VOLITIONRX LTD Form 10-KT April 16, 2012

III 10, 2012	UNITED STATES	
	SECURITIES AND EXCHANGE COMM	MISSION
	Washington, D.C. 20549	
	FORM 10-KT	
ANNUAL REPORT ACT OF	PURSUANT TO SECTION 13 OR 15(d) OF	THE SECURITIES EXCHANGE
1934		
For the Fisc	al Year Ended	
X .TRANSITION REPO	ORT PURSUANT TO SECTION 13 OR 15(d	) OF THE EXCHANGE ACT
For the Trai	nsition Period from <u>September 1, 2011</u> to <u>Dec</u>	cember 31, 2011
	VOLITIONRX LIMITED	
	(Exact name of registrant as specified in its	s charter)
Delaware	000-30402	91-1949078

**Delaware** (State or other jurisdiction of Incorporation)

000-30402 (Commission File Number)

er) (IRS Employer Identification Number)

150 Orchard Road

Orchard Plaza 08-02

Singapore 238841

(Address of principal executive offices)

Telephone: (201) 618-1750

**Facsimile:** +65 6333 7235 (Registrant s Telephone Number)

Indicate by	y check mark i	if the	registrant is	a well-known	seasoned issuer,	as defined ir	ı Rule 4	05 of th	e Securities .	Act.

Yes . No X.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes . No X.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes X. No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes . 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-KT or any amendment to this Form 10-KT.

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 report company" in Rule 12b-2 of the Exchange Act.
Large Accelerated Filer
Accelerated Filer
Non-Accelerated Filer .
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 December 31, 2011 was \$9,781,132 based upon the price (\$2.60) at which the common stock was last sold as of the last business day of the most recently completed fourth 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 in the over-the-counter market and quoted on the Over-The-Counter Bulletin Board

under the symbol VNRX.OB

As of April 10, 2012, there were 8,645,652 shares of the registrant outstanding.	s \$0.001 par value common stock issued and
Documents incorporated by reference: None	
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#### FORWARD-LOOKING STATEMENTS

This Transition Report on Form 10-KT contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ). 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:

The availability and adequacy of our cash flow to meet our requirements;
Economic, competitive, demographic, business and other conditions in our local and regional markets;
•
Changes or developments in laws, regulations or taxes in our industry;
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;
Competition in our industry;
The loss of or failure to obtain any license or permit necessary or desirable in the operation of our business;
Changes in our business strategy, capital improvements or development plans;
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 VNR references to VolitionRX Limited. All references to USD or United States Dollars refer to the legal currency of the United States of America.

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#### **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. The original business plan of the Company was to acquire and develop mineral properties. The Company leased the rights to explore a mining claim known as the Standard (the Standard Claim), but allowed the lease to expire in February 2008. The Company no longer has any rights to the minerals on the Standard Claim nor does it have any liabilities attached to the claim.

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 intends to carry on the business of Singapore Volition as its primary business. The Company is currently in the development stage.

Singapore Volition (registration number 201016543R) was incorporated on August 5, 2010 in Singapore as a Limited Private Company. The business plan of Singapore Volition is to acquire, develop and bring to production life science technologies. Singapore Volition has two subsidiaries, Belgian Volition SA (formerly ValiBio SA), a Belgium registered company incorporated on July 23, 2007 (Belgian Volition), and HyperGenomics Pte Limited, a Singapore registered company incorporated on March 7, 2011 (HyperGenomics Pte Limited). Singapore Volition purchased 99.9% of the shares of Belgian Volition from ValiRX PLC (ValiRX) pursuant to that certain Share Purchase Agreement with ValiRX dated September 22, 2010, and subsequently amended on June 9, 2011. A copy of the Share Purchase Agreement was filed as Exhibit 10.08 to our Amended Current Report on Form 8-K/A filed with the SEC on February 24, 2012. A copy of the Amendment was filed as Exhibit 10.15 to our Amended Current Report on Form 8-K/A filed with the SEC on January 11, 2012. As a result, Belgian Volition became a subsidiary of Singapore Volition. On March 7, 2011, Singapore Volition formed Hypergenomics Pte Limited as a wholly-owned subsidiary.

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

#### Description of Our Business

The Company is a development stage life sciences company focused on meeting the need for accurate, fast, inexpensive and scalable tests for detecting and diagnosing cancer and other diseases. We are in the development stage of our operations and are in the process of discovering and developing blood-based diagnostic tests intended for future commercialization through various channels within the United States and eventually throughout the world. We are currently developing six blood test product prototypes. Each product that we are developing can be commercialized for two distinct markets, the clinical in-vitro diagnostics ( IVD ) market and the research use only ( RUO ) market. Commercializing products on the RUO market means that we intend to sell our future 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, even if the products are being studied or tested for uses other than those intended. RUO products, however, are 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 in hospitals, clinics, etc. for patient diagnosis. None of the products that we are currently developing are available on either market.

Currently, there are very few blood tests available to detect cancer. The current blood tests available are primarily the prostate specific antigen (PSA) test for prostate cancer and the septin-9 test for colon cancer. The PSA test has very poor diagnostic accuracy (detects 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. The septin-9 colon cancer test has better diagnostic accuracy (detects approximately 70% of colon cancers and misdiagnoses about 10% of healthy people as positive for cancer) but is extremely expensive and technically complex. There are currently no blood tests for detecting lung cancer. Pancreatic cancer is currently not detectable by any means prior to symptomatic presentation of the patient by which time the disease is advanced and the patient life expectancy is short (a matter of a small number of months).

We do not anticipate earning 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

Everyone in the world has, or will be, touched by the effects of cancer. It is one of the world s most deadly diseases, accounting for around 13% of annual global deaths. <sup>1</sup> In the United States alone, there are 13.8 million cancer survivors. By 2020, this figure is expected to rise to 18.1 million and the cost of cancer to the U.S. is projected to reach \$158 billion. <sup>2</sup> These figures are mirrored in all regions of the world and will continue to grow as populations age. This is a large potential market of which diagnostics will be a significant part.

Inevitably, the chances of surviving cancer are greatly improved by early detection and diagnosis, however, there is currently no screening test for cancer in general, and very few effective mass screening tests for specific cancers. Further, current methods of cancer diagnosis are not cost effective and 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. Early, non-invasive, accurate cancer diagnosis remains a great unmet medical need and a huge commercial opportunity. For these reasons, cancer diagnostics is an active field of research and development both academically and in the industry.

