrants to an agent, as part remuneration in respect of the issuance of 237,500 shares for net proceeds of $654,464. The warrants are immediately exercisable over a period of three years at $3.75 per share. The warrants were valued at $72,694 using the Black-Scholes Option Pricing model using the following assumptions: Three year term, $3.99 stock price, $3.75 exercise price, 234% volatility, 0.96% risk free rate.

All of the 1,530,975 warrants issued on February 26, 2014, have been treated as a derivative liability, in accordance with ASC 815, owing to a ratchet provision in the warrant agreement being effective for the twelve months to February 26, 2015. The derivative liability was measured at $4,078,054 as at February 26, 2014. It was re-measured as of March 31, 2014, and revalued at $4,182,748. The derivative liability was further re-measured as of June 30, 2014, and revalued at $2,315,506, resulting in a gain of $1,867,241 for the three months ended June 30, 2014. At September 30, 2014, the derivative liability was re-measured and revalued at $6,446,068, resulting in a loss of $4,130,562 for the three months ended September 30, 2014.

On October 31, 2014, the Company amended the terms of 1,121,225 of the aforementioned 1,530,975 warrants that had been issued on February 26, 2014. As a result of the amendment, the ratchet provision on the 1,121,225 warrants ceased on October 31, 2014. The derivative liability was re-measured at that date, using the Black-Scholes Option Pricing model with the following assumptions: Five year term, $3.54 stock price, $2.20 exercise price, 235% volatility, 1.62% risk free rate. This resulted in a gain of $1,086,727 for the month of October 2014 and the 1,121,225 warrants ceased to be a derivative liability with their valuation of $3,924,967 being transferred into Additional paid-in capital.

Note 8 Warrants and Options (Continued)

On December 31, 2014 the remaining warrants treated as a derivative liability were re-measured. This resulted in a loss of $143,267 for the two months to December 31, 2014. The net gain for the three months to December 31, 2014 is therefore $943,460.

Below is a table summarizing the warrants issued and outstanding as of December 31, 2015.

Date Issued	Number Outstanding	Exercise Price $	Contractual Life (Years)	Expiration Date	Proceeds to Company if Exercised $
03/15/11	100,000	0.50	5	3/15/2016	50,000
03/24/11	100,000	0.50	5	3/24/2016	50,000
04/01/11	100,000	0.50	5	4/1/2016	50,000
06/21/11	100,000	0.50	5	6/21/2016	50,000
05/11/12	344,059	2.60	4	05/10/16	894,553
03/20/13	150,000	2.47	3	03/20/16 to 12/20/19	370,500
06/10/13	29,750	2.00	5	12/10/18	59,500
08/07/13	45,000	2.40	3	08/07/16	108,000
11/25/13	456,063	2.40	5	11/25/18	1,094,551
12/31/13	64,392	2.40	5	11/25/18	154,541
01/28/14	2,000	2.40	3	01/28/17	4,800
02/26/14	1,068,475	2.20	5	02/26/19	2,350,645
09/05/14	10,000	2.40	3	09/05/17	24,000
09/26/14	24,000	3.00	3	09/26/17	72,000
11/17/14	19,000	3.75	3	11/17/17	71,250
	2,612,739				**5,404,340**

b)

Options

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

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.

Note 8 Warrants and Options (Continued)

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 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 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.

During the year ended December 31, 2015, 40,000 options expired unexercised following the cessation of a consultant s contract.

2014

Options to purchase 25,000 shares were granted on May 16, 2014. These options vest in equal six monthly installments over three years from the date of grant, and expire three years after the vesting dates. The exercise prices are $3.00 for options vesting in the first year, $4.00 for options vesting in the second year, and $5.00 for options vesting in the third year. The Company has calculated the estimated fair market value of these options using the Black-Scholes Option Pricing model and the following assumptions: term 3 to 5.5 years, stock price $2.01, exercise prices $3.00-$5.00, 235% volatility, 0.80% risk free rate.

On August 5, 2014, it was approved at the Company s Annual General Meeting to increase the number of restricted shares that the Company is authorized to issue under the 2011 Equity Incentive Plan to 2,000,000.

On August 18, 2014, the Company granted options to purchase 670,000 shares. 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. 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 to 5.5 years, stock price $1.85, exercise prices $2.50-$3.00, 237% volatility, 1.58% risk free rate.

On August 18, 2014, the Company granted options to purchase 60,000 shares. These options vest in equal six monthly installments over three years, starting six months after the date of grant, and expire three years after the vesting dates. The exercise prices are $3.00 for options vesting in the first year, $4.00 for options vesting in the second year, and $5.00 for options vesting in the third year. The Company has calculated the estimated fair market value of these options using the Black-Scholes Option Pricing model and the following assumptions: term 3.5 to 6 years, stock price $1.85, exercise prices $3.00-$5.00, 237% volatility, 0.89% risk free rate.

During the year ended December 31, 2014, 60,000 options expired, following the cessation of a consultant s contract.

Note 8 Warrants and Options (Continued)

Below is a table summarizing the options issued and outstanding as of December 31, 2015.

Below is a table summarizing the options issued and outstanding as of December 31, 2015, which have a weighted average exercise price of $3.53 per share and a weighted average remaining contractual life of 3.0 years.

Date Issued	Number Outstanding	Exercise Price $	Contractual Life (Years)	Expiration Date	Proceeds to Company if Exercised $
11/25/11	630,000	3.00-5.00	4.5-7.0	05/25/16-11/25/18	2,520,000
09/01/12	30,000	4.31-6.31	3.0	03/01/16-09/01/18	159,300
03/20/13	37,000	2.35-4.35	3.0	09/20/16-03/20/19	123,950
09/02/13	16,300	2.35-4.35	3.0	03/02/14-09/02/16	54,605
05/16/14	25,000	3.00-5.00	3.0-5.5	11/16/17-05/16/20	100,000
08/18/14	670,000	2.50-3.00	4.5-5.5	02/18/19-02/18/20	1,842,500
05/18/15	20,000	3.80	4.5	11/18/19	76,000
07/23/15	327,000	4.00	4.5	01/23/20	1,308,000
08/17/15	75,000	3.75	5.0	08/17/20	281,250
	1,830,300				**6,465,605**

Total remaining unrecognized compensation cost related to unvested stock options is approximately $159,096 and is expected to be recognized over a period of 1.5 years.

Note 9 - Fair Value Measurements

On a recurring basis, we measure certain financial assets and liabilities based upon the fair value hierarchy as described in the Company s significant accounting policies in Note 3. The following table presents information about the Company s liabilities measured at fair value as of December 31, 2015:

	Level 1	**Level 2**	**Level 3**	**Fair Value at December 31, 2015**
Liabilities				
Derivative Liability	$ -	$ -	$ -	$ -

	Level 1	**Level 2**	**Level 3**

				Fair Value at December 31, 2014
Liabilities				
Derivative liability	$ -	$ 1,577,640	$ -	$ 1,577,640

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

Balance as of December 31, 2014	$	1,577,640
Exercise of warrants attached to derivative liability	$	(74,347)
Adjustment due to expiry of derivative liability	$	(1,163,549)
Fair value adjustments	$	(339,744)
Balance as of December 31, 2015	**$**	**-**

During the year ended December 31, 2015, the Company issued warrants for services at fair market value of $nil, options under the 2011 Equity Incentive Plan at fair market value of $950,455 and re-measured options, where their exercise period was extended, to fair market value of $705,818, an increase of $20,796. The Company did not issue shares of common stock for services and as at December 31, 2015, the Company had no derivative liabilities.

Note 10 - Derivative Financial Instruments

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

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

December 31, 2015		**December 31, 2014**	
Risk-free interest rate	0%	Risk-free interest rate	1.65%
Estimated volatility	0%	Estimated volatility	232.6%
Dividend rate	None	Dividend rate	None
Estimated term in years	0	Estimated term in years	4

Note 11 - Income Taxes

The Company has estimated net operating losses for the years ended December 31, 2015 and 2014 of $8,774,691 and $7,141,271, 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 20.25 percent and U.S. taxes at a rate of 35 percent, for a weighted average of 26 and 32 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:

	2015	2014
	$	$
Net loss	(9,530,242)	(8,213,529)
Tax adjustments	755,551	1,072,258
Estimated net operating losses	(8,774,691)	(7,141,271)
Tax rate	26%	32%

Income tax recovery at statutory rate	(2,306,549)	(2,247,408)
Valuation allowance	2,306,549	2,247,408
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, 2015 are as follows:

	2015	2014
	$	$
Net operating losses carried forward	5,792,392	4,295,152
Valuation allowance	(5,792,392)	(4,295,152)
Net deferred income tax asset	-	

Note 12 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 $1,142,971 (€1,048,020) to help fund the research endeavors of the Company in the area of colorectal cancer. The Company had received the entirety of these funds in respect of approved expenditures as of March 31, 2014. Under the terms of the agreement, the Company is due to repay $342,891 (€314,406) of this amount by installments over the period June 30, 2014 to June 30, 2023. The Company has recorded the balance of $800,079 (€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 $342,891 (€314,406) and the 6 percent royalty on revenue, is twice the amount of funding received. As at December 31, 2015, $282,908 (€259,406) was outstanding to be repaid to the Walloon Region under this agreement.

b)

Administrative Support Agreement

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

c)

Lease Obligations Payable

The Company leases three Tecan machines (automated liquid handling robots) under a lease classified as a capital lease. The total cost of this leased laboratory equipment is $600,325 (€550,454). The leased equipment is amortized on a straight line basis over five years. Total accumulated amortization related to the leased equipment is $70,038 (€64,220) for the year ended December 31, 2015 and $nil (€nil) for the year ended December 31, 2014.

