VOLITIONRX LTD
Form 10-K
March 18, 2015

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, 2014

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

For the Transition Period from _____ to _____

VOLITIONRX LIMITED

(Exact name of registrant as specified in its charter)

Delaware	**000-30402**	**91-1949078**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

1 Scotts Road #24-05 Shaw Centre Singapore 228208
(Address of principal executive offices)

Telephone: +1 (646) 650-1351

Facsimile: +32 8172 5651
(Registrant s Telephone Number)

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:

Title of class:
Common Stock, par value $0.001 per share

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

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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 is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. .

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2014 was $11,973,676 based upon the price ($1.53) at which the common stock was last sold as of the last business day of the most recently completed second fiscal quarter, multiplied by the approximate number of shares of common stock held by persons other than executive officers, directors and five percent stockholders of the registrant without conceding that any such person is an affiliate of the registrant for purposes of the federal securities laws. Our common stock is traded on the NYSE MKT and quoted under the symbol VNRX .

As of March 18, 2015, there were 17,934,715 shares of the registrant s $0.001 par value common stock issued and outstanding.

Documents incorporated by reference: None

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FORWARD-LOOKING STATEMENTS

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. These risks and uncertainties include the following:

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The availability and adequacy of our cash flow to meet our requirements;

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Economic, competitive, demographic, business and other conditions in our local and regional markets;

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Changes or developments in laws, regulations or taxes in our industry;

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Actions taken or omitted to be taken by third parties including our suppliers and competitors, as well as legislative, regulatory, judicial and other governmental authorities;

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Competition in our industry;

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The loss of or failure to obtain any license or permit necessary or desirable in the operation of our business;

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Changes in our business strategy, capital improvements or development plans;

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The availability of additional capital to support capital improvements and development; and

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Other risks identified in this report and in our other filings with the Securities and Exchange Commission or the SEC.

This report should be read 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.

Use of Term

Except as otherwise indicated by the context, references in this report to Company , we , us , our and VNRX references to VolitionRx Limited. All references to USD or United States Dollars 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 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 name change to VolitionRx Limited was approved by FINRA on October 7, 2011 and became effective on October 11, 2011.

On September 26, 2011, the Company, then under the name Standard Capital Corporation, and its controlling stockholders (the Controlling Stockholders) entered into a Share Exchange Agreement (the Share Exchange Agreement) with Singapore Volition Pte Limited, a Singapore registered company (Singapore Volition) and the shareholders of Singapore Volition (the Volition Shareholders), whereby the Company acquired 6,908,652 (100%) shares of common stock of Singapore Volition (the Volition Stock) from the Volition Shareholders. In exchange for the Volition Stock, the Company issued 6,908,652 shares of its common stock to the Volition Shareholders. The Share Exchange Agreement closed on October 6, 2011. As a result of the Share Exchange Agreement, Singapore Volition became our wholly-owned operating subsidiary and the Company now carries on the business of Singapore Volition as its primary business. Singapore Volition has two subsidiaries, Belgian Volition SA, a Belgium registered company (Belgian Volition) which it acquired as of September 22, 2010, and HyperGenomics Pte Limited, a Singapore registered company (HyperGenomics Pte Limited), which it formed as of March 7, 2011.

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, inexpensive and scalable tests for detecting and diagnosing cancer and other diseases. We have developed twenty blood assays to date, using technology based on our Nucleosomics® biomarker platform, that can be used individually or in combination to generate a profile which forms the basis of a blood test for a particular cancer.

Each assay that we have developed can be commercialized for two distinct markets:

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The clinical IVD market which can only be accessed after the assays have either been approved for clinical use in the United States by the FDA, or as a LDT in the United States under a CLIA waiver, and by CE marking in the EU; and

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The RUO market.

Given the much larger potential clinical IVD, market, we have decided to focus our resources on launching in the clinical IVD market. We currently plan to apply for the first of our CE Mark (European) approvals in the second quarter of 2015.

We expect that we will be required to do further United States trials to achieve FDA approval for our colorectal cancer test. We are committed to filing for FDA approval to allow patient access to our tests in the United States as soon as practicable. 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 LDT in 2015, pursuant to a yet to be negotiated relationship with a CLIA lab, while we concurrently seek FDA approval.

Commercializing products on the RUO market means that we intend to sell our products to medical schools, universities and commercial research and development departments for research use only. Products placed on the RUO market may be used for any research purpose. RUO products, however, are strictly not to be used for patient diagnosis. Commercializing products on the IVD market means that we intend to sell our future products to be used for patient diagnosis. None of the assays that we are currently developing are available for sale on the IVD market, and we began sales in the RUO market in 2014.

We intend to commercialize our products in the future through various channels within the EU, the United States and eventually throughout the rest of the world. We anticipate that because of their ease of use and low cost, our tests have the potential to become the first method of choice for cancer diagnostics, allowing detection of cancer at an earlier stage than typically occurs currently, and screening of individuals who, for reasons such as time, cost or dislike, are not currently screened. We believe our blood test has the potential to have significantly higher acceptance from patients as compared to fecal tests and colonoscopies which are invasive and unpleasant, resulting in low acceptance.

We do not anticipate earning significant revenues until such time as we able to fully market our intended products on either the RUO or IVD clinical diagnostics market. 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. The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish its plan of operations described herein and eventually attain profitable operations.

We anticipate that any additional funding that we will require will be in the form of equity financing from the sale of our common stock. However, there is no assurance that we will be able to raise sufficient funding from the sale of our common stock. The risky nature of our business enterprise places debt financing beyond the credit-worthiness required by most banks or typical investors of corporate debt until such time as our intended products are available on the market. We do not have any arrangements in place for any future equity financing. If we are unable to secure additional funding, we will cease or suspend operations. We have no plans, arrangements or contingencies in place in the event that we cease operations.