The global IVD market is forecast to grow at a rate of 6% to reach \$50.0 billion in 2012, driven by the increasing health care demands of an aging population. The market has been growing at a rate of 5-6% in recent years, reaching a value of \$36.5 billion in 2007.<sup>3</sup> The largest IVD market segment is diabetes diagnostics with a value of \$10 billion.<sup>4</sup> The cancer IVD market comprising cancer blood and tissue biopsy tests was \$4.7 billion in 2008 and growing at 11%.<sup>5</sup>

<sup>&</sup>lt;sup>1</sup> Cancer - Fact sheet N°297, World Health Organization, [online], Available at: http://www.who.int/mediacentre/factsheets/fs297/en/index.html, [accessed 8.23.2011]

<sup>&</sup>lt;sup>2</sup>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

<sup>&</sup>lt;sup>3</sup>The Top Ten Global In-Vitro Diagnostics Companies, March 6, 2009, [online], Available at: http://store.business-insights.com/Product/?productid=BI00021-001, [accessed 8.29.2011]

<sup>&</sup>lt;sup>4</sup>Diagnostics: Testing systems prove their worth, July 1, 2008, [online], Available at: http://www.ft.com/cms/s/0/47c5ec16-477e-11dd-93ca-000077b07658,dwp\_uuid=322c9222-4712-11dd-876a-0000779fd2ac.html, [accessed 8.29.2011]

<sup>&</sup>lt;sup>5</sup>Cancer IVD market expands to meet customer demand, May 1, 2008, [online], Available at: http://www.ivdtechnology.com/article/cancer-ivd-market-expands-meet-customer-demand, [accessed 8.29.2011]

Of this the two largest IVD market segments are:	
. Histology, immunohistochemistry and cytology of tissue samples (45% of IVD sales or approximately \$2 billion These are mostly used to confirm cancer diagnosis post-surgery and to determine cancer sub-type; and	ı).

The IVD market (all disease areas) is highly consolidated with the top 10 companies taking an 80% market share. Roche Diagnostics is the largest single company by market share with 20%. Siemens and Abbott both have 12% market share<sup>6</sup>. The cancer IVD market also contains many smaller development companies like ours.

Immunoassays, mostly of blood samples (30% of IVD sales or approximately \$1.5 billion). These are mostly used to monitor for disease progress and relapse. This market segment includes our future Nucleosomics<sup>TM</sup> products which

will be blood immunoassay tests for modified histones for the diagnosis of cancer.

The Company is focused on responding to the need for early, accurate diagnostic tests through the development of its proprietary technologies and product prototypes. The Company intends to develop a range of products over the next 5-10 years with both general and specific cancer tests, on increasingly simple formats. For the year ended December 31, 2010, the Company spent \$172,194 on research and development activities. For the twelve month period ended December 31, 2011, the Company spent \$1,508,870 on research and development activities. None of these costs are borne directly by customers as the Company is in the development stage and does not have any customers.

#### **Our Intended Products**

Each product that we are in the process of developing can be commercialized for two distinct markets, the clinical IVD market and the RUO market. To commercialize our future products on the clinical IVD market requires government approval (CE Marking in Europe and/or FDA approval in the U.S.). Commercializing our future products on the IVD market means that we intend to sell our future products to be used in hospitals, clinics, etc. for patient diagnosis. Commercializing our future products on the RUO market means that we intend to sell our future products to medical schools, universities and commercial research and development departments for RUO and not to be used for patient diagnosis. The RUO market does not require government approval, however, before any of our intended

products can be sold on the RUO market, they will 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 either the IVD or RUO market. The products that the Company is currently developing are described in detail below:

## NuQ<sup>TM</sup> Suite of Epigenetic Cancer Blood Tests

We are currently developing six epigenetic cancer blood test product prototypes based on our NuQ<sup>TM</sup> technology which is designed to detect the level of nucleosomes in blood. We are in the development stage of our operations and to date, we have no products available for sale on either the IVD or RUO market. 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 struct of DNA. The DNA in every human cell is not a random string but wound around protein complexes in a beads on a string structure. Each individual bead with associated DNA coiled around it is called a nucleosome. These nucleosomes then form additional structures with increasingly dense packing, culminating in chromosomes containing hundreds of thousands of nucleosomes.

<sup>6</sup>The Top Ten Global In-Vitro Diagnostics Companies, March 6, 2009, [online], Available at: http://store.business-insights.com/Product/?productid=BI00021-001, [accessed 8.29.2011]

Cancer is characterized by uncontrolled and rapid cell growth and also by an approximately matched, but slightly less, rapid cell death rate. When the cells die, the DNA is chopped up into individual nucleosomes which are released into he blood as summarized in Figure 1 below. When cells break up, they end up in the bloodstream to be recycled back nto the body. When a cancer is present, the number of cells being recycled is far higher than in a healthy body, so the system is overwhelmed, leaving the excess broken-up pieces, including the nucleosomes, in the blood. The structure of nucleosomes is not uniform but subject to immense variety. It is has been known for 4 or 5 years that nucleosomes n cancer cells are different in structure from those in healthy cells <sup>7</sup> .
Figure 1 Release of nucleosomes into blood

Additionally, blood nucleosome levels are 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). The Company s primary focus is on cancer diagnosis but we also intend to
pursue diagnostic opportunities in other disease areas.

The Company is in the process of developing the following  $NuQ^{TM}$  blood test products that fall into 3 main types and are intended to be used together to complement each other and to provide a total solution. To date, we do not have any products available for sale on either the IVD or RUO market.

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<u>NuQ-X<sup>TM</sup></u>: We are currently developing one blood test in the NuQ-X<sup>TM</sup> family to detect the presence of cancer by detecting nucleosomes containing specific nucleotides.

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<u>NuQ-V<sup>TM</sup></u>: We are currently developing four blood tests in the NuQ-V<sup>TM</sup> family to detect cancer and 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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<sup>&</sup>lt;sup>7</sup> 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

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<u>NuQ-M<sup>TM</sup></u>: We are currently developing one blood test in the NuQ-M<sup>TM</sup> family to detect cancer by detecting nucleosomes containing modified histones, the proteins that package and order DNA into nucleosomes. Our development work with this family of tests is at an earlier stage of development than the other family of tests and we hope to develop several other tests within this family in the future.

Generally, the above tests are being developed to work together in the following manner: 1) The basic NuQ- $X^{TM}$  test will be used as a frontline test for the presence of nucleosomes in the blood for the detection of cancer; 2) If the results of this test are negative, there is no cancer and further testing is unnecessary; 3) If the results of the NuQ- $X^{TM}$  test are positive, the patient may have cancer but further testing to detect cancer and to determine the specific subtype of cancer will need to be done using the NuQ- $X^{TM}$  tests and the NuQ- $X^{TM}$  test in conjunction (collectively called the NuQ- $X^{TM}$  panel ). To date, we have used the NuQ- $X^{TM}$  test and NuQ<sup>TM</sup> panel prototypes to test a small number of blood samples taken from lung, colon, and pancreatic cancer patients.

## **Early Clinical Studies**

Early clinical studies of the NuQ-X<sup>TM</sup> test prototype for the presence of circulating nucleosomes in the blood have been carried out on blood samples from 19 cancer patients (including lung, colon and pancreatic cancers) and 20 healthy patient controls. In these studies, a result was deemed positive if the level of circulating nucleosomes detected in the blood of a patient was elevated above the maximum level of the normal range expected of healthy people as commonly defined (the mean  $\pm$  2 standard deviations of the mean which statistically includes 95% of normal people). All tests were performed in duplicate. The results are shown in the graph below (bars show the error of duplicate analysis).

# Figure 2 Results of NuQ-XM test prototype clinical study carried out internally by the Company s scientists at its laboratory in Belgium.