The following is a schedule showing the future minimum lease payments under capital leases by years and the present value of the minimum payments as of December 31, 2015.

2016	$	88,391
2017	$	85,401
2018	$	82,513
2019	$	79,723
2020	$	37,228
Total minimum lease payments	$	373,256
Less: Amount representing interest	$	20,367
Present value of minimum lease payments	**$**	**352,889**

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

2016	$	166,429
2017	$	9,369
Thereafter	$	nil
Total	**$**	**175,798**

Note 12 Commitments and Contingencies (Continued)

d)

Bonn University Agreement

On July 11, 2012, the Company entered into an 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 $425,334 (€390,000). On April 16, 2014, the Company entered into an extension of this agreement, for a period of a further two years from June 1, 2014 to May 31, 2016. The total payments to be made by the Company in accordance with the extension of the agreement are $425,334 (€390,000).

e)

Hvidovre Hospital, Denmark Agreement

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 colorectal cancer. 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 $1,496,795 (DKR 10,245,000). On April 15, 2015, the Company amended the aforementioned collaborative research agreement with an additional commitment for samples costing $50,000, to be provided over a two year period, expiring on April 15, 2017.

f)

Legal Proceedings

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

Note 13 - Subsequent Events

On January 15, 2016, 100,000 warrants were exercised at $0.50 per share, resulting in cash proceeds of $50,000. As a result a total of 100,000 shares of common stock were issued.

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, 2015, 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, 2015, 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, 2015, the Company determined that there were control deficiencies that constituted material weaknesses, such as the failure to maintain sufficient internal controls over financial reporting for the cash process, where certain bank accounts do not require dual signature on payments.

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, 2015, 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, 2015, we did not maintain sufficient internal controls over financial reporting for all of the cash process, including failure to segregate cash handling and accounting functions, and did not require dual signature on some of the Company s bank accounts. We have developed, and are currently implementing, a remediation plan for this material weakness. We have continued to execute our remediation plan, which includes changing bank mandates to ensure dual authorization is present on all of our bank accounts and rationalizing the number of bank accounts held by us.

There have been no changes in our internal control over financial reporting during the fiscal fourth quarter of the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than completion of the actions taken to remediate the material weaknesses which existed as of December 31, 2014, as described above.

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:

1.

Dual authorization of bank payments instigated in 2015 has continued to be rolled out to all Group company bank accounts. As at March 11, 2016, the Company and its subsidiaries all have bank accounts that have dual authorization controls over payments.

2.

The purchase order authorization process implemented in the main trading subsidiary of the Group in 2015 will be rolled out to other Group companies in 2016.

ITEM 9B.

OTHER INFORMATION

None.

PART III

ITEM 10.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors and Executive Officers

The following table sets forth the names and ages of the Company s directors and executive officers as of December 31, 2015.

Name	Age	Position with the Company	Officer/Director Since
Cameron Reynolds	45	President	October 6, 2011
		Chief Executive Officer	October 6, 2011
		Director	October 6, 2011
David Kratochvil[1]	50	Chief Financial Officer	August 17, 2015
		Treasurer	August 17, 2015
Rodney Rootsaert	44	Secretary	October 6, 2011
Jason Terrell MD[2]	35	Chief Medical Officer	March 20, 2013
		Head of U.S. Operations	
Dr. Martin Faulkes	71	Director	October 6, 2011
		Executive Chairman	October 6, 2011
Guy Innes[3] [4] [5]	59	Director	October 6, 2011
Dr. Alan Colman[3]	67	Director	October 6, 2011
Dr. Habib Skaff[3] [4] [5]	38	Director	June 01, 2014

(1)

Mike O Connell served as VolitionRx s Chief Financial Officer from July 1, 2014 until his resignation on August 17, 2015.

(2)

Dr. Terrell converted from part-time to full-time status effective January 1, 2016.

(3)

Member of the Audit Committee

(4)

Member of the Compensation Committee

(5)

Member of the Nominations and Governance Committee

On November 5, 2014, our Board of Directors 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 www.volitionrx.com. 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 three members, Mr. Guy Innes (Chair), Dr. Habib Skaff and Dr. Alan Colman, 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. Guy Innes is designated as an audit committee financial expert.

Compensation Committee

Our compensation committee consists of two members, Mr. Guy Innes (Chair) and Dr. Habib Skaff, 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; and

.

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.

Nominations and Governance Committee

Our nominations and governance committee consists of two members, Mr. Guy Innes (Chair) and Dr. Habib Skaff, 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 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; and

.

reviewing and assessing, on an annual basis, the adequacy of the formal written charter on an annual basis; and generally advising our board of directors on corporate governance and related matters.

Nominating Procedures

The nominations and governance committee 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 will consider many factors when considering candidates for election to the board of directors, including that the proper skills and experiences are represented on the board of directors and that the composition of the board of directors satisfies applicable legal requirements. Depending upon the current needs of the board of directors, certain factors may be weighed more or less heavily by the committee. The nominations and governance committee will provide information progress updates to the board of directors and will meet to consider and recommend final director candidates to the entire board.

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.

Science Executives

The following table sets forth the names and ages of our Scientific Officers as of December 31, 2015:

Name	Age	Position	Officer/Director Since
Dr. Jacob Micallef	59	Chief Scientific Officer, Volition Rx	January 1, 2015
		Chief Scientific Officer, Belgian Volition	October 11, 2010
Dr. Mark Eccleston	44	Chief Scientific Officer, HyperGenomics	March 7, 2011

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. 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 the terms range from one to three years.

Background and Business Experience

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

CAMERON REYNOLDS serves as our President, Chief Executive Officer and Director. Prior to 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 CEO of Hypergenomics since March 7, 2011 and was appointed director and CEO of Volition Diagnostics UK Limited, on November 13, 2015. From 2004 until 2011, Mr. Reynolds founded and served as Managing Director and Director of Mining House Limited, 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 AIM, TSX and 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 transgenisis 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. From 2005 until present, Mr. Reynolds has 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. (KALG, OTC), Iofina Natural Gas PLC (IOF, AIM); Canyon Copper Corp. (TSX.V: CNC, OTCBB: CNYC), and Hunter Bay Resources (HBY, TSX-V). 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.

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 financial and accounting knowledge to the company.

RODNEY ROOTSAERT serves as our Secretary. Prior to the Share Exchange Agreement, he was the Administration and Legal Officer of Singapore Volition, a position he held since August 6, 2010. Mr, Rootsaert 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. Rootsaert 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. Rootsaert 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. Rootsaert 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.

JASON TERRELL MD serves as Chief Medical Officer and Head of U.S. Operations. Effective January 1, 2016, Dr. Jason Terrell MD 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. 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 University of Texas and 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. MARTIN FAULKES serves as Executive Chairman of the Board of Directors. Prior to 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. Mr. Faulkes has also been a director of Belgian Volition since August 10, 2011. From 1998 until the present day, Dr. Faulkes has focused on charitable activities, as the Founder and Sole Benefactor of the Dill Faulkes Educational Trust, a UK registered charity, where he is Chairman. He also sits on the Board of the Cambridge 800th Anniversary Campaign in the UK. 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 like airlines, utility companies, banks, and insurance, 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 CEO 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; namely sales, finance, recruitment, staff management and project control. Dr. Faulkes has over 30 years of entrepreneurial and managerial experience as the founder and CEO 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 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 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 & 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 the Share Exchange Agreement, Dr. Colman served as a Director of Singapore Volition from April 1, 2011 to December 15, 2015 and as Chairman of the Scientific Advisory Board of Singapore Volition since April 5, 2011. Dr. Colman received a BA (1971), MA (1975) and PhD (1975) from Oxford University. Dr. Colman is currently a Visiting Scholar at the Harvard University Department of Stem Cell and Regenerative Biology. 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, UK, from 2008 to 2009. Prior to joining the A*STAR Singapore Stem Cell Consortium, Dr. Colman was Chief Scientific Officer and then CEO for the Singaporean human embryonic stem cell company, ES Cell International from 2002 to 2007. Dr. Colman was the research director of the company PPL Therapeutics in Edinburgh, UK, 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. This company 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 on account of his work in biochemistry, stem cell research and pathology.

DR. HABIB SKAFF serves as a Director. Prior to 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 co-founded Intezyne Technologies in 2004 and serves as that company s Chief Executive Officer, where he is responsible for establishing and implementing strategic planning for the future. Dr. Skaff works closely with the Chief Scientific Officer to develop and implement Intezyne s intellectual property strategy as well as establish alliances with potential partners. He also leads Intezyne s fundraising through debt and equity financing and works closely with the CFO in this capacity. He is also President and Chairman of the Board of Directors of Intezyne. Dr. Skaff currently serves as

Chairman of Skaff Corporation of America, a position he has had since 1999. He guides strategic planning but is not involved in day-to-day operations. 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 he is a valuable asset to the company.