The Market

Cancer is one of the leading causes of death worldwide, accounting for around 8.2 million annual deaths globally.[5] In the United States alone, there were an estimated 14 million cancer survivors in 2010.[6] By 2020, this figure is expected to rise to 18.1 million. The American Cancer Society estimated the total health economic burden for cancer (including medical costs and loss of earnings) at approximately $216 billion for 2009 ($86 billion in direct medical costs and $130 billion in lost productivity due to early death).[7] The annualized cost of cancer care in the over 65 age group based on analysis of Medicare payments linked to Surveillance, Epidemiology, and End Results, or SEER, Program data is projected to reach $158 billion.[8,9] 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, colorectal cancer in the US 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.[10] The Pap test has had a similar impact in improving 5 year survival rates in women with precancerous and cancerous cervical lesions.[11]

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[5] Cancer-Fact sheet N 297, World Health Organization, [online], Available at: http://www.who.int/mediacentre/factsheets/fs297/en/index.html, [accessed 11.12.2014]

[6] 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, Available at http://www.ncbi.nlm.nih.gov/pubmed/21228314 [will begin testing the first cohort of retrospective samples in Q1 2015 10.31.2014]

[7] American Cancer Society, Economic Impact of Cancer, 31.03.2014 [online], available at http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer[accessed 11.12.2014]

[8] Surveillance, Epidemiology, and End Results Programme, [online] Available at http://seer.cancer.gov [accessed 11.12.2014]

[9] National Institutes of Health Cancer costs projected to reach at least $158 billion in 2020 , 12 January 2011, [online], Available at http://www.nih.gov/news/health/jan2011/nci-12.htm [accessed 10.31.2014]

[10] American Cancer Society, Colorectal Cancer Facts & Figures 2011-2013 [Online] available at http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-028312.pdf [accessed 11.12.2014]

[11] National Cancer Institute Fact Sheet: Cervical Cancer Screening (PDQ®) [Online] Available at http://www.cancer.gov/cancertopics/pdq/screening/cervical/HealthProfessional/page2 [accessed 11.12.2014]

Statistically, the chances of surviving cancer are greatly improved by early detection and treatment. However, there is currently no screening test for cancer in general, and very few effective blood tests for specific cancers in common clinical use. The only commonly used blood-screening test for any cancer is the 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.[12] The American Cancer Society recommends that prostate cancer screening should not occur without an informed decision making process regarding risks.[13] In 2012, the U.S. Preventative Services Task Force recommended against PSA-based screening for healthy men because of a moderate or high certainty that the service has no benefit or that the harms outweigh the benefits [14]. The test is still used to monitor patients after definitive diagnosis or treatment. There are currently no commonly used blood tests for screening for lung cancer 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.[15] 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,[16] driven by the increasing health care demands of an aging population. In the United States,[17] the IVD market is made up of:

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Histology, immunohistochemistry and cytology of tissue samples (expected to grow 6.8% per annum from 2011-2018, with an expected value of $25.5 billion by 2018).[18] 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), which will be the second largest market with a value of more than US$19.1 billion by 2018.[19] 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.

[12] National Cancer Institute Fact Sheet: Prostate-Specific Antigen (PSA) Test, [24 July 2012] [online], Available at http://www.cancer.gov/cancertopics/factsheet/detection/PSA, [accessed 10.31.2014]

[13] 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, available at http://www.ncbi.nlm.nih.gov/pubmed/20200110 [accessed 10.31.2014]

[14] U.S. Preventative Services Task Force, May 2012 [online], available at http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prostate-cancer-screening [accessed 10.31.2014]

[15] American Cancer Society. Colorectal Cancer, 2014 [online], Available at: http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-survival-rates, [accessed 11.04.2014

[16] Report: The Worldwide Market for In Vitro Diagnostic (IVD) Tests, 9th Edition, August 13, 2014 [online], Available for purchase at: http://www.kaloramainformation.com/Worldwide-Vitro-Diagnostic-8326563, [accessed 10.31.2014]

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

Mar 18, 2014 [online], Available for purchase at http://www.kaloramainformation.com/United-States-Vitro-8079142, [accessed 10.31.2014]

[18] In Vitro Diagnostics Market to 2018 - Consolidation, Decentralization and Demand for Genetic Testing to Shape the Competitive Landscape, March 23, 2012 [online], Available at http://www.marketresearch.com/GBI-Research-v3759/Vitro-Diagnostics-Consolidation-Decentralization-Demand-6871130 [accessed 11.12.2014]

[19] 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 2018, October, 2013 [online], Available at: http://www.marketsandmarkets.com/Market-Reports/immunoassay-market-436.html [accessed 11.04.2014]

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Testing is carried out at three principal locations:[20]

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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.

We are 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 5-10 years. For the year ended December 31, 2013, we spent approximately $2.5 million on research and development activities. For the year ended December 31, 2014, we spent approximately $4.0 million on research and development activities. None of these costs are borne directly by customers.

Our Intended Products

Commercialization of our future products on the clinical IVD market (e.g. for patient diagnosis in hospitals, clinics, etc.), requires government approval (CE Marking in Europe and/or FDA approval in the United States). We plan to begin the approval process in the EU and the United States in 2015. Commercializing our products on the RUO market (e.g. for uses other than patient diagnosis in medical schools, universities and commercial research and development departments, etc.) does not require government approval. However, before any of our products can be sold on the RUO market, they need to successfully complete beta-testing. Beta-testing involves providing the products to a few laboratories to identify and correct any problems in the products. None of the products that we are currently developing are available on the IVD market; however, we began sales in the RUO market in 2014. The products that we are currently developing are described in detail below:

NuQ® Suite of Epigenetic Cancer Blood Tests

We have developed twenty epigenetic NuQ® assays using our Nucleosomics® technology which are designed to detect the level and structure of nucleosomes in blood. Epigenetics is the science of how genes are switched on or off in the body s cells. A major factor controlling the switching on and off is the structuring of DNA. The DNA in human cells is packaged as protein complexes in a beads on a string structure. Each individual protein/DNA bead is called a nucleosome. These nucleosomes then form additional structures with increasingly dense packing, culminating in chromosomes containing hundreds of thousands of nucleosomes.

Figure 1 A nucleosome

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[20] Report: The United States Market for In Vitro Diagnostic Tests Mar 18, 2014 [online], Available for purchase at http://www.kaloramainformation.com/United-States-Vitro-8079142/, [accessed 11.12.2014]

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.[21]

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 20 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. To date, we do not have any products available for sale on the IVD market.

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NuQ®-X: We are currently developing 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 are currently developing 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 are currently developing nine 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 are currently developing five blood assays in the NuQ®-A family to detect cancer by detecting nucleosome-protein adducts.

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NuQ®- T: We are currently developing 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 938 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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[21] 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

NuQ® Research Kits

We have launched our first RUO products for use in cell culture in 2014, although we have decided to focus our limited resources on clinical products in 2015 after our encouraging initial results in the Denmark trials in colorectal cancer. The research products are 96 well semi-manual kits for the simultaneous analysis of 48 samples, the usual format for research products (a 96 well kit can be used to analyze some 48 samples in duplicate). The most expensive component in the manufacture of products is the pairs of antibodies employed. Initially, these are purchased or licensed on a small scale, but we have commenced development of our own antibodies which we believe will reduce costs. Total small scale production costs, for our lowest cost kit is currently $130 per kit. This kit is marketed at $495 to the end user. The more expensive kits currently cost $300 per kit to manufacture and have selling prices between $795 - $1275 per kit. We anticipate a reduction in the production price to approximately $100 per kit, as we continue to develop our own antibodies.