Figure 2 shows the Optical Density (colour) result produced in the NuQ- $X^{TM}$  test of serum samples taken from healthy volunteers and subjects diagnosed with lung, colon or pancreatic cancer (as well as positive and negative control samples). Blood samples were taken and the serum was separated in the usual way - approximately 10 mL blood was drawn by venepuncture into a glass tube and allowed to clot. The tube was centrifuged for approximately 10 minutes at approximately 3000 x g. The serum was removed to a plastic tube and frozen until analysed by ELISA.  $10 \mu \text{L}$  (0.01 mL) of serum was tested using the Nucleosomics ELISA procedure. This was a typical ELISA analytical procedure using 2 antibodies that bind to nucleosomes. The first antibody is immobilised on a plastic surface and the second antibody is linked to a detectable enzyme to monitor antibody nucleosome binding. Uniformly low antibody-nucleosome binding was detected in samples from healthy subjects. Higher antibody-nucleosome binding was detected in samples from subjects diagnosed with cancer.

In addition, 12 other disease patient controls (Inflammatory Bowel Disease) were tested using the NuQ-X<sup>TM</sup> test. Some patients were positive for nucleosomes, but these nucleosomes were found to contain different proportions of histone variants and histone modifications and were distinguishable from cancer nucleosomes using the prototype NuQ<sup>TM</sup> panel. This involved a further four ELISA tests on the same samples to determine the relative proportions of four different types of nucleosomes in the samples.

The studies were carried out internally by the Company s scientists at its laboratory in Belgium using a small number of patient samples from two hospitals in Belgium and samples taken from healthy volunteers in the United Kingdom. The results of these studies have not been submitted to or published in any journals (peer reviewed or otherwise). The Company intends to conduct large scale clinical validations, both retrospective and prospective, of these test prototypes for colon, lung, and pancreatic cancers as well as additional cancer types.

## NuQ<sup>TM</sup> Research Kits

The Company is currently planning the manufacture of its first RUO products and intends to commence sales in the second quarter of 2012. The research products will be 96 well semi-manual kits of the the NuQ-X<sup>TM</sup> test, NuQ-V<sup>TM</sup> and/or the NuQ-M<sup>TM</sup> tests for the simultaneous analysis of 48 blood samples, the usual format for research products (a 96 well kit can be used to analyze some 48 samples as samples are tested in duplicate). The most expensive component in the manufacture of products will be the pairs of antibodies employed. Initially, we anticipate that these will be purchased or licensed at a cost of \$14 - \$110 USD per kit (for the lowest and highest cost per pair we are currently using), but the Company has commenced development of its own antibodies which we believe will reduce costs to less than \$10 USD per kit. Other production costs are expected to be less than \$30 USD per kit as summarized in Table 1. We expect total initial production costs to be around \$50-\$140 USD per kit and we anticipate a subsequent drop in the production price the first year to approximately \$40 USD per kit, as the Company continues to develop its own antibodies.

The selling price will be in the region of \$700 - \$1,200 USD per kit. The NuQ<sup>TM</sup> assay technology is proprietary to the Company 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 the Company s intended NuQ-MM 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. Currently, such products sell in the U.S. market for between \$400 - \$475 USD per kit (and even higher in Europe). We intend to sell our NuQ<sup>TM</sup> research kits at a higher market price because:

1.

All of the NuO<sup>TM</sup> products are protected by multiple patents giving the Company market exclusivity;

2.

 $NuQ-M^{TM}$  kits are designed to detect modified histones in intact nucleosomes without any sample pre-extraction steps and are hence much easier to use; and

3.

The NuQ-V<sup>TM</sup> and NuQ-X<sup>TM</sup> tests are designed to detect histone variants and other nucleosome structures for which there are no current competitors that the Company is aware of.

The Company has purchased the components to manufacture 250 NuQ-X<sup>TM</sup> test kits internally at the Company s laboratory in Belgium for beta-testing at a total cost of approximately \$33,000 USD. A table of the components of the kits and approximate costs are summarized in Table 1 below. If beta-testing is successful, the Company will begin to sell the kits in the second quarter of 2012. Other than the antibodies, all of the components of the kits such as the box, bottles, and wells, will be the same for each test.

Components of NuQ-X <sup>TM</sup> test kits	Cost (USD \$) Per Kit
Antibodies (solid phase & detection)	\$107.94
Microtiter plate (96 wells)	\$5.82
Enzyme Substrate (10 ml per kit)	\$7.80
Detection enzyme conjugate	\$0.37
Chemical components of STOP	\$0.29
Chemical components of buffers	\$1.31
Freeze drying costs	\$1.01
Instructions	\$1.31
Box & labels	\$2.61
Bottles (3x 20ml & 2 x 5ml glass)	\$3.17
Total	\$131.63

Table 1 Approximate component costs for each kit for the first 250 kits to be manufactured internally at the Company s laboratory in Belgium.

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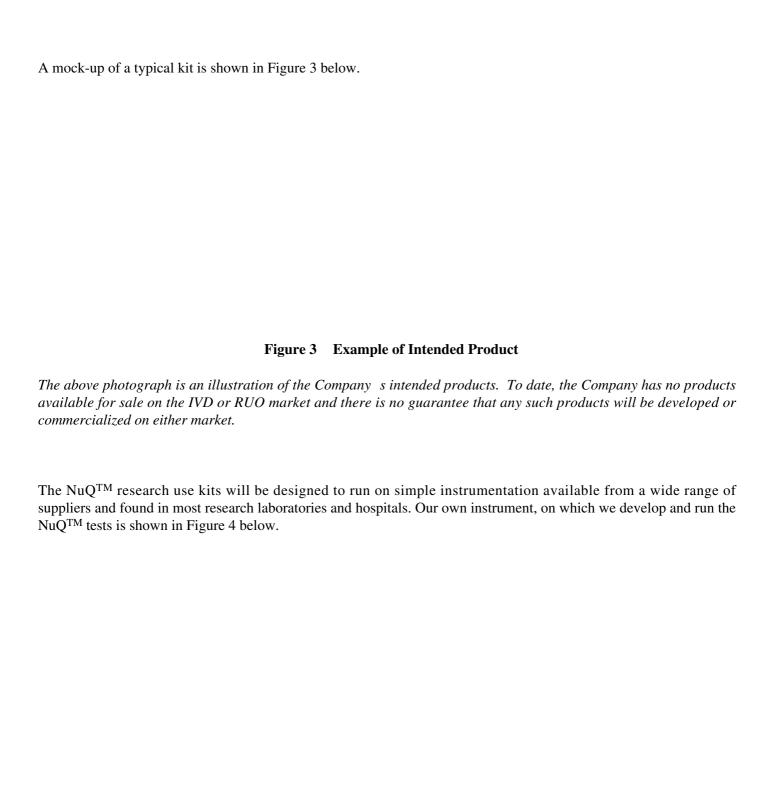


Figure 4 Example of lab instrument for running ELISA tests

## NuOTM Clinical Diagnostic Products

There are three main segments of the clinical IVD market that the Company intends to adapt its future NuQ<sup>TM</sup> 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 (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 U.S. 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<sup>TM</sup> tests that we are in the process of developing are designed for ELISA systems. A typical example of an ELISA system is shown below in Figure 5.