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

DR. JACOB MICALLEF serves as Chief Scientific Officer of the Company and Chief Scientific Officer and Director of Belgian Volition. 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 UK on 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 SA, a subsidiary of Singapore 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 Pharmaceuticals. Over a 15-year period, starting in 1985, Dr. Micallef worked for the World Health Organization (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. Jacob 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.

DR. MARK ECCLESTON serves as Chief Scientific Officer of Hypergenomics. Prior to the Share Exchange Agreement Dr. Eccleston served as a Science Executive Officer of HyperGenomics since March 7, 2011, but was not otherwise involved with Singapore Volition. In 2010, Dr. Eccleston founded OncoLytika Limited, or OncoLytika, which focuses on opportunity recognition and product/process innovation within start-ups as well as established companies, where his main responsibilities are advising companies on business development and preclinical project management. From 2008 to 2009, Dr. Eccleston held a program management position at Valirx., where he ran multiple epigenetics-based diagnostic and therapeutics programs. Dr. Eccleston has also held various other roles in business and industry including: Chief Scientific Officer from 2005 to 2008 as consultant to Cambridge Applied Polymers, where he devised and managed multiple high value consultancy projects for clients including Cadburys, Kellogg s, Reckitt Benckiser, Proctor and Gamble, and Umbro as well as a Spanish company specializing in non-woven (polymeric) fabric, Tesalca; and CEO of Vivamer Ltd. in 2002, a company spun out from Cambridge University where he was responsible for commercialization of drug delivery and imaging technologies based on extensive work in this area during his academic career. Mr. Eccleston is a biotechnology entrepreneur with over 18 years of experience in the sector, both in academia and in industry. In light of this and Dr. Eccleston s past work in biotechnology, epigenetics and diagnostics, Dr. Eccleston was appointed as a Chief Scientific Officer of our subsidiary HyperGenomics.

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 VolitionRx, Singapore Volition or its subsidiaries, has been involved in any legal proceedings required to be disclosed pursuant to Item 401(f) of Regulation S-K.

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.

Compliance with Section 16(a) of the Exchange Act

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 and 4 and amendments thereto furnished to us under Rule 16a-3(e) during the year ended December 31, 2015, Forms 5 and any amendments thereto furnished to us with respect to the year ended December 31, 2015, and the representations made by the reporting persons to us, we believe that during the year ended December 31, 2015, 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:

.

late filing of Form 4 s by each of Mr. Reynolds; Dr. Faulkes; Mr. Innes; and Mr. Rootsaert to report the granting of an aggregate of 275,000 options on August 18, 2014 under the Company s 2011 Equity Incentive Plan;

.

late filing of Form 4 s by each of Mr. Reynolds; Dr. Faulkes; Mr. Innes; Dr. Colman; Dr. Skaff and Mr. Rootsaert to report the amendment to the exercise period from three to four years from vesting for an aggregate of 270,000 options granted on November 25, 2011 under the Company s 2011 Equity Incentive Plan;

.

late filing of Form 4 by Dr. Faulkes to report the exercise of a warrant to purchase 250,000 shares of Common Stock;

.

late filing of Form 4 by Dr. Micallef to report the cashless exercise of 50,000 options granted under the Company s 2011 Equity Incentive Plan;

.

Form 5 filed by Dr. Micallef to include the beneficial ownership of spouse that was omitted from original Form 3 and subsequent Form 4; and

.

late filing of Form 4 by Mr. Reynolds to report beneficial ownership of spouse.

45

ITEM 11.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the principal positions of our named executive officers at VolitionRx and the compensation paid to such persons, including in their capacities as officers of Singapore Volition and its subsidiaries, for the fiscal years ended December 31, 2015 and 2014. 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 Principal Position	Year Ended December 31,	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Cameron Reynolds[2]	2015	121,672	-0-	-0-	199,287	-0-	-0-	145,340	466,299
President, CEO and Director	2014	-0-	-0-	-0-	99,427	-0-	-0-	129,149	228,576
Dr Jacob Micallef[3]	2015	-0-	46,760	-0-	224,905	-0-	-0-	147,209	418,874
Chief Scientific Officer	2014	-0-	-0-	-0-	126,293	-0-	-0-	150,826	277,119
Rodney Rootsaert [4]	2015	118,351	-0-	-0-	123,174	-0-	-0-	4,128	245,653
Secretary	2014	-0-	-0-	-0-	58,669	-0-	-0-	84,338	143,007
Jason Terrell [5]	2015	-0-	-0-	-0-	21,348	(42,131)	-0-	-0-	(20,783)
Chief Medical Officer	2014	-0-	-0-	-0-	240,615	22,388	-0-	-0-	263,003
David Kratochvil[6]	2015	82,500	-0-	-0-	165,572	-0-	-0-	32,864	280,936
CFO and Treasurer	2014	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-
Mike O Connell[7]	2015	-0-	-0-	-0-	3,304	-0-	-0-	167,461	170,765
Former CFO and Treasurer	2014	-0-	-0-	-0-	32,632	-0-	-0-	107,559	140,191

(1)

All Option and Warrant Awards have been calculated based upon the aggregate grant date fair value computed in accordance with FASB ASC Topic 718.

(2)

Cameron Reynolds is currently the President, Chief Executive Officer and a Director of VolitionRx, the Chief Executive Officer and a Director of Singapore Volition, a director of Belgian Volition, the Chief Executive Officer and a Director of HyperGenomics, and the Chief Executive Officer and a Director of Volition Diagnostics UK Limited.

Cameron Reynolds receives compensation pursuant to an agreement, or the PB Commodities Consulting Agreement, dated August 6, 2010, entered into by and between Singapore Volition and PB Commodities Pte Limited, or PB Commodities. The PB Commodities Consulting Agreement provides office space, office support staff, and consultancy services to Singapore Volition for the structuring, management, fundraising and development and implementation of its business plan. The term of the PB Commodities Consulting Agreement is twelve months, commencing on September 1, 2010, with automatic extensions of twelve months and a three month notice required for termination of the PB Commodities Consulting Agreement. Effective August 1, 2015, the PB Commodities Consulting Agreement was amended to remove the provision of office space and office support staff from the services being provided thereunder. As part of the PB Commodities Consulting Agreement, Singapore Volition shall pay consultancy fees each month to PB Commodities for the services of Cameron Reynolds (see the following paragraph regarding Mr. Reynolds Consulting Agreement with PB Commodities). For the years ended December 31, 2015 and 2014, PB Commodities received $148,247 and $143,679, respectively, from Singapore Volition for the services of Mr. Reynolds, pursuant to the PB Commodities Consulting Agreement. The foregoing description of the 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.

Cameron Reynolds receives compensation from PB Commodities, as described in the previous paragraph, pursuant to an Employment Agreement, or the Reynolds Employment Agreement, dated September 4, 2010, in exchange for serving as an executive officer of PB Commodities and performing consulting services on its behalf. The term of the Reynolds Employment Agreement is twelve (12) months, which shall be automatically extended for additional terms of twelve (12) months. Under the Reynolds Employment Agreement, Mr. Reynolds only performs consulting services to Singapore Volition (see previous paragraph). In exchange for these services, Mr. Reynolds received $8,000 per month (which increased to $8,800 on April 1, 2014) from PB Commodities. 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 10.5.

On January 1, 2015, Mr. Reynolds entered into a Consultancy Agreement with PB Commodities, or the Reynolds Consultancy Agreement, which superseded the Reynolds Employment 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. 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. For the years ended December 31, 2015 and 2014, Mr. Reynolds received $145,340 and $129,149, respectively, pursuant to the Reynolds Consultancy Agreement and the Reynolds Employment Agreement. Between July 1, 2011 and March 31, 2014 Mr. Reynolds also received a housing allowance of $3,000 per month, which decreased to an average of $1,998 per month for the period from March 1, 2014 to December 31, 2014. For the years ended December 31, 2015 and 2014, Mr. Reynolds received $0 and $25,949 respectively, as a housing allowance which is included in the figures of $145,340 and $129,149 as compensation received by Mr. Reynolds for the years ended December 31, 2015 and 2014, respectively. The housing allowance ended on December 31, 2014. 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 10.16.

Cameron Reynolds receives compensation from VolitionRx pursuant to an Executive Employment Agreement, or the Reynolds Executive Employment Agreement, effective as of January 1, 2015, 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 10.17.

On November 25, 2011, Cameron Reynolds was granted an option to purchase 120,000 shares of common stock of VolitionRx under the 2011 Equity Incentive Plan, or the Plan, dated November 17, 2011. On August 18, 2014, Mr. Reynolds was granted an option to purchase 100,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015 Mr. Reynolds was granted an option to purchase 55,000 shares of common stock of VolitionRx under the Plan. None of these options have been exercised. See note (8) below for a discussion of the terms of options granted under the Plan and the calculation of fair market value of options granted under the Plan.

(3)

Dr. Jacob Micallef is currently the Chief Scientific Officer of VolitionRx (appointed January 1, 2015) and Chief Scientific Officer and a Director of Belgian Volition. There are no employment agreements by and between Dr. Micallef and VolitionRx or Belgian Volition.