The NuQ® assay technology is proprietary to us so no direct competition exists. However, some competitors manufacture simple generic modified histone ELISA kits, which are the closest competitors currently on the market, to our intended NuQ®-M products. The generic products offered by competitors do not measure modified histones in intact nucleosomes but require chemical extraction of histones from samples prior to use.

The NuQ® research use kits are designed to run on simple instrumentation available from a wide range of suppliers and found in most research laboratories and hospitals. Our own instrument, on which we develop and run the NuQ® tests, is shown in Figure 3 below.

Figure 3 Example of lab instrument for running ELISA tests

NuQ® Clinical Diagnostic Products

There are three main segments of the clinical IVD market that we intend to adapt our future NuQ® products to in the future.

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 10 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. As of the date of this Report, we do not have an anticipated timeframe for licensing our Nucleosomics® technology.

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. As of the date of this Report, we have not entered into any discussions or negotiations with diagnostic companies for the sale of ELISA plates.

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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 in 2017 and in the United States in 2018, 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 require 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 Doctor s Office or Home Use Tests

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 in 2017. As of the date of this Report, 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. Time to diagnosis can take up to 9 years from when the symptoms appear. 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 will receive 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. The test is too early in its development for us to accurately determinate the manufacturing costs and sale price of the test. The test is not currently being developed for the RUO market.

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. Although as with the Nucleosomics® RUO kits, we have decided to focus on our clinical 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. We aim to file new in house methodology patents for HyperGenomics® in 2015.

We realized our first revenue of $50,000 from contract research in 2012. We will allocate resources to the HyperGenomics® research kit as soon as is practical given our focus on the Nucleosomics® clinical products in 2015, Beta-testing is expected to take approximately six (6) 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.

The launch of the HyperGenomics® test into the IVD market in Europe and the United States will follow 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.

Validation Studies

We have two main validation studies currently underway in colorectal cancer and two smaller studies:

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A retrospective symptomatic 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 (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 (Phase I); and (ii) validate that profile in a second blind cohort (Phase II). As part of Phase I, at the end of the third quarter 2014, approximately 20% of the Retrospective CRC Trial samples have been analyzed with a combination of NuQ® assays. Additional NuQ® assays are currently being tested on these Phase I samples. Phase II will commence 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.

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A prospective colorectal cancer study with Hvidovre Hospital in Denmark with 14,000 samples to be collected over 20-24 months from April 2014 from patients who have had a fecal occult blood test (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.

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A prospective colorectal cancer study with CHU-UCL Mont Godinne Hospital in Belgium with approximately 250 patients with suspected colorectal cancer to be collected. Collection began in 2012 and was completed in the fourth quarter of 2014. The trial supported the early clinical development of our non-invasive cancer detection blood tests for colorectal cancer.

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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 (CRPC), the less aggressive form.

We are also conducting a large prospective study with University Hospital in Bonn, Germany on approximately 4,000 patients to be collected to evaluate the performance of our assays on patients with the twenty most prevalent cancer types. We intend to commence testing the first samples from this study in 2015.

During the fifteen months preceding the date of this Report, we have announced the following preliminary results from our trials:

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November 7, 2013: Tested 90 samples taken from patients using one NuQ® assay. Detected 75% of patients with colorectal cancer, or CRC, at 70% specificity compared to healthy samples. The results were validated in a second set of 113 samples taken from patients with CRC. *Presented at CNAPS conference, Baltimore, USA. Also published in May 2014 Anticancer Research journal http://ar.iiarjournals.org/content/34/5/2357.abstract?etoc.*

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December 2, 2013: Tested 39 samples taken from patients using a combination of two NuQ® assays. Detected 85% of patients with CRC at 85% specificity and over 50% of patients with precancerous polyps. *Presented at the Clinical Genomics and Informatics Europe Conference, Portugal.*

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March 17, 2014: Tested serum and plasma samples from 39 patients referred for colonoscopy; 9 patients newly diagnosed with prostate cancer; and 10 male control subjects. Detected 85% of patients with CRC at 85% specificity. Detected over 50% of patients with precancerous polyps. Detected approx. 80% of patients with prostate cancers at 70% specificity. Profiles of two cancers shown to be different. *Presented at The International Society of Oncology*

and Biomarkers Congress (ISOBM), Barcelona, Spain.

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September 11, 2014: Tested 938 samples taken from patients aged over 50 years with symptoms indicative of colorectal cancer. Samples were collected between 2010 and 2012 from patients with CRC, polyps or adenomas, benign bowel diseases or other malignancies or symptoms, all of whom have undergone a colonoscopy. Under the trials design, we can have anonymized access to the Danish national registries and databases in relation to these samples. Results were age and gender adjusted and all the figures are cancer/polyps versus no comorbidities and no co findings at a specificity of 78%. Samples tested using a three NuQ® assay panel. Detected 84% of patients with CRC including early and late stage CRC, and 60% of patients with precancerous polyps. *Presented at the 2014 Aegis Capital Healthcare & Technology Conference, Nevada, USA.*

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October 9, 2014: Additional analysis performed on 830 of the 938 samples tested from patients aged over 50 years with symptoms indicative of CRC the results of which were first announced on September 11, 2014. Among the 830 subjects, a total of 59 CRC cases were identified by colonoscopy, including 35 colon cancer and 24 rectal cancer cases. Of the 59 CRC cases, the NuQ® blood test was able to detect both early (I or II) and late (III or IV) stage cases as summarized in the following table:

Stage of Colorectal Cancer	**Stage of Colorectal Cancer**	**Number of Cancer Cases Identified by NuQ® Test**	**Corresponding Percentage of Cancer Cases Identified by NuQ® Test**
Early	Stage I	6 of 8	75%
Early	Stage II	19 of 20	95%
Late	Stage III	16 of 20	80%
Late	Stage IV	9 of 11	82%

Presented at the 9th International Conference of Anticancer Research, Greece.