One option that may be available to the Company in the future is to license our  $NuQ^{TM}$  technology on a non-exclusive basis to a global diagnostics company. As of the date of this Report, the Company has not entered into any discussions or negotiations with diagnostic companies or established an anticipated timeframe for licensing our  $NuQ^{TM}$  technology.

Another option that may be available to the Company is to sell manual and/or semi-automated 96 well ELISA plates for use by these laboratories. As of the date of this Report, the Company has 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 found in any oncology clinic and tests can be performed during patient consultations. The Company intends to contract with an instrument manufacturer to produce these instruments for point-of-care NuQ<sup>TM</sup> testing for the oncologist s office, general doctor s office or at home testing. The Company hopes to enter the point-of-care clinical market in Europe in 2013 and in the U.S. in 2014, as the Company will first need to adapt its 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, the Company cannot accurately predict the costs to manufacture these devices or their selling price. As of the date of this Report, the Company has not entered into any discussions or negotiations regarding the manufacture or sale of these devices. See Figure 6 for an example of a point-of-care device.

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The above photograph is an illustration of the Company's intended products. To date, the Company has no products available for sale on the IVD or RUO market and there is no guarantee that any such products will be developed or commercialized on either market.

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Disposable Home Use or Doctor s Office Tests: Disposable home use or doctor s office tests are single shot disposable devices which can be purchased over the counter at any chemist shop or pharmacy and test a drop of blood taken from a finger prick. The test is administered at a doctor s office using a point-of-care device or 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 7 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.

Edgar Filing: VOLITIONEX LTD - Form 10-KT
The above photograph is an illustration of the Company's intended products. To date, the Company has no products available for sale on the IVD or RUO market and there is no guarantee that any such products will be developed or commercialized on either market.

The Company intends to contract with a specialist company to adapt the NuQ<sup>TM</sup> test prototypes to the doctor s office or home use system and to contract with a manufacture for the production of these tests. As of the date of this Report, the Company has not entered into any discussions or negotiations with a specialist company or manufacturer. Initially, the Company intends 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. The Company does not yet have an estimated timeframe for entering into this market. Further, at this early stage of our development, the Company cannot accurately determine the manufacturing costs or selling price of these tests.

## <u>HyperGenomics</u><sup>TM</sup>

The Company is in the process of developing HyperGenomics<sup>TM</sup> tissue tests to be administered once cancer has been detected to determine the specific subtype of disease and to help decide the most appropriate therapy. Selecting the correct treatment approach can significantly improve outcome, reduce side effects and deliver cost savings. Currently, confirmation of the presence of cancer is done by cytology and immunocytochemistry which are time consuming and expensive. Further, many biopsies taken to confirm the presence of cancer are negative and must be repeated. HyperGenomics Pte Limited, a subsidiary of the Company, holds a worldwide exclusive licence to the patent application for the HyperGenomics technology from Imperial College, London. The HyperGenomics<sup>TM</sup> tests for cancer will be performed on cancer tissue obtained either by biopsy or by surgical resection to determine the cancer subtype and to determine optimal treatment regimens. The HyperGenomics<sup>TM</sup> tissue tests are being developed to be able to characterize individual tumors by epigenetic profiling at a detailed and deep level and in a cost effective way.

In regards to the RUO market, currently the HyperGenomics<sup>TM</sup> test is in the prototype development stage. Once the prototype development is completed (expected end 2012), the Company will then perform beta-testing which shall take approximately six (6) months to complete and will cost approximately \$50,000 USD. If beta-testing is successful, the Company expects its HyperGenomics<sup>TM</sup> test to be rolled out onto the RUO market in Europe and in the U.S. in 2013. The HyperGenomics<sup>TM</sup> test is too early in its development for the Company to accurately determinate the manufacturing costs and sale price of the test.

For the IVD market, the Company expects to work on the clinical proof of concepts and validations for the HyperGenomics<sup>TM</sup> test in 2012. The launch of the HyperGenomics<sup>TM</sup> test into the IVD market in Europe and the U.S. 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.

## **Endometriosis Test**

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. 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. Due to difficulties in this process, the diagnosis can take approximately 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 ( NuQ Endo ) in June 2011 and the Company is now in the process of developing the test based on its existing NuQ<sup>TM</sup> technology. The NuQ Endo test is designed 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. Hypothesis-testing and clinical proof of concept work (to demonstrate that the test is feasible or has the potential to be used and effective) on the endometriosis test is currently being carried out in the Company s laboratory. The Company will continue with validation of the NuQ Endo endometriosis test in 2012. The Company will review the best ways of commercializing a product on the IVD market in the late first quarter of 2012 if the validations prove its diagnostic potential. If the Company is successful in developing a reliable test, we hope to partner with large pharmaceutical companies to bring these tests to the IVD clinical market. The NuQ Endo test is too early in its development for the Company to accurately determinate the manufacturing costs and sale price of the test. The NuQ Endo test is not currently being developed for the RUO market.

## **Intellectual Property**

The Company holds eight families of patents covering the products currently being developed. Three are licensed form world-class research institutions, two are patents authored by Belgian Volition and three are patents authored by Singapore Volition.

## Nucleosomics<sup>TM</sup> Intellectual Property

Singapore Volition holds an exclusive license to the following patent from Chroma Therapeutics Limited:

**Nucleosomics WO2005019826:** Detection of Histone Modifications in Cell-Free Nucleosomes (Patent that underlies the NuQ-M<sup>TM</sup> tests)

Application Date: August 18, 2003

Status: Granted in Europe; Pending in U.S.

For more information, see the section entitled Material Contracts of Singapore Volition and its Subsidiaries and

Exhibits 10.04, 10.09 and 10.12.

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: Pending Worldwide

For more information, see the section entitled Material Contracts of Singapore Volition and its Subsidiaries and

Exhibit 10.14.

Belgian Volition authored the following patent application covering its total NuQ<sup>TM</sup> assay technology:

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

Application Date: September 1, 2011

Status: Pending Worldwide

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Belgian Volition authored the following patent application covering its NuQ-V <sup>TM</sup> technology:
NuQ-V Patent UK1115098.4 and U.S. 61530304: Method for Detecting Nucleosomes containing Histone Variants
Application Date: September 1, 2011
14

Status: Pending Worldwide
Singapore Volition authored the following patent application covering its NuQ-X <sup>TM</sup> technology:
NuQ-X Patent UK1115095.0 and U.S. 61530295: Method for detecting Nucleosomes containing Nucleotides
Application Date: September 1, 2011
Status: Pending Worldwide
Singapore Volition authored the following patent application covering a NuQ-A <sup>TM</sup> 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. As of the date of this Report, the Company has no immediate plans for the development of a blood test under this patent.
NuQ-A Patent UK1121040.8 and U.S. 61568090: Method for detecting Nucleosome Adducts
Application Date: December 7, 2011
Status: Pending Worldwide
HyperGenomics <sup>TM</sup> Intellectual Property

HyperGenomics Pte Limited holds a worldwide exclusive licence to the following patent application from Impe College, London:	erial
HyperGenomics WO03004702: Method for Determining Chromatin Structure	
Application Date: July 5, 2001	
Status: Pending in Europe and U.S.	
For more information, see the section entitled Material Contracts of Singapore Volition and its Subsidiaries Exhibits 10.01, 10.02, 10.03, 10.16 and 10.17.	and
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: Pending Worldwide	
For more information, see the section entitled Material Contracts of Singapore Volition and its Subsidiaries Exhibits 10.08 and 10.15.	and

# Future Intellectual Property Strategy

The Company intends to continue its development of the NuQ <sup>TM</sup> and HyperGenomics <sup>TM</sup> technologies and will
continue to apply for patents for future product developments. The Company s strategy is to protect the technologies
with patents in Europe and the U.S. Following product development, each product, based on the technologies, will be
further protected individually by new patent filings worldwide.