Dr. Micallef receives compensation pursuant to a consultancy agreement, or the 2015 Micallef Agreement, dated January 1, 2015, entered into by and between VolitionRx and Borlaug Limited, or Borlaug. 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 commenced effective January 1, 2015, and continues until terminated as provided in the 2015 Micallef Agreement. In exchange for such services, VolitionRx pays Borlaug a monthly fee of £6,014 GBP which increased on March 1, 2015 to £8,333 GBP per month following the up-listing of the Company to the NYSE MKT. The 2015 Micallef Agreement superseded the consultancy agreement, dated January 1, 2011, entered into by and between Belgian Volition and Borlaug, pursuant to which Borlaug received a monthly fee of £5,467 GBP (which increased to £6,014 GBP on April 1, 2014) and bonuses upon the achievement of certain milestones. For the years ended December 31, 2015 and 2014, Borlaug received $193,969 and $150,826, respectively for fees and bonuses. 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 10.18.

On November 25, 2011, Dr. Micallef was granted an option to purchase 120,000 shares of common stock of VolitionRx under the Plan. This option has subsequently been assigned to Borlaug. Dr. Micallef is a controlling director of Borlaug and has voting and dispositive control over shares of VolitionRx s common stock held by Borlaug and shares issuable to Borlaug upon the exercise of stock purchase options and stock purchase warrants. On December 3, 2012, Borlaug was granted an option to purchase 50,000 shares of common stock of VolitionRx under the Plan. On August 18, 2014, Borlaug was granted an option to purchase 130,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Borlaug was granted an option to purchase 55,000 shares of common stock of VolitionRx under the Plan. On December 9, 2015, Borlaug exercised the 50,000 options granted on December 3, 2012 under the Plan at $3.01 per shares in a cashless exercise that resulted in the issuance of 14,166 shares of common stock to Borlaug. See note (8) below for a discussion of the terms of options granted under the Plan and the calculation of fair market value of options granted under the Plan.

(4)

Rodney Rootsaert is currently the Secretary of VolitionRx, a director of Singapore Volition, a director of HyperGenomics, the Secretary and a Director of Belgian Volition and a Director of Volition Diagnostics UK Limited.

Rodney Rootsaert receives compensation from VolitionRx pursuant to an Employment Agreement, or the Rootsaert Employment Agreement, effective as of January 1, 2015, in exchange for serving as the Corporate Secretary of VolitionRx. The term of the Rootsaert Employment Agreement is three (3) years, which shall be automatically extended for successive periods of two (2) years. In exchange for his services, Mr. Rootsaert received £4,500.00 GBP per month from VolitionRx which increased on March 1, 2015 to £6,666 GBP per month following the up-listing of the Company to the NYSE MKT. Effective January 1, 2015, the Rootsaert Employment Agreement superseded the agreement, dated August 6, 2010, entered into by and between Singapore Volition and PB Commodities and the Employment Agreement, dated September 4, 2010 between PB Commodities and Mr. Rootsaert, pursuant to which Mr. Rootsaert received $6,000 per month (which increased to $6,600 on April 1, 2014). For the years ended December 31, 2015 and 2014, Mr. Rootsaert received $118,351 and $77,400, respectively. The foregoing description of the 2015 Rootsaert Employment Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.19.

Mining House Limited, or Mining House, provides consultancy and office support services to Singapore Volition for £1,450 GBP (approximately $2,146 USD) per month commencing on November 1, 2010, which was reduced to £450 GBP (approximately $666) on April 1, 2014; additionally, Singapore Volition is required to pay for all reasonable expenses incurred by Mining House in providing these services. For the year ended December 31, 2015, Singapore Volition paid approximately $16,022 to Mining House split between $8,257 for consultancy and office support services and $7,765 for expenses. For the year ended December 31, 2014, Singapore Volition paid approximately $22,882 to Mining House split between $13,876 for consultancy and office support services and $9,006 for expenses. By reason of his directorship of Mining House, Mr. Rootsaert is deemed to have received compensation in the form of one half (1/2) of the consultancy and office support services received by Mining House, along with Mr. Laith Reynolds for the years ended December 31, 2015 and December 31, 2014. For the years ended December 31, 2015 and 2014, Mr. Rootsaert is deemed to have received $4,128 and $6,938, respectively, from Mining House. There is no written agreement by and between Mining House and Singapore Volition setting forth the terms of this arrangement.

On November 25, 2011, Rodney Rootsaert was granted an option to purchase 60,000 shares of common stock of VolitionRx under the Plan. On August 18, 2014, Mr. Rootsaert was granted an option to purchase 60,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015 Mr. Rootsaert was granted an option to purchase 35,000 shares of common stock of VolitionRx under the Plan. None of these options have been exercised. See note (8) below for a discussion of the terms of options granted under the Plan and the calculation of fair market value of options granted under the Plan.

(5)

Jason Terrell is currently the Chief Medical Officer of VolitionRx and Head of U.S. Operations.

Jason Terrell receives compensation from VolitionRx pursuant to an Employment Agreement, effective January 1, 2016, 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. Effective January 1, 2016, the 2016 Terrell Employment Agreement superseded the consultancy agreement, dated March 20, 2013, entered into by and between Dr. Terrell and VolitionRx, pursuant to which Dr. Terrell received compensation through a warrant agreement for serving in a part-time capacity as the Company s Chief Medical Officer and Head of U.S. Operations. Under the terms of the warrant he is entitled to subscribe for 200,000 shares of common stock at an exercise price of $2.47. The warrants are to expire three years after vesting. 25,000 warrants vested immediately on March 20, 2013. A further 25,000 warrants vested on October 1, 2014 upon VolitionRx signing an agreement to commence a clinical trial of VolitionRx s proprietary screening kits and devices for the detection of certain diseases in the United States. A further 25,000 warrants are to vest upon VolitionRx signing a second U.S. clinical trial agreement. 50,000 warrants are to vest on the date VolitionRx receives approval from the FDA for the sale and distribution in the United States of its first proprietary screening kit or device for the detection of a certain disease. A further 50,000 warrants are to vest upon the receipt of FDA approval for the sale and distribution in the United States of its second proprietary screening kit or device for the detection of a certain disease that is different from the first proprietary screening kit. 25,000 warrants are to vest on the date of VolitionRx signing an agreement with a laboratory/group certified through the CLIA for the use of VolitionRx s proprietary screening kits and devices for the detection of certain diseases in humans in the United States. 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 10.24.

We have calculated the fair market value of the 25,000 warrants that vested immediately at $57,046 using the Black Scholes Option Pricing Model using the following assumptions: three year term, $2.48 stock price, $2.47 exercise price, 253% volatility, 0.38% risk free rate. The 25,000 warrants that vested on October 1, 2014 have been valued at $104,281 using the Black Scholes Option Pricing model using the following assumptions: 3 year term, $4.21 stock price, $2.47 exercise price, 235% volatility, 1.0% risk free rate. We carried out a re-measurement of the 150,000 unvested warrants as at December 31, 2015 in accordance with ASC 505. We estimated that the vesting of these warrants will take place over the 3 years to January 1, 2019. The unvested warrants were re-measured at $402,899 using Black Scholes Option Pricing model using the following assumptions: 1 to 3 year term, $4.50 stock price, $2.47 exercise price, 66% to 90% volatility, 0.65% to 1.31% risk free rate.

The 50,000 vested warrants were exercised by Jason Terrell on October 7, 2014. On August 18, 2014, Dr. Terrell was granted an option to purchase 25,000 shares of common stock of VolitionRx under the Plan. None of these options have been exercised. See note (8) below for a discussion of the terms of options granted under the Plan and the calculation of fair market value of options granted under the Plan.

(6)

David Kratochvil has served as the CFO and Treasurer of VolitionRx since August 17, 2015.

David Kratochvil receives compensation from VolitionRx pursuant to an Employment Agreement, effective as of August 17, 2015, 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. Effective August 17, 2015, the Kratochvil Employment Agreement superseded the consultancy agreement, dated June 15, 2015, or the Kratochvil Consultancy Agreement, entered into by and between VolitionRx and Vista Capital Advisors, LLC, or Vista Capital, pursuant to which Vista Capital received $15,000 per month the services provided by Mr. Kratochvil to VolitionRx. For the years ended December 31, 2015 and 2014, Mr. Kratochvil received $115,364 and $0, respectively. Included in the figure of $115,364 is $30,000 received by Mr. Kratochvil under the Kratochvil Consultancy Agreement for the years ended December 31, 2015 and $2,864 of medical premiums reimbursed. 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 10.25.

On August 17, 2015 Mr. Kratochvil was granted an option to purchase 75,000 shares of common stock of VolitionRx under the Plan. None of these options have been exercised. See note (8) below for a discussion of the terms of options granted under the Plan and the calculation of fair market value of options granted under the Plan.

(7)

Mike O Connell served as the CFO and Treasurer of VolitionRx until August 17, 2015. There are no employment agreements by and between Mr. O Connell and VolitionRx and Mr. O Connell receives no employment compensation in exchange for his services as an executive officer of VolitionRx.