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November 24, 2014: Pilot lung cancer study tested both sputum (airway secretions, or mucus coughed up from the lower respiratory tract) and blood samples from the same 46 patients with either non-small cell lung cancer, chronic obstructive pulmonary disease (COPD) or with no disease (healthy) across various NuQ® assay panels. 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) and discriminate lung cancer from COPD. 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) and also able to discriminate lung cancer from COPD. The blood assay data is adjusted for age and smoking risk. *Presented at the the Science for Business BioWin Day 2014 in Louvain-la-Neuve, Belgium.*

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January 7, 2015: Tested 60 samples taken from patients using a panel of 5 NuQ® assays; 25 patients diagnosed with stage IIa or stage IIb pancreatic cancer; 10 patients with other pancreatic diseases including chronic pancreatitis, intraductal papillary mucinous neoplasm (IPMN; a pre-cancerous condition which may lead to pancreatic cancer), serous cystadenoma (a benign tumor) and tubular adenoma in papilla vateri (another type of benign tumor); and 25 samples taken from healthy subjects. Our NuQ® test was able to detect 21 of the 25 pancreatic cancer cases from healthy subjects (84% sensitivity), with only two false positive results among the 25 healthy subjects (92% specificity). Furthermore, the same panel of NuQ® assays was able to distinguish 19 of the pancreatic cancer cases (76% sensitivity) from all other subjects including healthy subjects and those with other pancreatic diseases with only a single false positive for one healthy subject and two false positives for subjects with other pancreatic diseases, one of which was a subject with pre-cancerous IPMN condition (91% specificity).

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 is licensed from a pharmaceutical company and seven are authored by our subsidiaries.

Nucleosomics® Intellectual Property

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

Nucleosomics® WO2005019826: Detection of Histone Modifications in Cell-Free Nucleosomes (Patent that underlies the NuQ®-M tests)

Application Date: August 18, 2003

Status: Granted in Europe; Pending in United States

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Singapore Volition holds the 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 and China; Pending in Europe, United States, Canada, South Africa, India, Brazil, Japan, Singapore

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Belgian Volition authored the following patent application covering its total NuQ® assay technology:

NuQ® Patent UK1115099.2 and U.S. 61530300: Method for Detecting Nucleosomes

Application Date: September 1, 2011

Status: Pending in Europe, United States

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Belgian Volition authored the following patent application covering its NuQ®-V technology:

NuQ®-V Patent UK1115098.4 and U.S. 61530304: Method for Detecting Nucleosomes containing Histone Variants

Application Date: September 1, 2011

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

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Singapore Volition authored the following patent application covering its NuQ®-X technology:

NuQ®-X Patent UK1115095.0 and U.S. 61530295: Method for detecting Nucleosomes containing Nucleotides

Application Date: September 1, 2011

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

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Singapore Volition authored 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.

NuQ®-A Patent UK112130.5 and U.S. 61568090: Method for detecting Nucleosome Adducts

Application Date: December 7, 2011

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

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Singapore Volition authored 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.

NuQ®-M US1770893: Method for detecting Histone Modifications in Nucleosomes

Application Date: February 28th, 2013

Status: Pending Worldwide

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Singapore Volition was the applicant for and has been assigned the following patent:

US61770922: Method for Predicting Therapy Efficacy using Nucleosome Structure Biomarkers

Application Date: February 28th, 2013

Status: Pending Worldwide

Endometriosis Intellectual Property

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Singapore Volition authored the following patent application for its endometriosis test:

Endometriosis Diagnostic UK1012662.1: Method for Detecting the Presence of a Gynaecological Growth

Application Date: July 28, 2010

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

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 with patents in Europe and the U.S. The protection of the technologies underlying products will then provide multiple cover for each product. We believe that this will provide:

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Market exclusivity through multiple protection for each future product.

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Full protection reaching at least to 2031 for each new product 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 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 (CE Marking), 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. To date, we have not begun the CE Marking or FDA approval process for any of our tests currently under development.

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 EU 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).

We are currently engaged in the first two requirements listed above for the first NuQ®-X assay. The remaining 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 the NuQ®-X assay in 2015. 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 Laboratory Developed Test

A laboratory-developed test, or LDT, is a type of in-vitro diagnostic test that is designed, manufactured and used within a single laboratory. LDTs can be single or multianalyte tests used to help diagnose a patient s state of health. LDTs cannot be used directly for disease screening, as the FDA would regulate this.

The FDA, while it always has claimed the power to regulate LDTs, historically has not enforced the more stringent premarket review and other applicable FDA requirements for many LDTs, especially the relatively simple lab tests that are available on a limited basis. FDA refers to its prior decision to not overtly regulate LDTs as involving its exercise of enforcement discretion. In the absence of the FDA actively regulating LDTs, the primary federal agency exercising control over LDTs has been the Centers for Medicare & Medicaid Services, or the CMS, under the Clinical Laboratory Improvement Amendments, or CLIA. A CLIA certified laboratory is required to determine, validate and submit performance characteristics on around 50 known and 50 unknown samples including:

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Accuracy;

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Precision;

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Analytical sensitivity;

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Analytical specificity to include interfering substances;

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Reportable range of test results for the test system;

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Reference intervals (normal values); and

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Any other performance characteristic required for test performance.

On July 31, 2014 the FDA notified Congress of the Agency s intent to issue a draft oversight framework for LDTs based on risk to patients rather than whether a conventional manufacturer or a single laboratory made them. The FDA issued draft guidance on October 3, 2014 regarding its oversight of LDTs which was subject to public comment until February 2, 2015. This oversight includes pre-market review for higher-risk LDTs although the framework would be phased in over many years. There is uncertainty regarding the impact and even the legal status of the FDA s decision with challenges expected in the US courts. The initial focus for the FDA is on high-risk test categories which includes definitive diagnosis in the absence of a confirmatory technique. Within a CLIA lab, specific claims for use of the Nucleosomics® technology will therefore be limited, for example, to adjunctive diagnostics, such as identification of circulating blood nucleosomes associated with colorectal cancer. Confirmation of diagnosis will be provided by colonoscopy as with the fecal test.

We do not intend to establish a CLIA laboratory in the United States due to the costs and time frame associated with this. Pending completion of our review of the regulatory environment in the United States, including the effect of the Draft Guidance, we aim initially to enter the United States market by identifying a licensing partner for the Nucleosomics® technology for establishment of an LDT for adjunctive diagnostics to aid in colorectal cancer diagnosis.

United States FDA Approval

Our diagnostic products are designated as medical devices by the FDA. Among other things, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical devices distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets. We estimate the cost of obtaining FDA approval to be approximately $5 million per product. FDA approval is more expensive and will likely take at least twice as long as CE Marking in Europe.

Unless an exemption applies, each medical device that we wish to market in the United States must first receive either clearance of a 510(k) pre-market notification or approval of a Product Market Approval, or PMA, from the FDA. The FDA s 510(k) clearance process usually takes from three to twelve months, but it can take significantly longer and clearance is never guaranteed. The process of obtaining PMA approval is much more costly, lengthy and uncertain. It generally takes from one to three years and approval is not guaranteed. The FDA decides whether a device must undergo either the 510(k) clearance or PMA approval process based upon statutory criteria. These criteria include the level of risk that the agency determines is associated with the device and a determination of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II. Class III devices are those devices which are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. In the United States, cancer diagnostics usually are considered Class III products, the highest classification (in Europe, cancer diagnostics are not in the high classification group except for home use). As such, our future products may have to undergo the full PMA process of the FDA.