We believe that this will provide:

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. Market exclusivity through a double layer of patent protection (primarily the protection of the underlying technology
on which all the tests are based and, secondarily, specific patent protection for each future product).  .
A full 20-year protection for each new product developed (e.g. a NuQ <sup>TM</sup> product developed in 2010 would continue to be protected in all markets until 2030, beyond expiration of the parent technology patent in 2023).
<u>Trademarks</u>
Europe Granted Trademarks

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**NuQ** (covers associated brand names including NuQ-X, NuQ-V, NuQ-M, NuQ Endo, etc.)

European Community Trade Mark No. 009979675

In Classes 01, 05, 10. 42

Registration Date: November 28, 2011

Initial Duration: 10 years

From: May 19, 2011

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## Hypergenomics

European Community Trade Mark No. 009979626

In Classes 01, 05, 10. 42

Registration Date: November 28, 2011

Initial Duration: 10 years

From: May 19, 2011

## **Europe Trademark Application Pending**

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## **Nucleosomics**

European Community Trade Mark Application No. 009979551

Classes 01, 05, 10. 42

Application Date: May 19, 2011

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## **United States** Trademark Application Pending

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## NuQ

Application Date: May 20, 2011

United States Trade Mark Application No. 85/326467

Classes 01, 05, 10 and 42

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## Hypergenomics

Application Date: May 20, 2011

United States Trade Mark Application No. 85/326495

Classes 01, 05, 10 and 42

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#### **Nucleosomics**

Application Date: May 20, 2011

United States Trade Mark Application No. 85/326500

Classes 01, 05, 10 and 42

#### Government Approval

All of the Company's intended products are designed to be non-invasive, meaning they cannot harm the subject other than through misdiagnosis. The Company's strategy is to begin selling its future products for RUO purposes, which requires no regulatory approval, while simultaneously going through the process of obtaining regulatory approval for IVD products to be used clinically on cancer patients. Conformité Européenne (CE) Marking is a rough equivalent of the United States. Food and Drug Administration (FDA) approvals process, although it is a somewhat lighter regime. The Company will first focus on the regulatory process in Europe (CE Marking), due to the grant of the NuQ<sup>TM</sup> patent in Europe and due to the lighter regulatory requirements to obtain CE Marking than to obtain FDA approval in the U.S. This will be followed closely by the regulatory process in the U.S. 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, the Company has not begun the CE Marking or FDA approval process for any of its tests currently under development.

## Europe CE Marking

Manufacturers in the European Union ( EU ) 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, the Company must meet certain requirements as set forth in the In-Vitro Diagnostic Medical Devices Directive which applies to the Company s diagnostic products. The requirements to procure CE Marking for In-Vitro Diagnostic Medical products are: (i) analytical validation of the products; (ii) clinical validation of the products (which can be retrospective clinical studies using biobank patient samples, i.e. blood samples from historic patients); (iii) implementation of regulatory compliant manufacture; and (iv) 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 U.S.).

The Company is currently engaged in requirements (i) and (ii) for the NuQ-X<sup>TM</sup> test and the NuQ<sup>TM</sup> panel. Requirements (iii) and (iv) are general requirements that apply to all of the Company's intended products. In compliance with the In-Vitro Diagnostic Medical Devices Directive and the CE Marking process, the Company has ensured that all development and validation is carried out in a manner consistent with regulatory approval. Additionally, the Company has maintained proper records so that its future products can be approved as quickly and simply as possible. The Company has engaged a regulatory advisor to lead in requirement (iv) for all of its future products. All of these requirements must be completed prior to the submission of an application for CE Marking. The Company will submit applications, which will contain a dossier of all relevant analytical, clinical and manufacturing data following retrospective clinical studies which will require a total of approximately six (6) months to complete. We estimate the cost of obtaining CE Marking will be approximately \$500,000 USD per test. The Company expects that CE Marking for the NuQ-X<sup>TM</sup> test and NuQ<sup>TM</sup> panel products will be applied for by the end of 2012. 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 national agencies, such as Customs authorities and/or the Departments of Health, Industry and Labor, 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: i) visit commercial, industrial and storage premises on a regular basis; ii) visit work places and other premises where products are put into service and used; iii) organize random checks; and iv) 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. FDA Approval

The Company s 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 U.S. 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 U.S. to international markets. We estimate the cost of obtaining FDA approval to be approximately \$825,000 USD per product. FDA approval is more expensive and will 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 U.S. must first receive either clearance of a 510(k) pre-market notification or approval of a Product Market Application (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 or even longer 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 U.S., cancer diagnostics 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, most of the Company s future products will likely 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 ( 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 U.S.

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-X <sup>TM</sup> Test:
Research Use Only Market
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The Company s first intended product, the NuQ-XM test for the presence of circulating nucleosomes based on our proprietary NuQ <sup>TM</sup> technology is developed and the first beta-testing is complete. However, this NuQ-X <sup>TM</sup> test has since been improved with a new antibodies combination and the Company will start beta-testing on this improved test in the first quarter of 2012. If beta-testing is successful, the test will be released into the RUO market as a research kit in the U.S. and Europe in the second quarter of 2012.
In-Vitro Diagnostics Market
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<b>CE Marking (Europe)</b> : In preparation for release into the IVD market in Europe, the NuQ-X <sup>TM</sup> test is expected to undergo large scale retrospective clinical validations during 2012 which shall take approximately nine (9) months to complete. Once the retrospective validations are completed, the test will be submitted for CE Mark approval. We estimate the cost of obtaining CE Marking will be approximately \$500,000 USD.

**FDA Approval (U.S.)**: FDA approval in the U.S. is expected to require longer large scale prospective clinical validation studies and these will also be commenced in 2012 and are expected to be completed in 2014. When completed, the data will be submitted to the FDA for U.S. market approval. We estimate the cost of obtaining FDA approval will be approximately \$825,000 USD.

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### **NuO**<sup>TM</sup> Panel Tests:

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#### **Research Use Only Market**

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The  $NuQ^{TM}$  panel of tests are in the final stages of development for the RUO market. Beta-testing of the  $NuQ^{TM}$  panel tests is expected to begin the second quarter of 2012 and shall take approximately one month to complete. The expected costs of beta-testing of the  $NuQ^{TM}$  panel tests total less than \$20,000 USD. If beta-testing is successful, the Company intends to bring its  $NuQ^{TM}$  panel products to the research market during 2012 by selling the tests as research kits.