Mike O Connell received compensation pursuant to a consultancy agreement, or the O Connell Agreement, dated May 2, 2014, entered into by and between VolitionRx and Isosceles Finance Limited, or Isosceles. Under the terms of the O Connell Agreement, Isosceles will make available to VolitionRx the services of Mr. O Connell to provide CFO services and shall provide additional accountancy and financial control services to VolitionRx. The term of the O Connell Agreement is twelve (12) months, which shall be automatically extended for successive periods of twelve (12) months until terminated as provided in the Agreement. The services are to be provided on a time and materials basis. Isosceles continues to provide general accountancy and financial control services to the Company after Mr. O Connell resigned as CFO and has received fees of $71,968 since the resignation of Mr. O Connell on August 17, 2015. For the years ended December 31, 2015 and 2014, Isosceles received $239,429 and $107,559, respectively, pursuant to the O Connell Agreement. The foregoing description of the O Connell Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.22.

On August 18, 2014, Mike O Connell was granted an option to purchase 60,000 shares of common stock of VolitionRx under the Plan. Mr. O Connell exercised 20,000 options under the Plan at $3.00 per shares in a cashless exercise that resulted in the issuance of 4,810 shares of common stock to Mr. O Connell. See note (8) below for a discussion of the terms of options granted under the Plan and the calculation of fair market value of options granted under the Plan.

(8)

November 25, 2011 Grants: Under the terms of the 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 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 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.

August 18, 2014 Grant to Michael O Connell, these options vest in equal six monthly installments over three years, starting six months after the date of grant, and expire three (3) years after the vesting dates. The exercise prices are $3.00 for options vesting in the first year, $4.00 for options vesting in the second year, and $5.00 for options vesting in the third year. On August 14, 2015, the Company amended the vesting date of the second installment of 10,000 stock options, originally granted on August 18, 2014, so that they vest on August 16, 2015.

The Company has 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 3.5 to 6 years, stock price $1.85, exercise prices $3.00-$5.00, 237% volatility, 0.89% risk free rate.

July 23, 2015 Grants: Under the terms of the 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 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%.

Additional Narrative Disclosure

VolitionRx believes that it is in its best interest to secure the services of key executives and that it is appropriate to provide such executives with protection in the event their employment with VolitionRx is terminated under certain circumstances. Therefore VolitionRx entered into employment agreements with Cameron Reynolds on January 1, 2015, with Rodney Rootsaert on January 1, 2015, with David Kratochvil on August 11, 2015 and with Dr. Jason Terrell on December 29, 2015. VolitionRx additionally entered into a consultancy agreement or the 2015 Micallef Consultancy Agreement with Borlaug for the services of Dr. Jacob Micallef on January 1, 2015.

Pursuant to the employment agreements with each of Mr. Reynolds, Mr. Rootsaert and Mr. Kratochvil, 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 Consultancy 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 employment agreement with Dr. Jason Terrell, 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, Singapore Volition and its subsidiaries as of the fiscal year ended December 31, 2015.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

Name	Number of Securities Underlying Unexercised Options (#)exercisable	Number of Securities Underlying Unexercised Options (#) unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that have not Vested (#)	Market Value of Shares of Units of Stock that Have not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or other Rights that have not Vested ($)
Cameron Reynolds[1]	24,000[2]	-0-	-0-	$3.00	May 25, 2016	-0-	-0-	-0-	-0-
	24,000[2]	0	-0-	$3.00	November 25, 2016	-0-	-0-	-0-	-0-
	24,000[2]	-0-	-0-	$4.00	May 25, 2017	-0-	-0-	-0-	-0-
	24,000[2]	-0-	-0-	$4.00	November 25, 2017	-0-	-0-	-0-	-0-
	24,000[2]	-0-	-0-	$5.00	May 25, 2018	-0-	-0-	-0-	-0-
	24,000[2]	-0-	-0-	$5.00	November 25, 2018	-0-	-0-	-0-	-0-
	62,500[3]	-0-	-0-	$2.50	February 18, 2019	-0-	-0-	-0-	-0-

	62,500[3]	-0-	-0-	$3.00	February 18, 2020	-0-	-0-	-0-	-0-
	-0-	-0-	65,000[4]	$4.00	January 23, 2020	-0-	-0-	-0-	-0-
Dr. Jacob Micallef[5]	20,000	-0-	-0-	$3.00	May 25,2016	-0-	-0-	-0-	-0-
	20,000	-0-	-0-	$3.00	November 25, 2016	-0-	-0-	-0-	-0-
	20,000	-0-	-0-	$4.00	May 25, 2017	-0-	-0-	-0-	-0-
	20,000	-0-	-0-	$4.00	November 25, 2017	-0-	-0-	-0-	-0-
	20,000	-0-	-0-	$5.00	May 25, 2018	-0-	-0-	-0-	-0-
	20,000	-0-	-0-	$5.00	November 25, 2018	-0-	-0-	-0-	-0-
	65,000	-0-	-0-	$2.50	February 18, 2019	-0-	-0-	-0-	-0-
	65,000	-0-	-0-	$3.00	February 18, 2020	-0-	-0-	-0-	-0-
	-0-	-0-	55,000	$4.00	January 23, 2020	-0-	-0-	-0-	-0-

Rodney Rootsaert[6]	10,000	-0-	-0-	$3.00	May 25, 2016	-0-	-0-	-0-	-0-
	10,000	-0-	-0-	$3.00	November 25, 2016	-0-	-0-	-0-	-0-
	10,000	-0-	-0-	$4.00	May 25, 2017	-0-	-0-	-0-	-0-
	10,000	-0-	-0-	$4.00	November 25, 2017	-0-	-0-	-0-	-0-
	10,000	-0-	-0-	$5.00	May 25, 2018	-0-	-0-	-0-	-0-
	10,000	-0-	-0-	$5.00	November 25, 2018	-0-	-0-	-0-	-0-
	30,000	-0-	-0-	$2.50	February 18, 2019	-0-	-0-	-0-	-0-
	30,000	-0-	-0-	$3.00	February 18, 2020	-0-	-0-	-0-	-0-
	-0-	-0-	35,000	$4.00	January 23, 2020	-0-	-0-	-0-	-0-
Jason Terrell[7]	12,500	-0-	-0-	$2.50	February 18, 2019	-0-	-0-	-0-	-0-
	12,500	-0-	-0-	$3.00	February 18, 2020	-0-	-0-	-0-	-0-
Mike O Connell[8]	-0-	-0-	-0-	N/A	N/A	-0-	-0-	-0-	-0-
David Kratochvil[9]	75,000	-0-	-0-	$3.75	August 17, 2020	-0-	-0-	-0-	-0-

(1)

On November 25, 2011, Cameron Reynolds was granted an option to purchase 120,000 shares of common stock of VolitionRx under the Plan. On August 18, 2014, Mr. Reynolds was granted an option to purchase 100,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Mr. Reynolds was granted an option to purchase 55,000 shares of common stock of VolitionRx under the Plan. See the footnotes to the section entitled Summary Compensation Table above for further discussion of each of the options granted under the Plan.

(2)

Includes an option to purchase 4,000 shares of common stock of VolitionRx under the Plan granted to the spouse of Cameron Reynolds.

(3)

Includes an option to purchase 12,500 shares of common stock of VolitionRx under the Plan granted to the spouse of Cameron Reynolds.

(4)

Includes an option to purchase 10,000 shares of common stock of VolitionRx under the Plan granted to the spouse of Cameron Reynolds.

(5)

On November 25, 2011, Dr. Micallef was granted an option to purchase 120,000 shares of common stock of VolitionRx under the Plan. This option has subsequently been assigned to Borlaug. On August 18, 2014, Borlaug was granted an option to purchase 130,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Borlaug was granted an option to purchase 55,000 shares of common stock of VolitionRx under the Plan. See the footnotes to the section entitled Summary Compensation Table above for further discussion of each of the options granted under the Plan.

(6)

On November 25, 2011, Rodney Rootsaert was granted an option to purchase 60,000 shares of common stock of VolitionRx under the Plan. On August 18, 2014, Mr. Rootsaert was granted an option to purchase 60,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Mr. Rootsaert was granted an option to purchase 35,000 shares of common stock of VolitionRx under the Plan. See the footnotes to the section entitled Summary Compensation Table above for further discussion of each of the options granted under the Plan.

(7)

On August 18, 2014, Dr. Terrell was granted an option to purchase 25,000 shares of common stock of VolitionRx under the Plan. See the footnotes to the section entitled Summary Compensation Table above for further discussion of each of the warrants and the option granted to Dr. Terrell. Dr. Terrell was additionally granted a warrant to purchase 200,000 shares of common stock of VolitionRx at an exercise price of $2.47 per share. On October 7, 2014 Dr. Terrell exercised the warrant to purchase 50,000 shares of common stock for $123,500.

(8)

On August 18, 2014, Mike O Connell was granted an option to purchase 60,000 shares of common stock of VolitionRx under the Plan. On August 17, 2015, Mr. O Connell resigned from the Company and the [unvested] option to purchase 40,000 shares of common stock of VolitionRx expired in accordance with its terms. On November 18, 2015, Mr. O Connell exercised 20,000 options under the Plan at $3.00 per shares in a cashless exercise that resulted in the issuance of 4,810 shares of common stock to Mr. O Connell. See the footnotes to the section entitled Summary Compensation Table above for further discussion of each of the options granted under the Plan.