A clinical trial may be required in support of a 510(k) submission and is generally required for a PMA application. These trials generally require an effective Investigational Device Exemption, or IDE, from the FDA for a specified number of patients, unless the product is exempt from IDE requirements or deemed a non-significant risk device eligible for more abbreviated IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin 30 days after the submission of the IDE application unless the FDA or the appropriate institutional review boards at the clinical trial sites place the trial on clinical hold.

Once the application and approval process is complete and the product is placed on the clinical diagnostics market, regardless of the classification or pre-market pathway, it remains subject to significant regulatory requirements. The FDA may impose limitations or restrictions on the uses and indications for which the product may be labeled and promoted. Medical devices may only be marketed for the uses and indications for which they are cleared or approved. FDA regulations prohibit a manufacturer from promoting a device for an unapproved or off-label use. Manufacturers that sell products to laboratories for research or investigational use in the collection of research data are similarly prohibited from promoting such products for clinical or diagnostic tests.

Further, our future manufacturing processes and those of our future suppliers will be required to comply with the applicable portions of the FDA s Quality Systems Regulations, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of our intended products. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

The FDA has broad regulatory and enforcement powers. If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions ranging from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure or recall of our future products, total or partial shutdown of production, withdrawal of approvals or clearances already granted, and criminal prosecution. The FDA can also require us to repair, replace or refund the cost of products that we manufactured or distributed. Furthermore, the regulation and enforcement of diagnostics and equipment by the FDA is an evolving area that is subject to change. While we believe that we are and will continue to be in compliance

with the current regulatory requirements and policies of the FDA, the FDA may impose more rigorous regulations or policies that may expose us to enforcement actions or require a change in our business practices. If any of these events were to occur, it could materially adversely affect us.

Product Development and Plan of Operations

NuQ® Assays (Cancer and Other Conditions):

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Research Use Only Market

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The NuQ® suite of assays has been released for the RUO market.

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In-Vitro Diagnostics Market

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CE Marking (Europe): A pilot NuQ® panel of 3 assays underwent external third party retrospective clinical validations during 2012 which took approximately nine (9) months to complete. A larger NuQ® panel of assays commenced large scale retrospective clinical validations in 2013 which will continue during 2015. Once the retrospective validations are completed, the tests will be submitted for CE Mark approval. We estimate the cost of obtaining CE Marking will be approximately $500,000.

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FDA Approval (United States): FDA approval is expected to require longer large scale prospective clinical validation studies and is expected to commence in 2015 and be completed in 2017. When completed, the data will be submitted to the FDA for United States market approval. We estimate the cost of obtaining FDA approval will be approximately $5 million.

We completed initial external testing on a variety of cancers in 2012-2013 based on our Nucleosomics® technology. Cancers were selected by medical need and commercial value and large scale retrospective (CE Mark) and prospective (FDA) clinical validation studies for the cancers identified as most promising in the 2012 studies commenced in 2013. We expect to produce a rolling pipeline of products for different types of cancers over the next three (3) to five (5) 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. As of the date of this Report, 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. As of the date of this prospectus, we have not entered into any discussions or negotiations with diagnostic companies or established an anticipated timeframe regarding the sale of ELISA plates.

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Point-of-Care Devices: We intend to enter the point-of-care clinical market in Europe in 2017 and in the United States in 2018. The approximate manufacturing costs or sales price per device have not yet been determined. As of the date of this Report, 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. As of the date of this Report, 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. However the development of the current pipeline of intended products for the RUO market would be delayed, as would clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market. In the event of an ongoing lack of financing, we may be obliged to discontinue operations.

Sales and Marketing Strategy

The first sales of our NuQ® products were for the RUO market, as the RUO market does not require government approval, as compared to the clinical IVD market. We have however decided to focus our efforts on launching our first products in the clinical market in the EU given our very encouraging results in Denmark, the much larger potential of the IVD market and our limited resources, which require us to focus our efforts. Pending completion of our review of the regulatory environment in the United States, including the effect of the Draft Guidance, we aim to enter the United States market by adopting a licensing model to a CLIA laboratory in the United States. Our RUO products are available for sale to researchers via our product website, *http://www.nucleosomics.com* and through a contracted distributor.

We intend to primarily sell our RUO products through distribution agreements in those markets and territories where we have no real prospect of obtaining traction alone or where the entry barriers are high. We plan to enter into tightly drawn distribution agreements outlining the territory and sectors to be covered. We will maintain control through strict oversight and by centralized production centers that will provide supplies to distributors. We estimate such distributors will take approximately 30-40% of the sales prices of any products sold through these channels. We have entered into three distribution agreements. The first wholesale order of these RUO products commenced in June 2014.

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 2015. We intend to license NuQ® tests for LDT use in the United States and 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.

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 FDA has historically exercised enforcement discretion over tests developed by and used within single laboratories, known as LDTs. The CMS has regulated laboratories, including those that develop LDTs, under the Clinical Laboratory Improvement Amendments (42 U.S.C. 263a) since 1988. Reagents used for the production of LDTs (Analyte Specific Reagents) are subject to less overt FDA regulation and can be sold to clinical laboratories to perform high complexity testing provided such tests are developed are labeled in accordance with FDA requirements, including a statement that their analytical and performance characteristics have not been established. We believe that Analyte Specific Reagents that we have developed, including antibodies with specificity for histone modifications and histone variants, may be sold to clinical reference laboratories in the United States and do not currently require FDA approval or clearance. However, on October 3, 2014, the FDA issued draft guidance implementing a new framework for the regulation of LDTs, which could include pre-market review. As these regulations are not yet final, we cannot be sure that the FDA will not require that one or more of our reagents would require premarket approval. Further, we cannot guarantee that the FDA would consider licensing of our intellectual property as labeling, which would subject the Analyte Specific Reagents we supply to FDA regulation including, but not limited to, PMA.

The FDA has recently proposed a new regulatory oversight framework for LDTs which, if adopted as proposed, will continue the FDA s current enforcement discretion for traditional LDTs that are:

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designed, manufactured and used within a single laboratory;

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manufactured and used by a health care facility laboratory (such as one located in a hospital or clinic) for a patient that is being diagnosed and/or treated at that same health care facility or within the facility s healthcare system;

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comprised only of components and instruments that are legally marketed for clinical use; and

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interpreted by qualified laboratory professionals without the use of automated instrumentation or software for interpretation.