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#### **In-Vitro Diagnostics Market**

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CE Marking (Europe): The NuQ<sup>TM</sup> panel of tests have undergone the initial research phase and are in final stages of development and initial validation data for colon, lung and pancreatic cancers. The NuQ<sup>TM</sup> panel tests are expected to undergo large scale retrospective clinical validations in colon, lung, and pancreatic cancers during 2012 and take approximately nine (9) months to complete. 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 USD.

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**FDA Approval (U.S.)**: FDA approval is expected to require longer large scale prospective clinical validation studies and is expected to commence in 2012 and be completed in 2014. When completed, the data will be submitted to the FDA for U.S. market approval. We estimate the cost of obtaining FDA approval will be approximately \$825,000 USD.

In parallel with the large scale clinical validation studies for colon, lung, and pancreatic cancers, the Company will commence initial testing on further cancers in 2012 based on the Company s NuQ<sup>M</sup> technology. These will be selected by medical need and commercial value and the first will be breast cancer. It is expected that, if initial clinical

studies are positive, large scale retrospective (CE Mark) and prospective (FDA) clinical validation studies for breast cancer will commence in the third quarter of 2012. A rolling pipeline of products for different types of cancers is expected to be produced over the next three (3) to five (5) years.

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Hypergenomics <sup>TM</sup> Test:
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Research Use Only Market
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Currently, the HyperGenomics <sup>TM</sup> test is in the prototype development stage. Once the prototype development is completed (expected end 2012), the Company will then perform beta-testing which shall take approximately six (6) months to complete and will cost approximately \$50,000 USD. If beta-testing is successful the Company expects its HyperGenomics <sup>TM</sup> test to be rolled out onto the RUO market in Europe and in the U.S. in 2013. The HyperGenomics <sup>TM</sup> test is too early in its development for the Company to accurately determinate the manufacturing costs and sale price of the test.
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In-Vitro Diagnostics Market
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The Company expects to work on the clinical proof of concepts and validations for the HyperGenomics <sup>TM</sup> test in 2012. The launch of the HyperGenomics <sup>TM</sup> test into the IVD market in Europe and the U.S. 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.
NuQ Endo <sup>TM</sup> Endometriosis Test:
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**Research Use Only Market** 

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The Company does not intend to bring the  $NuQ\ Endo^{TM}$  test to the RUO market and instead will focus its efforts on bringing it to the IVD market.

In-Vitro Diagnostics Market

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Currently, the NuQ Endo<sup>TM</sup> test is undergoing hypothesis-testing and clinical proof of concept work. The Company expects to continue with validations for the NuQ Endo<sup>TM</sup> test in 2012. Once the proof of concepts and validations are completed, expected end of 2012, the Company will then perform beta-testing which shall take approximately six (6) months to complete and will cost approximately \$50,000 USD. If the Company is successful in developing a reliable test, we hope to partner with large pharmaceutical companies to bring these tests to the IVD market in Europe and the U.S. The NuQ Endo<sup>TM</sup> test is too early in its development for the Company to accurately determinate the manufacturing costs and sale price of the test. 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.

# **NuO**<sup>TM</sup> Clinical Diagnostic Products:

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#### **Centralized Laboratory Market**

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License of NuQ<sup>TM</sup> technology to a global diagnostics company: The Company may license our NuQ<sup>TM</sup> 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, the Company has not entered into any discussions or negotiations with diagnostic companies or established an anticipated timeframe for licensing our NuO<sup>TM</sup> technology.

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Sell manual and/or semi-manual ELISA plates to centralized laboratories: The Company 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 Report, the Company has 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: The Company expects to enter the point-of-care clinical market in Europe in 2013 and in the U.S. in 2014. The approximate manufacturing costs or sales price per device have not yet been determined. As of the date of this Report, the Company has not entered into any discussions or negotiations regarding the manufacture or sale of these devices.

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Disposable Home Use or Doctor s Office Tests: The Company intends to contract with a specialist company to adapt the NuQ<sup>TM</sup> tests to the doctor s office or home use system and contract with their manufacture. 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, the Company has not entered into any discussions or negotiations with a specialist company or manufacturer. The Company does 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, 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 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, the Company may be obliged to discontinue operations, which will adversely affect the value of its common stock.

#### Sales and Marketing Strategy

The first use of our future NuQ<sup>TM</sup> products will be for RUO, as the RUO market does not require government approval as opposed to the clinical IVD market. We believe that by selling our intended products in the RUO market, we will drive awareness of our Company and our intended products which in turn, will lead to future sales in both the RUO and IVD clinical markets. The Company s future products will be available for sale to researchers via the Company s product website, http://www.nucleosomics.com. Initially, the Company will provide its products to carefully chosen opinion leaders to provide further validation and product feedback.

The Company will use the following methods to generate revenues from its intended products:

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<u>Direct Sales</u>: As the Company desires to launch its intended products into both the RUO and IVD markets as quickly as possible, direct sales will be the first path to market the future suite of NuQ<sup>TM</sup> products as well as all of the

Company s other future products when they are first available for sale. We hope to achieve initial sales through strong existing contacts and a dedicated product website. As of the date of this Report, the Company has not begun direct sales or entered into any sales agreements for any of its intended products.

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<u>Product Sales Partners</u>: If the Company is able to sell its intended products, the Company will strive to carry out the majority of its sales of diagnostic and research products through contracted sales and marketing partners. This will be organized by territory, by region and end user, e.g. clinical vs. research. We estimate such partners will take approximately 30% to 40% of the sales prices of any products sold through these channels. While initial discussions have been commenced, the Company has not finalized any formal partnerships.

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<u>Distribution Agreements</u>: Distribution agreements will be used primarily in markets and territories where the Company has no real prospect of obtaining traction alone or where the entry barriers are high. The Company plans to enter into tightly drawn distribution agreements outlining the territory and sectors to be covered. Control will be maintained by the Company through strict oversight and by centralized production centers that will provide supplies to distributors. We estimate such distributors will take approximately 30% of the sales prices of any products sold through these channels. As of the date of this Report, the Company has not entered into any distribution agreements.

The Company s future products will require several dynamic and evolving sales models tailored to different worldwide markets, users and products. The Company has decided to focus its sales strategy on the initial RUO market in 2012 and develop a flexible strategy for its future IVD products through the later part of 2012. We hope to progressively grow to large volumes of tests sold to centralized laboratories and eventually reach the mass diagnostics testing market. The exact nature of the ideal sales strategy will evolve as the Company continues to develop its intended products and seek entry into the RUO and IVD markets.

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#### **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 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 of diagnostic health care products. The federal government also has increased funding in recent years to fight health care fraud, and various agencies, such as the U.S. 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.

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.