(9)

On August 17, 2015, David Kratochvil was granted an option to purchase 75,000 shares of common stock of VolitionRx under the Plan. See the footnotes to the section entitled Summary Compensation Table above for further discussion of each of the options granted under the Plan.

Long-Term Incentive Plans

As at December 31, 2015 and 2014, 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 compensation paid to executive officers who were also directors for all services rendered in all capacities to VolitionRx, Singapore Volition and its subsidiaries for the fiscal year ended December 31, 2015 is set forth in the section entitled Executive Compensation Summary Compensation Table . No executive officer is paid compensation for services as a director.

The following table sets forth the compensation paid to the directors who were not executive officers of VolitionRx for the fiscal year ended December 31, 2015. Unless otherwise specified, the term of each director is that as set forth under that section entitled Directors, Executive Officers and Corporate Governance -- Term of Office.

Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards[1] ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Guy Innes[2]	37,500	-0-	56,590	-0-	-0-	-0-	94,090
Dr. Martin Faulkes[3]	146,140	-0-	132,177	-0-	-0-	-0-	278,317
Dr. Alan Colman[4]	62,000	-0-	20,978	-0-	-0-	-0-	82,978
Dr. Habib Skaff[5]	37,500	-0-	42,128	-0-	-0-	-0-	79,628

(1)

All Option Awards have been calculated based upon the aggregate grant date fair value computed in accordance with FASB ASCTopic 718.

(2)

Guy Innes is currently a Director of VolitionRx. There are no employment agreements by and between Guy Innes and VolitionRx.

On March 31, 2015 Guy 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 Innes Independent Director Agreement superseded the Letter of Appointment as Non-Executive Director, or the Innes Letter of Appointment, entered into with Singapore Volition on September 23, 2010, pursuant to which Mr. Innes received $6,250 per calendar quarter for serving as non-executive director of Singapore Volition, commencing upon the admission of the shares of Singapore Volition to a recognized exchange, as per the terms set forth in the letter. Upon completion of the Share Exchange Agreement which closed on October 6, 2011 Mr. Innes was appointed as a non-executive director of VolitionRx and the non-executive director s fees became payable by VolitionRx. 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 10.31.

On November 25, 2011, Guy Innes was granted an option to purchase 30,000 shares of common stock of VolitionRx under the Plan. On August 18, 2014, Mr. Innes was granted an option to purchase 30,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Mr. Innes was granted an option to purchase 15,000 shares of common stock of VolitionRx under the Plan. See note (8) to the section entitled Summary Compensation Table above for further discussion of the options granted under the Plan.

(3)

Dr. Martin Faulkes is currently a Director of VolitionRx, and Belgian Volition. There are no employment agreements by and between Dr. Faulkes and VolitionRx or Belgian Volition.

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 commencing March 1, 2015. The Faulkes Executive Chairman Agreement superseded the Letter of Appointment as Executive Chairman, or the Faulkes Letter of Appointment, entered into with Singapore Volition on July 13, 2011, pursuant to which Dr. Faulkes received $22,500 per calendar quarter for serving as executive chairman of the Board of Directors of Singapore Volition, with payment of fees commencing upon the admission of the shares of Singapore Volition to a recognized exchange. Upon completion of the Share Exchange Agreement which closed on October 6, 2011 Dr. Faulkes was appointed as executive chairman of VolitionRx and the executive chairman s fees became payable by VolitionRx. On April 1, 2014 the quarterly fee received by Dr. Faulkes increased to $8,250. The foregoing description of Faulkes Executive Chairman Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.30.

On November 25, 2011, Dr. Faulkes was granted an option to purchase 30,000 shares of common stock of VolitionRx under the Plan. On August 18, 2014, Dr. Faulkes was granted an option to purchase 60,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Dr. Faulkes was granted an option to purchase 40,000 shares of

common stock of VolitionRx under the Plan. See note (8) to the section entitled Summary Compensation Table above for further discussion of the options granted under the Plan.

(4)

Dr. Alan Colman is currently a Director of VolitionRx. There are no employment agreements by and between Dr. Colman and VolitionRx.

On March 31, 2015 Dr. Alan 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 USD per calendar quarter commencing March 1, 2015. The Colman Independent Director Agreement superseded the Letter of Appointment as Non-Executive Director, or the Colman Letter of Appointment, entered into with Singapore Volition on May 25, 2011, pursuant to which Dr. Colman received $6,000 per month in cash or stock or a combination of both, at his sole discretion, for serving as non-executive director of Singapore Volition, commencing April 1, 2011. Following completion of the Share Exchange Agreement which closed on October 6, 2011 Dr. Colman was appointed as a non-executive director of VolitionRx and the non-executive director s fees became payable by VolitionRx. 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 10.31.

On April 1, 2011, Singapore Volition entered into a Warrant Agreement with Dr. Colman pursuant to which he received warrants to purchase up to 100,000 shares of Singapore Volition at an exercise price of $0.50 per share, per the terms set forth in the agreement. Pursuant to the terms of the Share Exchange Agreement which closed on October 6, 2011 the warrant of Singapore Volition became a warrant of VolitionRx. The warrants vested on April 1, 2011 and shall expire on April 1, 2016. As of the years ended December 31, 2015 and 2014, 0 and 0 of these warrants have been exercised, respectively. We have calculated the estimated fair market value of the warrants granted to Dr. Colman as $48,431 using the Black-Scholes Option Pricing model and the following assumptions: stock price at valuation, $0.50; expected term of five years, exercise price of $0.50, a risk free interest rate of 2.24%, a dividend yield of 0% and volatility of 190%. The foregoing description of the Colman Letter of Appointment does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.10.

On November 25, 2011, Dr. Colman was granted an option to purchase 30,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Dr. Colman was granted an option to purchase 10,000 shares of common stock of VolitionRx under the Plan. See note (8) to the section entitled Summary Compensation Table above for further discussion of the options granted under the Plan.

(5)

Dr. Habib Skaff is currently a Director of VolitionRx. There are no employment agreements by and between Dr. Skaff and VolitionRx.

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 Skaff Independent Director Agreement superseded the Letter of Appointment as Non-Executive Director or the Skaff Letter of Appointment, entered into with VolitionRx on May 28, 2014, pursuant to which Dr. Skaff received $6,250 per calendar quarter for serving as non-executive director of VolitionRx with effect from June 1, 2014. 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 10.31.

On November 25, 2011, Dr. Skaff was granted an option to purchase 24,000 shares of common stock of VolitionRx under the Plan. On August 18, 2014, Dr. Skaff was granted an option to purchase 25,000 shares of common stock of VolitionRx under the Plan. On July 23, 2015, Dr. Skaff was granted an option to purchase 10,000 shares of common stock of VolitionRx under the Plan. See note (8) to the section entitled Summary Compensation Table above for further discussion of the options granted under the Plan.

Security Holders Recommendations to Board of Directors

Stockholders can direct communications to our Secretary, Rodney Rootsaert, 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. Rootsaert 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 11, 2016, 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. Unless otherwise indicated, the stockholders listed below possess sole voting and investment power with respect to the shares they own.

As of March 11 2016, there were 18,863,272 common shares issued and outstanding, 1,803,910 shares issuable upon the exercise of options within 60 days, and 2,362,739 shares issuable upon the exercise of stock purchase warrants within 60 days.

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 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 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.

		Amount and Nature Of Beneficial Ownership	**Percent of Class** (**)
Name and Address of Beneficial Owner	**Title of Class**	(#)	**(%)**
Rodney Rootsaert (1)	Common	1,159.088	6.10%

1 Scotts Road, #24-05 Shaw Centre Singapore 228208			
Dr. Martin Faulkes (2) 1 Scotts Road, #24-05 Shaw Centre Singapore 228208	Common	1,835,101	9.63%
Guy Innes (3) 1 Scotts Road, #24-05 Shaw Centre Singapore 228208	Common	1,559,534	8.10%
Cameron Reynolds (4) 1 Scotts Road, #24-05 Shaw Centre Singapore 228208	Common	1,467,303	7.64%
Dr. Alan Colman (5) 1 Scotts Road, #24-05 Shaw Centre Singapore	Common	206,937	1.09%
Dr. Jacob Micallef (6) 1 Scotts Road, #24-05 Shaw Centre Singapore 228208	Common	460,912	2.40%
Jason Terrell (7) 1 Scotts Road, #24-05 Shaw Centre Singapore 228208	Common	86,364	0.46%
Habib Skaff (8) 1 Scotts Road, #24-05 Shaw Centre Singapore 228208	Common	76,723	0.41%

David Kratochvil (9)	Common	75,000	0.40%
1 Scotts Road, #24-05 Shaw Centre			
Singapore 228208			
Other officers (10)	Common	720,532	3.71%
All Officers and Directors as a Group	**Common**	**7,647,494**	**36.21%**
(15 Persons)			
Concord International, Inc. (11)	Common	1,004,088	5.32%
150 Orchard Road, Orchard Plaza, #08-02			
Singapore 238841			
Cotterford Company Limited (12)	Common	1,447,616	7.52%
Alma House, 7 Circular Road, Douglas			
Isle of Man, IM1 1AF			
United Kingdom			
James E Besser (13)	Common	1,443,715	7.61%
Manchester Management Company, LLC,			
3 West Hill Place,			
Boston, Massachusetts 02114			
USA			

** The percent of class as calculated herein is based on 18,863,272 common shares issued and outstanding, 1,803,910 shares issuable upon the exercise of options within 60 days, and 2,362,739 shares issuable upon the exercise of stock purchase warrants within 60 days, as of March 11 2016.