The proposals were subject to public comment until February 2, 2015. Changes in the FDA position could negatively affect our operations.

Please refer to the section above titled Government Approval for additional information regarding the draft guidance.

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. Volition is implementing 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.

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 above titled Government Approval for additional information.

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 guiac 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 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, 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.

WHERE YOU CAN GET ADDITIONAL INFORMATION

We file annual, quarterly and current reports, proxy statements and other information 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. 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

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 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 currently rent this space for approximately $1,500 a month. Currently, this space is sufficient to meet our needs, however, once we expand our business to a significant degree, we will have to find a larger space. We do not foresee any significant difficulties in obtaining any required additional space. We do not currently own any real estate.

On February 29, 2012, Belgian Volition entered into a lease agreement for larger laboratory and office space at 20A Rue de Séminaire, 5000, Namur, Belgium for approximately $5,091 per month commencing April 1, 2012 for a leasing term of two years and eight months. Additionally, Belgian Volition shall pay $1,992 per month as a provision against expenses. Commencing December 1, 2014 the lease was extended for an additional leasing term of two years at approximately $5,590 per month. Additionally, Belgian Volition shall pay $970 per month as a provision against expenses.

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 COMPANY S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common Stock

Our common stock was quoted on the OTC Bulletin Board from April 12, 2007 under the symbol SNDC.OB. Effective October 11, 2011 our symbol was changed to VNRX.OB to reflect the Company s name change. Because we were quoted on the OTC Bulletin Board, our securities may have been less liquid, received less coverage by security analysts and news media, and generated lower prices than might otherwise be obtained if they were listed on a national securities exchange. On February 6, 2015, we up-listed our common stock onto the NYSE MKT.

The following table sets forth the high and low bid prices for our common stock per quarter as reported by the OTCBB for 2014 and 2013 based on our fiscal year end December 31. These prices represent quotations between dealers without adjustment for retail mark-up, markdown or commission and may not represent actual transactions.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(Jan. 1 Mar. 31)	(Apr. 1 Jun. 30)	(Jul. 1 Sept. 30)	(Oct. 1 Dec. 31)
2013 High	2.90	3.00	2.22	2.79
2013 Low	1.31	2.00	0.25	1.25
2014 High	3.25	2.75	9.28	4.32
2014 Low	2.05	1.30	1.45	3.25

Record Holders

As at March 18, 2015, an aggregate of 17,934,715 shares of our common stock were issued and outstanding and were owned by approximately 223 holders of record, based on information provided by our transfer agent.

Recent Sales of Unregistered Securities

1.

Quarterly Issuances

On or about October 3, 2014, 50,000 warrants were exercised for total proceeds of $123,500. As a result, an aggregate total of 50,000 shares of common stock were issued at a price of $2.47 per share to 1 U.S. Accredited Investor.

On or about October 9, 2014, the Company issued 91,757 shares of common stock to 7 non-U.S. investors and 10 U.S. Accredited Investors at a price of $2.50 per share, for an aggregate amount of $229,393.

On or about 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 was issued to 15 U.S Accredited Investors,. $57,000 had been paid in fees to an agent and $1,036 was paid in escrow fees and charges

On or about November 21, 2014 the Company issued 3,115 shares of common stock at a price of $3.00 per share for cash proceeds of $9,345 to 6 U.S. Investors and 6 non-U.S. investors.

The shares issued to the U.S. Accredited Investors above were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended, (Securities Act), and Rule 506 of Regulation D, as more specifically set forth below, on the basis that the securities were offered and sold in a non-public offering to an accredited investor as defined in Rule 501 of Regulation D. The shares issued to the non-U.S. Investors were issued pursuant to Rule 903 of Regulation S, as more specifically set forth below, on the basis that the investor was not a U.S. person as defined in Regulation S, was not acquiring the shares for the account or benefit of a U.S. person, and the sale of the shares was completed in an "offshore transaction .

2.

Subsequent Issuances

On February 6, 2015 The Company issued 2,475,000 shares of common stock at a price of $3.75 to 3 U.S. Underwriters, for net cash proceeds of $8.5 million

On February 13, 2015, 343,383 shares of common stock were issued at a price of $3.75 per share to 3 U.S. Underwriters. Net proceeds of $1.2 million were received.

On February 23, 2015, 25,000 warrants were exercised at a price of $2.20 per share, giving cash proceeds of $55,000. As a result a total of 25,000 shares of common stock were issued to 1 U.S. Accredited Investor.

On March 6, 2015, 400,000 shares of common stock were issued at a price of $3.75 per share to 5 non-U.S. Investors, for net cash proceeds of $1.4 million.

The shares issued to the U.S. Accredited Investors above were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended, (Securities Act), and Rule 506 of Regulation D, as more specifically set forth below, on the basis that the securities were offered and sold in a non-public offering to an accredited investor as defined in Rule 501 of Regulation D.

Exemption From Registration. *The shares of Common Stock referenced herein were issued in reliance upon one of the following exemptions:*

(a)

The shares of Common Stock referenced herein were issued in reliance upon the exemption from securities registration afforded by the provisions of Section 4(2) of the Securities Act of 1933, as amended, ("Securities Act"), based upon the following: (a) each of the persons to whom the shares of Common Stock were issued (each such person, an "Investor") confirmed to the Company that it or he is an "accredited investor," as defined in Rule 501 of Regulation D promulgated under the Securities Act and has such background, education and experience in financial and business matters as to be able to evaluate the merits and risks of an investment in the securities, (b) there was no public offering or general solicitation with respect to the offering of such shares, (c) each Investor was provided with certain disclosure materials and all other information requested with respect to the Company, (d) each Investor acknowledged that all securities being purchased were being purchased for investment intent and were "restricted securities" for purposes of the Securities Act, and agreed to transfer such securities only in a transaction registered under the Securities Act or exempt from registration under the Securities Act and (e) a legend has been, or will be, placed on the certificates representing each such security stating that it was restricted and could only be transferred if subsequently registered under the Securities Act or transferred in a transaction exempt from registration under the Securities Act.