#### **Competition**

We anticipate facing competition primarily from large healthcare, pharmaceutical and diagnostic companies such as Abbott Laboratories Inc., Cepheid Inc., Philips, GE Healthcare, Siemens, Gen-Probe Incorporated, MDxHealth SA, EpiGenomics AG, 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, 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 future competitors also offer broad product lines outside of the diagnostic testing market and have brand recognition. Moreover, our future 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, <a href="https://www.sec.gov">www.sec.gov</a>.

#### 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 150 Orchard Road, Orchard Plaza 08-02, Singapore 238841. We currently rent this space for approximately \$1,500 USD 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.

Belgian Volition rented laboratory and office space at Facultés Universitaires Notre-Dame de la Paix located at 61 rue de Bruxelles, B-5000, Namur, Belgium for approximately \$1,007 (€778 EUR) per month pursuant to a lease entered into with the University on January 31, 2011 for a leasing term of one year. On February 1, 2012, Belgian Volition entered into an amended leasing agreement with the University, extending the original lease for an additional three months. On January 26, 2012 Belgian Volition entered into a new lease agreement to maintain its existing laboratory space only at the University for \$1,294 (€1,000 EUR) per month commencing April 1, 2012 for a leasing term of one year.

On 29 February 2012, Belgian Volition entered into a lease agreement for larger laboratory and office space at 20A Rue de Séminaire, 5000, Namur, Belgium for approximately \$4,960 (€3,833 EUR) per month commencing April 1, 2012 for a leasing term of two years. Additionally, Belgian Volition shall pay \$1,941 (€1,500) EUR per month as a provision against expenses.

#### ITEM 3.

#### LEGAL PROCEEDINGS

We know of no material, existing or pending legal proceedings against our Company, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which our director, officer or any affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to our interest.

#### 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 is currently quoted on the OTC Bulletin Board. Our common stock has been quoted on the OTC Bulletin Board since 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 are quoted on the OTC Bulletin Board, our securities may be less liquid, receive less coverage by security analysts and news media, and generate lower prices than might otherwise be obtained if they were listed on a national securities exchange.

The following table sets forth the high and low bid prices for our common stock per quarter as reported by the OTCBB for 2010 and 2011 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 (	First Quarter		Second Quarter		Third Quarter		Fourth Quarter	
		(Jan. 1	Mar. 31)	(Apr. 1	Jun. 30)	(Jul. 1	Sept. 30)	(Oct. 1	Dec. 31)	
2011	High	0.25		0.25		0.	25	5.	00	
2011	Low	0.25		0.25		0.	25	0.	.25	
2010	High	0.25		0.25		0.	25	0.	25	
2010	Low	0.25		0.25		0.	25	0.	25	

#### Record Holders

As at April 10, 2012, an aggregate of 8,645,652 shares of our common stock were issued and outstanding and were owned by approximately 83 holders of record, based on information provided by our transfer agent.

Recent Sales of Unregistered Securities
None.
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,

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 February 20, 2004, the Company s shareholders approved a Stock Option Plan (the Plan) whereby a maximum of 5,000,000 common shares were authorized but unissued to be granted to directors, officers, consultants and non-employees who assisted in the development of the Company. The value of the stock options to be granted under the Plan will be determined using the Black-Scholes valuation model. To date, no stock options have been granted under this Plan. On October 6, 2011, the Plan was cancelled by written consent of the Board of Directors.

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.

# 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.

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

This Transition Report on Form 10-KT contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ). 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, 2011, the Company had cash of \$347,892 and non-cash prepaid expenses of \$320,833, and other current assets of \$30,749. The Company had current liabilities of \$534,364. This represents a working capital deficit, excluding non-cash prepayments of \$320,833, of \$155,723. During 2012 to date the Company has received subscriptions for 368,150 new shares totaling \$644,250 before expenses, in connection with a private placement that is ongoing. Therefore, as of the date of filing this report, the Company s cash reserves are only adequate to fund operations for a limited period of time.

We intend to use our cash reserves to fund further research and development activities. We expect to receive a certain amount of additional grant funds over the period to May 31, 2012, but this is not assured and otherwise we do not currently have any source of revenues and expect to rely on additional financing. We are pursuing plans to seek further capital through the sale of additional stock by way of private placement; however to date this placement has raised only a limited amount of funds and 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 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, 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 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. Some of these resources were acquired during the period ended December 31, 2011 and are reflected in the costs for that period, others have been acquired since, and others are dependent upon obtaining additional financing. 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 term objectives of the business plan, in particular the development of our intended products for the RUO market and 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 short term.

# Results of Operations

# Year Ended December 31, 2011

The following table sets forth the Company s results of operations for the year ended on December 31, 2011 and the comparative period from inception on August 5, 2010 through December 31, 2010.

	Year Ended December 31, 2011 (\$)	For the period from August 5, 2010 (Date of Inception) to December 31, 2011 (\$)	Increase/ (Decrease) (\$)	Percentage Increase/ (Decrease) (%)
Revenues	-	-	-	-
Operating Expenses	(2,608,463)	(894,120)	(1,714,343)	192%
Other Income (Expenses)	-	-	-	-
Income Taxes	-	-	-	-
Net Loss	(2,608,463)	(894,120)	(1,714,343)	192%
Basic and Diluted Loss Per				
Common Shares	(0.45)	(0.30)	(0.15)	50%
Weighted Average Basic and Diluted Common Shares				
Outstanding	5,768,132	3,019,881	2,748,251	91%

#### **Revenues**

The Company had no revenues from operations in the year ended December 31, 2011. The Company s operations are in the development stage.

# **Operating Expenses**

For the year ended December 31, 2011, the Company s operating expenses increased by \$1,714,343, or 192%. 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 increased by \$530,854 due to the twelve month period in 2011 compared to five months in 2010, the grant of options valued at \$350,766 to certain key management, and to additional staff and associated costs. Research and development expenses increased by \$1,336,677 due to increased R&D activity. Professional fees decreased by \$392,690 due to a reduction in fees related to fundraising and business development. General and administrative expenses increased by \$239,502, due to the twelve month period in 2011 compared to five months in 2010 and to additional business activity.

#### **Net Loss**

For the year ended December 31, 2011, our net loss was \$2,608,463, an increase of \$1,714,343 or 192% over the comparative period from inception on August 5, 2010 through December 31, 2010. 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 the 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

In September 2011, the FASB issued ASU 2011-08 to amend and simplify tests for goodwill impairment by permitting an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a two-step goodwill impairment test. The amendments in ASU 2011-08 are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Adoption of this new guidance is not expected to have a material impact on the Company s financial statements.

In May 2011, the FASB issued ASU 2011-04 to amend the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurement to (1) clarify the application of existing fair value measurement requirements and (2) change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. The primary purpose of the amendments is to achieve common fair value measurement and disclosure requirements in U.S. GAAP and IFRSs. The amendments in ASU 2011-04 are to be applied prospectively for interim and annual periods beginning after December 15, 2011. Adoption of this new guidance is not expected to have a material impact on the Company s financial statements.

The Company has implemented all new accounting pronouncements that are in effect. These pronouncements did not have any material impact on the financial statements unless otherwise disclosed, and the Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are 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**

(Formerly Standard Capital Corporation)

(A Development Stage Company)

# FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2011 and 2010

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#### SADLER, GIBB & ASSOCIATES, LLC

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors		
VolitionRX Limited.		