(1)

Rodney Rootsaert is VolitionRx s Secretary. Mr. Rootsaert is also the Administrative and Legal Officer and a Director of Singapore Volition, a director of HyperGenomics, the Secretary and a Director of Belgian Volition and a Director of Volition Diagnostics UK Limited. Mr. Rootsaert s beneficial ownership includes 0 shares of common stock and 155,000 shares issuable upon the exercise of stock purchase options which vested on May 25, 2012, November 25, 2012, May 25, 2013, November 25, 2013, May 25, 2014, November 25, 2014, February 18, 2015 and January 23, 2016 under the 2011 Equity Incentive Plan dated November 17, 2011. Further, Rodney Rootsaert is a controlling director of Concord International, Inc. and has voting and dispositive control over the 1,004,088 shares of common

stock beneficially owned by Concord International, Inc. Cameron Reynolds is a potential beneficiary.

(2)

Dr. Martin Faulkes is a Director of VolitionRx, and Belgian Volition. Dr. Faulkes beneficial ownership includes: 1,291,067 shares of common stock; 130,000 shares issuable upon the exercise of stock purchase options, which vested on May 25, 2012, November 25, 2012, May 25, 2013, November 25, 2013, May 25, 2014, November 25, 2014, February 18, 2015 and January 23, 2016 under the 2011 Equity Incentive Plan dated November 17, 2011; and 58,034 shares issuable upon the exercise of stock purchase warrants. Dr. Faulkes is also the Chairman, a Director and a Trustee of The Dill Faulkes Educational Trust Limited or DFET, a company limited by guarantee (with no share capital or stockholders) and a registered UK charity (Charity No. 1070864) and shares voting and dispositive control over the 356,000 shares of common stock beneficially owned by DFET.

(3)

Guy Innes is a Director of VolitionRx. Mr. Innes beneficial ownership includes: 1,170,197 shares of common stock; 100,000 shares issuable upon the exercise of stock purchase warrants which vested on March 24, 2011; 75,000 shares issuable upon the exercise of stock purchase options which vested on May 25, 2012, November 25, 2012, May 25, 2013, November 25, 2013, May 25, 2014, November 25, February 18, 2015 and January 23, 2016 under the 2011 Equity Incentive Plan dated November 17, 2011; and 214,337 shares issuable upon the exercise of stock purchase warrants.

(4)

Cameron Reynolds is VolitionRx s President, Chief Executive Officer and a member of the Board of Directors. Mr. Reynolds is also the Chief Executive Officer and a Director of Singapore Volition, a director of Belgian Volition, Chief Executive Officer and a Director of HyperGenomics and Chief Executive Officer and a Director of Volition Diagnostics UK Limited. Mr. Reynolds beneficial ownership includes: 1,130,702 shares of common stock (which includes 26,858 shares of common stock held by Mr. Reynolds spouse) ; 334,000 shares issuable upon the exercise of stock purchase options which vested on May 25, 2012, November 25, 2012, May 25, 2013, November 25, 2013, May 25, 2014, November 25, 2014, February 18, 2015 and January 23, 2016 under the 2011 Equity Incentive Plan dated November 17, 2011 (which includes 59,000 shares issuable upon the exercise of stock purchase options held by Mr. Reynolds spouse); and 2,601 shares issuable upon the exercise of stock purchase warrants (which includes 1,429 shares issuable upon the exercise of stock purchase warrants held by Mr. Reynolds spouse).

(5)

Dr. Alan Colman is a Director of VolitionRx. Dr. Colman s beneficial ownership includes: 53,937 shares of common stock; 100,000 shares issuable upon the exercise of stock purchase warrants which vested on April 1, 2011; 40,000 shares issuable upon the exercise of stock purchase options which vested on May 25, 2012, November 25, 2012, May 25, 2013, November 25, 2013, May 25, 2014, November 25, 2014 and January 23, 2016 under the 2011 Equity Incentive Plan dated November 17, 2011; and 13,000 shares issuable upon the exercise of stock purchase warrants.

(6)

Dr. Jacob Micallef is Volition Rx s Chief Scientific Officer, a Director and the Chief Scientific Officer of Belgian Volition. Dr. Micallef s beneficial ownership includes 97,166 shares of common stock (which includes 11,000 shares issuable upon the exercise of common stock held by Dr. Micallef s spouse) and 21,000 shares issuable upon the exercise of stock purchase warrants (which includes 11,000 shares issuable upon the exercise of stock purchase warrants held by Dr. Micallef s spouse). Further, Dr. Micallef is a controlling director of Borlaug Limited and has voting and dispositive control over 28,456 shares of common stock beneficially owned by Borlaug Limited, 9,290 shares issuable to Borlaug Limited upon the exercise of stock purchase warrants, and 305,000 shares issuable upon the exercise of stock purchase options which vested on May 25, 2012, November 25, 2012, December 13, 2012, May 25,2013, November 25, 2013, May 25, 2014, November 25, 2014, February 18, 2015 and January 23, 2016 under the 2011 Equity Incentive Plan dated November 17, 2011.

(7)

Dr. Jason Terrell is the Chief Medical Officer and Head of U.S. Operations of VolitionRx. Dr. Terrell s beneficial ownership includes: 61,364 shares of common stock and 25,000 shares issuable upon the exercise of stock purchase options which vested on February 18, 2015 under the 2011 Equity Incentive Plan dated November 17, 2011.

(8)

Dr. Habib Skaff is a Director of VolitionRx. Dr. Skaff s beneficial ownership includes: 14,580 shares of common stock and 59,000 shares issuable upon the exercise of stock purchase options which vested on May 25, 2012, November 25, 2012, May 25, 2013, November 25, 2013, May 25, 2014, November 25, 2014, February 18, 2015 and January 23, 2016 under the 2011 Equity Incentive Plan dated November 17, 2011; and 3,143 shares issuable upon the exercise of stock purchase warrants.

(9)

David Kratochvil is VolitionRx Chief Financial Officer. Mr. Kratochvil s beneficial ownership includes 0 shares of common stock and 75,000 shares issuable upon the exercise of stock purchase options which vested on August 17, 2015 under the 2011 Equity Incentive Plan dated November 17, 2011.

(10)

The other officers of the Company have beneficial ownership of 183,323 shares of common stock and 530,959 shares issuable upon the exercise of stock purchase options under the 2011 Equity Incentive Plan dated November 17, 2011; and 11,250 shares issuable upon the exercise of stock purchase warrants.

(11)

Concord International, Inc. s beneficial ownership includes 1,004,088 shares of common stock. Rodney Rootsaert is a controlling director of Concord International, Inc. and has voting and dispositive control over the 1,004,088 shares of common stock. Cameron Reynolds is a potential beneficiary.

(12)

Cotterford Company Limited s beneficial ownership includes: 1,048,947 shares of common stock, 94,516 shares issuable upon the exercise of stock purchase warrants which vested on June 21, 2011; and 304,153 shares issuable upon the exercise of stock purchase warrants. Jack Murphy holds investment and voting control over the shares of common stock beneficially owned by Cotterford Company Limited.

(13)

This information has been derived from a Schedule 13G filed with the SEC on February 16, 2016. Based on the information contained in the filing, Manchester Management Company, LLC and James Besser have shared voting power and dispositive power with respect to, and beneficially own, an aggregate of 1,258,715 shares of common stock. Further, Mr. Besser has sole voting and dispositive power over an additional 185,000 shares of 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

We adopted, and our stockholders approved, the VolitionRx Limited 2015 Stock Incentive Plan, or the Plan, effective as of August 18, 2015. Under such 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 1,000,000 shares of our common stock are reserved for issuance under the Plan. The purpose of the 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 Plan replaces the 2011 Equity Incentive Plan which was also approved by the stockholders. No further grants will be made under the 2011 Equity Incentive Plan.