(b)

The shares of common stock referenced herein were issued pursuant to and in accordance with Rule 506 of Regulation D and Section 4(2) of the Securities Act. We made this determination in part based on the representations of the Investor(s), which included, in pertinent part, that such Investor(s) was an accredited investor as defined in Rule 501(a) under the Securities Act, and upon such further representations from the Investor(s) that (a) the Investor is acquiring the securities for his, her or its own account for investment and not for the account of any other person and not with a view to or for distribution, assignment or resale in connection with any distribution within the meaning of the Securities Act, (b) the Investor agrees not to sell or otherwise transfer the purchased securities unless they are registered under the Securities Act and any applicable state securities laws, or an exemption or exemptions from such registration are available, (c) the Investor either alone or together with its representatives has knowledge and experience in financial and business matters such that he, she or it is capable of evaluating the merits and risks of an investment in us, and (d) the Investor has no need for the liquidity in its investment in us and could afford the complete loss of such investment. Our determination is made based further upon our action of (a) making written disclosure to each Investor prior to the closing of sale that the securities have not been registered under the Securities Act and therefore cannot be resold unless they are registered or unless an exemption from registration is available, (b) making written descriptions of the securities being offered, the use of the proceeds from the offering and any material changes in the Company s affairs that are not disclosed in the documents furnished, and (c) placement of a legend on the certificate that evidences the securities stating that the securities have not been registered under the Securities Act and setting forth the restrictions on transferability and sale of the securities, and upon such inaction of the Company of any general solicitation or advertising for securities herein issued in reliance upon Rule 506 of Regulation D and Section 4(2) of the Securities Act.

(c)

The shares of Common Stock referenced herein were issued pursuant to and in accordance with Rule 903 of Regulation S of the Act. We completed the offering of the shares pursuant to Rule 903 of Regulation S of the Act on the basis that the sale of the shares was completed in an "offshore transaction", as defined in Rule 902(h) of Regulation S. We did not engage in any directed selling efforts, as defined in Regulation S, in the United States in connection with the sale of the shares. Each investor represented to us that the investor was not a "U.S. person", as defined in Regulation S, and was not acquiring the shares for the account or benefit of a U.S. person. The agreement executed between us and each investor included statements that the securities had not been registered pursuant to the Act and that the securities may not be offered or sold in the United States unless the securities are registered under the Act or pursuant to an exemption from the Act. Each investor agreed by execution of the agreement for the shares: (i) to resell the securities purchased only in accordance with the provisions of Regulation S, pursuant to registration under the Act or pursuant to an exemption from registration under the Act; (ii) that we are required to refuse to register any sale of the securities purchased unless the transfer is in accordance with the provisions of Regulation S, pursuant to registration under the Act or pursuant to an exemption from registration under the Act; and (iii) not to engage in hedging transactions with regards to the securities purchased unless in compliance with the Act. All certificates representing the shares were or upon issuance will be endorsed with a restrictive legend confirming that the securities had been issued pursuant to Regulation S of the Act and could not be resold without registration under the Act or an applicable exemption from the registration requirements of the Act.

Re-Purchase of Equity Securities

None.

Dividends

We have not 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

On November 17, 2011, the Company adopted and approved the 2011 Equity Incentive Plan (the Plan), for the directors, officers, employees and key consultants of the Company. Pursuant to the Plan, the Company is authorized to issue nine hundred thousand (900,000) restricted shares, $0.001 par value, of the Company s Common Stock. Options over 720,000 shares were granted on November 25, 2011. The 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 for options vesting in the first year, $4 for options vesting in the second year, and $5 for options vesting in the third year. Options over 30,000 shares were granted on September 01, 2012. The 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 $4.31 for options vesting in the first year, $5.31 for options vesting in the second year, and $6.31 for options vesting in the third year. Options over 100,000 shares were granted on December 13, 2012. The options vested on the grant date and expire three years after the vesting date. The exercise price is $3.01 per share. Options over 37,000 shares were granted on March 20, 2013. The 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 $2.35 for options vesting in the first year, $3.35 for options vesting in the second year, and $4.35 for options vesting in the third year. Options over 16,300 shares were granted on September 2, 2013. The 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 $2.35 for options vesting in the first year, $3.35 for options vesting in the second year, and $4.35 for options vesting in the third year.

During the year ended December 31, 2013, 30,000 options expired following termination of employment.

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.

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. 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.

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

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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.

Liquidity and Capital Resources

As of December 31, 2014, the Company had cash of $2,138,964 and other current assets of $196,754. The Company had current liabilities of $2,713,077. This represents a working capital deficit of $377,359. Current liabilities include an amount of $1,577,640 in respect of a derivative liability. After excluding this liability there is an operating working capital surplus of $1,200,281.

On February 6, 2015, the Company received $8.5million net proceeds for 2,475,000 shares of common stock for an aggregate purchase price of $3.75 per share concurrent with an up-listing to the NYSE MKT. In addition, on February 13, 2015, 343,383 shares of common stock were issued at a price of $3.75 per share, with net proceeds of $1.2 million being received, and on March 6, 2015, 400,000 shares of common stock were issues at a price of $3.75 per share, with net proceeds of $1.4 million.

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 stock by way of private placement, but there is no assurance that we will be successful in raising further funds.

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

Overview of Operations

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

Results of Operations

Year Ended December 31, 2014

The following table sets forth the Company s results of operations for the year ended on December 31, 2014 and the comparative period for the year ended December 31, 2013.

	Year Ended December 31, 2014 ($)	Year Ended December 31, 2013 ($)	Increase/ Decrease ($)	Percentage Increase/ Decrease (%)
Revenues	14,785	-	14,785	-
Operating Expenses	(5,952,200)	(4,575,912)	(1,376,288)	30%
Net Other (Expenses)/Income	(2,276,114)	865,623	(3,141,737)	-363%
Income Taxes	-	-	-	-
Net Loss	(8,213,529)	(3,710,289)	(4,503,240)	121%
Basic and Diluted Loss Per Common Share	(0.61)	(0.34)	(0.27)	79%
Weighted Average Basic and Diluted Common Shares Outstanding	13,435,253	10,832,369	2,602,884	24%

Revenues

The Company had revenues of $14,785 from operations in the year ended December 31, 2014, compared to no revenues in the comparative period for the year ended December 31, 2013. The Company s operations are still predominantly in the development stage.

Operating Expenses

For the year ended December 31, 2014, the Company s operating expenses increased by $1,376,288, or 30%. Operating expenses are comprised of salaries and office administrative fees, research and development expenses, professional fees, and other general and administrative expenses. Salaries and office administrative fees showed an increase of $408,991 over 2013 expenses. This is mainly explained by an increase in share option amortization expense of $248,211, following additional share options being granted in August 2014. Other expense areas to increase included the cost of $42,055 for warrants issued to consultants and Chief Financial Officer fees of$77,659. Research and development expenses increased by $1,540,258, due to an increase of $366,650 spent on a new Danish Study in 2014, an increase of $191,701 in share option expense and an increase of $172,915 in net payroll costs, the latter was mainly due to an increase in headcount. There was also an increase in patent costs of $229,782 year on year. Samples, antibody purchases and associated costs also increased by $172,630. Professional fees decreased by $88,006. This is explained in part by the fact that P.R. fees were reduced by $250,833 in 2014, offset by an increase in share options expense, legal and investor relations fees. General and administrative expenses decreased by $134,955 year on year. This is mainly related to a decrease in fundraising services costs in the Income Statement in 2014.