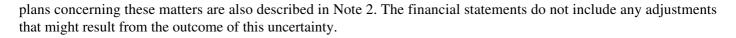
(A Development Stage Company)

We have audited the accompanying balance sheets of VolitionRX Limited as of December 31, 2011 and 2010, and the related statements of operations, stockholders—equity (deficit) and cash flows for the years ended December 31, 2011 and 2010. 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 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 Limited as of December 31, 2011 and 2010, and the results of their operations and cash flows for the years ended December 31, 2011 and 2010, 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 financial statements, the Company had accumulated losses of \$3,502,583 as of December 31, 2011, which raises substantial doubt about its ability to continue as a going concern. Management s



# /s/ Sadler, Gibb & Associates, LLC

Sadler, Gibb & Associates, LLC

Salt Lake City, UT

April 16, 2012

# VOLITIONRX LIMITED

(A Development Stage Company)

Consolidated Balance Sheet

(Expressed in US dollars)

	December 31,	December 31,
	2011	2010
	\$	\$
ASSETS		
Cash	347,892	47,481
Prepaid expenses Other current assets	320,833 30,749	17,670
Total Current Assets	699,474	65,151
Property and equipment, net Intangible assets, net	22,969 1,522,811	1,208 1,151,522
Total Assets	2,245,254	1,217,881
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities  Notes payable	255,519	228,000 59,943
Related party payables	278,845	260,867
Note payable related party	-	900,000
Total Current Liabilities	534,364	1,448,810
Grant repayable	621,935	-
Total Liabilities	1,156,299	1,448,810
STOCKHOLDERS EQUITY/(DEFICIT)		
Common stock	8,646	4,145

Authorized: 200,000,000 shares, at \$0.001 par value Issued and outstanding: 8,645,652 shares and 4,144,967 shares, respectively Additional paid-in capital 4,578,254 668,338 Share subscriptions received 30,000 Other comprehensive income/(loss) 4,638 (39,292)Deficit accumulated during the development stage (3,502,583)(894,120)Total Stockholders Equity (Deficit) 1,088,955 (230,929)Total Liabilities and Stockholders Equity (Deficit) 2,245,254 1,217,881

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

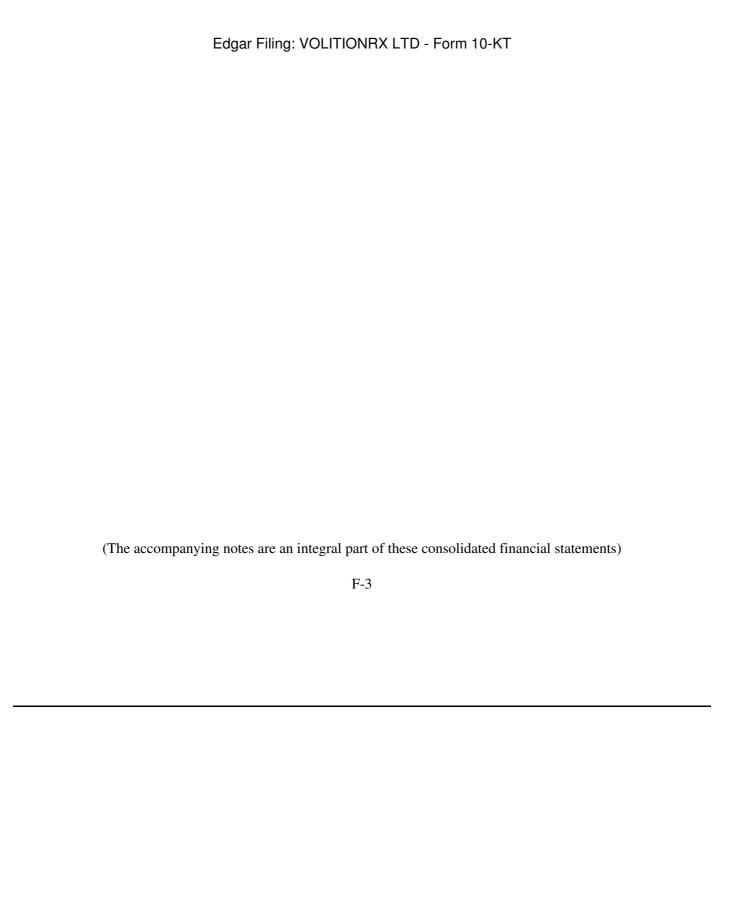
# **VOLITIONRX LIMITED**

(A Development Stage Company)

Consolidated Statements of Operations

(Expressed in US dollars)

		For the period from	For the period from
	For the year	August 5, 2010	August 5, 2010
	ended	(Date of Inception) to December 31,	(Date of Inception) to December 31,
	December 31,	2010	2011
	2011	\$	\$
	\$		
Revenue			
Expenses			
General and administrative	275,060	-	
Professional fees Salaries and office administrative fees	203,849 620,684	•	·
Research and development	1,508,870	*	
Total Operating Expenses	2,608,463	3 894,120	3,502,583
Net Loss	(2,608,463	(894,120)	(3,502,583)
Net Loss per Share Basic and Diluted	(0.45	(0.30)	
Weighted Average Shares Outstanding Basic and			
Diluted Diluted	5,768,132	3,019,881	



# **VOLITIONRX LIMITED**

(A Development Stage Company)

Consolidated Statement of Cash Flows

(Expressed in US dollars)

	For the	For the period from	For the period from
	year ended	August 5, 2010	August 5, 2010
	December 31,	(Date of Inception) to December 31,	(Date of Inception) to December 31,
	2011 \$	2010 \$	2011 \$
Operating Activities Net loss	(2,608,463)	(894,120)	(3,502,583)
Adjustments to net loss relating to non-cash operating items:			
Depreciation and amortization	118,617	21,102	139,719
Warrants and options granted for services	407,036		407,036
Common stock issued for services	362,482	-	
Amortization of stock issued in advance of services	29,167		29,167
Changes in operating assets and liabilities:			
Other current assets	(14,687)	15,813	1,126
Accounts payable and accrued liabilities	(3,305)	196,487	193,182
Related party payables	23,088	47,154	70,242
Net Cash Used In Operating Activities	(1,686,065)	(178,404)	(1,864,469)
Investing Activities			
Purchases of property and equipment	(34,865)		(34,865)
Financing Activities			
Proceeds from issuance of common shares	1,595,906	267,323	1,863,229
Grants received	676,346	·	676,346
Proceeds from note payable		59,942	59,942
Repayment of note payable related party	(255,807)	(100,000)	(355,807)
Cash acquired through reverse merger	100		100
Net Cash Provided By Financing Activities	2,016,545	227,265	2,243,810

Effect of foreign exchange on cash	4,796	(1,380)	3,416
Increase in Cash	300,411	47,481	347,892
Cash Beginning of Period	47,481		
Cash End of Period	347,892	47,481	347,892

Supplemental Disclosures of Cash Flow Information Interest paid Income tax paid

Non Cash Financing Activities::