Plan category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)**	**Weighted-average exercise price of outstanding options, warrants and rights(b)**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
Equity compensation plans approved by security holders:			
- 2011 Equity Incentive Plan	1,830,300	$3.53	-0-
- 2015 Stock Incentive Plan	-0-	-0-	1,000,000
Equity compensation plans not approved by security holders	-0-	-0-	-0-
Total	1,830,300	$3.53	1,000,000

ITEM 13.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

On August 6, 2010, Singapore Volition entered into an agreement with PB Commodities Consulting Agreement. At the time of the PB Commodities Consulting Agreement, Laith Reynolds (former Director of Singapore Volition), Cameron Reynolds (current President, CEO and a Director of VolitionRx Limited) and Rodney Rootsaert (current Secretary of VolitionRx Limited) were serving as Directors of PB Commodities. Subsequently, Mr. Cameron Reynolds resigned as a Director of PB Commodities on May 1, 2011 and Mr. Rootsaert resigned on September 20, 2011. PB Commodities does not operate for profit. The PB Commodities Consulting Agreement provides office space, office support staff, and consultancy services to Singapore Volition for the structuring, management, fundraising and development and implementation of its business plan. In exchange, Singapore Volition paid an initial set up fee to PB Commodities of $11,250, plus $6,500 per month (increased from 6,270 on March 1, 2015 and increased from $5,700 per month on April 1, 2014) for office space and staff services. Singapore Volition is also required to pay for all reasonable expenses incurred. Effective August 1, 2015, the PB Commodities Consulting Agreement was amended to remove the provision of office space and office support staff from the services being provided thereunder. Under the terms of the PB Commodities Consulting Agreement Singapore Volition additionally pays consultancy fees each month to PB Commodities for the services of Cameron Reynolds (approximately $21,300 (increased from $8,000 on September 1, 2015; increased from $6,500 on March 1, 2015; reduced from $8,800 on January 1, 2015; and increased from $8,000 on April 1, 2014)). Until January 1, 2015, Singapore Volition also paid consultancy fees each month to PB Commodities for the services of Rodney Rootsaert ($6,600 (increased from $6,000 on April 1, 2014). The term of the PB Commodities Agreement is twelve months, commencing on September 1, 2010, with automatic extensions of twelve months and a three month notice required for termination of the PB Commodities Consulting Agreement. For the fiscal years ended December 31, 2015 and December 31, 2014, Singapore Volition was invoiced approximately $193,000 USD and $327,000 USD, respectively, by PB Commodities. The foregoing description of the 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 October 1, 2011, Hypergenomics entered into an agreement, which we refer to as the Agreement with PB Commodities. At the time of the Agreement, Laith Reynolds (former Director of Singapore Volition) was serving as a Director of PB Commodities. The Agreement provides office space and office support staff to Hypergenomics for $1,450 USD per month. Hypergenomics is also required to pay for all reasonable expenses incurred. The term of the Agreement is twelve months, commencing on October 1, 2011, with automatic extensions of twelve months and a three month notice required for termination of the Agreement. On August 1, 2015 the Agreement was terminated. For the fiscal years ended December 31, 2015 and December 31, 2014 Hypergenomics was invoiced approximately $10,150 USD and $17,400 USD, respectively, from PB Commodities. The foregoing description of the Agreement does not purport to summarize all terms and conditions thereof and is qualified in its entirety by reference to Exhibit 10.13.

Charlotte Reynolds is the spouse of Cameron Reynolds (current President, CEO and a Director of VolitionRx Limited). Ms. Reynolds currently serves as Communications Manager pursuant to an employment agreement, which we refer to as the Employment Agreement with Singapore Volition, a position she has held since November 1, 2010. (At the time of entering the Employment Agreement Ms. Reynolds was not the spouse of Cameron Reynolds.) The term of the Employment Agreement is one (1) year which shall be automatically extended for successive periods of one (1) year. In exchange for her services Ms. Reynolds received £3,500 per month (increased from $4,400 on March 1, 2015; and increased from $4,000 on April 1, 2014). For the years ended December 31, 2015 and 2014, Ms. Reynolds received $41,619 and $51,600, respectively, pursuant to the Employment Agreement. Between July 1, 2011 and March 31, 2014 Ms. Reynolds also received a housing allowance of $1,250 per month, which increased to $1,375 per month for the period from April 1, 2014 to June 30, 2014 and then decreased to an average of $454 per month from July 1, 2014 to December 31, 2014. For the years ended December 31, 2015 and 2014, Ms. Reynolds received $0 and $13,327, respectively, as a housing allowance. The housing allowance ended on December 31, 2014.

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 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 issuer s 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 Dr. Habib Skaff, Guy Innes and Dr. Alan Colman are independent directors 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

	Year Ended December 31, 2015	Year Ended December 31, 2014
Audit fees	$ 37,660	$ 51,650
Audit-Related fees	$ 6,700	$ -0-
Tax fees	$ 8,886	$ 4,315
All other fees	$ -0-	$ -0-
Total	**$ 53,246**	**$ 55,965**

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.

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
2.1	Share Purchase Agreement by and between Singapore Volition and Valirx dated September 22, 2010.	8-K/A	000-30402	2.01	5/8/12	
2.2	Supplementary Agreement to the Share Purchase Agreement by and between Singapore Volition and Valirx dated June 9, 2011.	8-K/A	000-30402	10.15	1/11/12	

2.3	Share Exchange Agreement by and among Standard Capital Corporation, the controlling shareholders of Standard Capital Corporation and Singapore Volition dated September 26, 2011.	8-K	000-30402	2.1	9/29/11
2.4	Agreement, Consent and Waiver by and between Standard Capital Corporation and its Shareholders dated September 27, 2011.	8-K/A	000-30402	10.28	4/5/12
3.1	Amended and Restated Certificate of Incorporation, as currently in effect.	8-K	000-30402	3.01	10/7/13
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 Nucleosomics™ by and between ValiBio SA and The Walloon Region dated December 17, 2009.	8-K/A	000-30402	10.05	2/24/12

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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#	Employment Agreement by and between PB Commodities and Cameron Reynolds dated September 4, 2010.	8-K/A	000-30402	10.24	2/24/12	
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#	Master Consultancy Services Agreement by and between Singapore Volition and OncoLytika dated October 1, 2010.	10-K	000-30402	10.14	4/1/13	
10.8#	Consultancy Services Agreement between Singapore Volition and OncoLytika dated March 20, 2015.	10-Q	001-36833	10.34	5/12/15	
10.9	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	
10.10#	Letter of Appointment as Non-Executive Director by and between Singapore Volition and Dr. Alan Colman dated May 25, 2011.	8-K/A	000-30402	10.13	1/11/12	

10.11	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
10.12#	Letter of Appointment as Executive Chairman by and between Singapore Volition and Dr. Martin Faulkes dated July 13, 2011.	8-K/A	000-30402	10.19	1/11/12

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.13#	Agreement by and between HyperGenomics and PB Commodities dated October 1, 2011.	8-K/A	000-30402	10.27	2/24/12	
10.14	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	
10.15	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	
10.16#	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	
10.17#	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	
10.18#	Consultancy Agreement by and between VolitionRx and Borlaug dated as of January 1, 2015.	S-1/A	333-200628	10.27	1/23/15	
10.19#	Employment Agreement by and between VolitionRx and Rodney Rootsaert effective as of January 1, 2015.	S-1/A	333-200628	10.28	1/23/15	
10.20#	Master Consultancy Services Agreement by and between Belgian Volition and OncoLytika dated January 1, 2014.	S-1/A	333-200628	10.29	1/23/15	

10.21#	Belgian 2015 Eccleston Consultancy Services Agreement between Belgian Volition and OncoLytika dated March 20, 2015.	10-Q	001-36833	10.35	5/12/15
10.22#	Agreement by and between VolitionRx and Isosceles dated May 2, 2014.	S-1/A	333-200628	10.30	1/23/15

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.23#	Letter of Appointment as Non-Executive Director by and between VolitionRx and Dr. Habib Skaff dated May 28, 2014.	S-1/A	333-200628	10.31	1/23/15	
10.24#	Employment Agreement by and between VolitionRx and Jason Terrell MD, dated December 29, 2015.					X
10.25#	Employment Agreement by and between VolitionRx and David Kratochvil dated August 11, 2015.					X
10.26#	2011 Equity Incentive Plan dated November 17, 2011.	8-K	000-30402	4.01	11/18/11	
10.27#	Sample Stock Option Agreement.	8-K	000-30402	4.02	11/18/11	
10.28#	Sample Stock Award Agreement for Restricted Stock.	8-K	000-30402	4.03	11/18/11	
10.29#	2015 Stock Incentive Plan and related form agreements.	S-8	333-208512	4.6	12/11/15	
10.30#	Faulkes Executive Chairman Agreement with VolitionRx dated March 31, 2015.	10-Q	001-36833	10.32	5/12/15	
10.31#	Independent Director Agreement.	10-Q	001-36833	10.33	5/12/15	
21.1	List of Subsidiaries.					X
23.1	Consent of independent registered public accounting firm.					X

24.1	Power of Attorney (included on the signature page of this report).	X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.	X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.	X
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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 Annual 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 11, 2016

By: */s/ Cameron Reynolds*
Cameron Reynolds
President, Chief Executive Officer and Director

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Cameron Reynolds	President, Chief Executive Officer and Director	March 11, 2016
Cameron Reynolds	(Principal Executive Officer)	
/s/ David Kratochvil	Chief Financial Officer and Treasurer	March 11, 2016
David Kratochvil	(Principal Financial and Accounting Officer)	
/s/ Dr. Martin Faulkes	Director	March 11, 2016

Dr. Martin Faulkes		
/s/ Guy Innes	Director	March 11, 2016
Guy Innes		
/s/ Dr. Alan Colman	Director	March 11, 2016
Dr. Alan Colman		
/s/ Dr. Habib Skaff	Director	March 11, 2016
Dr. Habib Skaff		