In comparison, for the year ended December 31, 2013, the Company s operating expenses increased by $437,894, or 11% from 2012. Operating expenses are comprised of salaries and office administrative fees, research and development expenses, impairment of patents, professional fees, and other general and administrative expenses. Salaries and office administrative fees were materially unchanged. Research and development expenses decreased by $269,377, due principally to a reduction of $383,291 in share option expense offset by an increase of $120,828 in net payroll costs, the latter primarily reflecting an increase in headcount. Impairment of patents was $350,000 (2012 $Nil) due to discovery of an earlier filed patent similar to one licensed by the Company. Professional fees increased by $371,256 due to additional fees for public relations and investor relations services to raise the profile of the company. General and administrative expenses decreased by $14,031 due to a reduction in fundraising services expense.

Net Other Expenses/Income

For the year ended December 31, 2014, the Company recorded net other expenses of $2,276,114, representing other income of $143,987, relating to grant funds received from public bodies in respect of approved expenditures, where there is no obligation to repay, offset against a loss of $2,420,101, relating to the valuation of a derivative liability, resulting from the issuance of 1,500,000 warrants attached to the issuance of 1,500,000 shares, together with 30,975

warrants issued to agents on February 26, 2014. On October 31, 2014, 1,121,225 of the aforementioned warrants had their terms changed and ceased to be a derivative liability.

For the year ended December 31, 2013, the Company recorded other income of $865,623, representing grant funds received.

Net Loss

For the year ended December 31, 2014, our net loss was $8,213,529, an increase of $4,503,240 or 121% over the comparative period for the year ended December 31, 2013. The change is a result of the changes 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.

Future Financings

We will continue to rely on equity sales of our common shares in order to continue to fund our business operations. Issuances of additional shares will result in dilution to existing stockholders. There is no assurance that we will achieve any additional sales of equity securities or arrange for debt or other financing to fund our operations and other activities.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

Recently Issued Accounting Pronouncements

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

The Company has limited operations and is considered to be in the development stage. In the quarterly period ended September 30, 2014, the Company elected to early adopt Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. The adoption of this ASU allows the Company to remove the inception to date information and all references to the development stage.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

VOLITIONRX LIMITED

Consolidated Financial Statements

For the Years Ended December 31, 2014 and 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors

VolitionRx LTD

We have audited the accompanying consolidated balance sheets of VolitionRx LTD (the Company) as of December 31, 2014 and 2013 and the related consolidated statements of operations, stockholders equity and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the 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 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 financial statements referred to above present fairly, in all material respects, the financial position of VolitionRx LTD as of December 31, 2014 and 2013, and the results of their operations and cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The accompanying 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 had accumulated losses of $19,509,451 and negative cash flows from operations as of December 31, 2014, which raises substantial doubt about its ability to continue as a going concern. Management s plans concerning these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Salt Lake City, UT

March 18, 2015

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VOLITIONRX LIMITED

(Consolidated Balance Sheets

(Expressed in US dollars)

	December 31, 2014	December 31, 2013
	$	$
ASSETS		
Cash	2,138,964	888,704
Prepaid expenses	144,095	82,135
Other current assets	52,659	34,612
Total Current Assets	2,335,718	1,005,451
Property and equipment, net	288,585	63,265
Intangible assets, net	808,726	1,002,043
Total Assets	3,433,029	2,070,759
LIABILITIES		
Accounts payable and accrued liabilities	797,909	518,086
Management and directors fees payable	146,016	222,294
Derivative Liability	1,577,640	-
Deferred grant income	191,512	216,894
Total Current Liabilities	2,713,077	957,274
Grant repayable	351,773	432,811
Total Liabilities	3,064,850	1,390,085
STOCKHOLDERS EQUITY		
Preferred Stock		
Authorized: 1,000,000 shares, at $0.001 par value		
Issued and outstanding: Nil shares and Nil respectively	-	-

Common Stock		
Authorized: 100,000,000 shares, at $0.001 par value		
Issued and outstanding: 14,691,332 shares and 11,679,757 respectively	14,691	11,680
Additional paid-in capital	19,966,771	12,024,711
Accumulated other comprehensive loss	(103,832)	(59,795)
Accumulated Deficit	(19,509,451)	(11,295,922)
Total Stockholders Equity	368,179	680,674
Total Liabilities and Stockholders Equity	3,433,029	2,070,759

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

VOLITIONRX LIMITED

Consolidated Statements of Operations and Comprehensive Loss

(Expressed in US dollars)

	For the year ended December 31, 2014	For the year ended December 31, 2013
	$	$
Revenue	14,785	-
Expenses		
General and administrative	299,051	434,006
Professional fees	533,716	621,722
Salaries and office administrative fees	1,075,410	666,419
Research and development	4,044,023	2,503,765
Impairment of patents	-	350,000
Total Operating Expenses	5,952,200	4,575,912
Net Operating Loss	(5,937,415)	(4,575,912)
Other Income/(Expenses)		
Grants received	143,987	865,623
Loss on derivative liabilities	(2,420,101)	-
Net Other Income/ (Expenses)	(2,276,114)	865,623
Provision for Income Taxes	-	-
Net Loss	(8,213,529)	(3,710,289)
Other Comprehensive Loss	-	-
Foreign currency translation adjustments	(44,037)	(25,519)
Total Other Comprehensive Loss	(44,037)	(25,519)
Net Comprehensive Loss	(8,257,566)	(3,735,808)
Net Loss per Share Basic and Diluted	(0.61)	(0.34)
Weighted Average Shares Outstanding Basic and Diluted	13,435,253	10,832,369

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

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VOLITIONRX LIMITED

Consolidated Statements of Cash Flows

(Expressed in US dollars)

	For the year ended December 31, 2014 $	For the year ended December 31, 2013 $
Operating Activities		
Net loss	(8,213,529)	(3,710,289)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	142,131	146,396
Impairment of intangible asset	-	350,000
Stock based compensation	767,483	282,012
Common stock and warrants issued for services	708,182	472,425
Amortization of stock issued in advance of services	-	250,833
Non-operating income grants received	(143,987)	(865,623)
Loss on derivative re-measurement	1,424,554	-
Derivative expense	995,547	-
Changes in operating assets and liabilities:		
Prepaid expenses	(78,335)	