

VOLITIONRX LTD
Form 10-K
November 29, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended August 31, 2011

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

For the transition period from _____ to _____

VOLITIONRX LIMITED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of Incorporation)

000-30402
(Commission File Number)

91-1949078
(IRS Employer
Identification Number)

150 Orchard Road

Orchard Plaza 08-02

Singapore 238841

(Address of principal executive offices)

(201) 618-1750

(Registrant's Telephone Number)

Copy of all Communications to:

Carrillo Huettel, LLP

3033 5th Avenue, Suite 400

San Diego, CA 92103

Phone: 619-546-6100

Fax: 619-546-6060

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes . No .

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

Yes . No .

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

Yes . No .

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

Yes . No .

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. .

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of February 28, 2011 was \$NIL based upon the price (\$NIL) at which the common stock was last sold as of the last business day of the most recently completed second fiscal quarter, multiplied by the approximate number of shares of common stock held by persons other than executive officers, directors and five percent stockholders of the registrant without conceding that any such person is an affiliate of the registrant for purposes of the federal securities laws. Our common stock is currently quoted on the Over-The-Counter Bulletin Board under the symbol VNRX.OB .

As of November 28, 2011, there were 8,120,652 shares of the registrant's \$0.001 par value common stock issued and outstanding.

Documents incorporated by reference: None

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements 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:

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

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

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

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

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Competition in our industry;

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

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

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

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.

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. Singapore Volition has two subsidiaries, Belgian Volition SA, a Belgium registered company (Belgian Volition), and HyperGenomics Pte Limited, a Singapore registered company (HyperGenomics Pte Limited). Singapore Volition owns 99.9% of the issued and outstanding shares of Belgian Volition and 100% of the issued and outstanding shares of HyperGenomics Pte Limited.

On September 22, 2011, the Company 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 life sciences company focused on meeting the urgent 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, developing and commercializing diagnostic tests. We believe that our tests will be able to better detect and characterize cancer and other disease states than existing methods, which in turn will provide better patient outcomes and contain healthcare costs. We focus on blood-based tests that we intend to sell through various channels within the United States and throughout the world, subject to regulatory clearance or approval.

We do not anticipate earning revenues until such time as we are able to fully market our products. 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 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 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.¹ 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.² 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 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 industry.

The global In-Vitro Diagnostics (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 ageing population. The market has been growing at a rate of 5-6% in recent years, reaching a value of \$36.5 billion in 2007.³ The largest IVD market segment is diabetes diagnostics with a value of \$10 billion.⁴ The cancer IVD market comprising cancer blood and tissue biopsy tests was \$4.7 billion in 2008 and growing at 11%.⁵

Of this the two largest IVD market segments are:

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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

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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 Nucleosomics products which are blood immunoassay tests for modified histones for the diagnosis and prognosis of cancer.

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.⁶ The cancer IVD market also contains many smaller development companies developing and selling novel products, such as the Company.

The Company is responding to the need for early, accurate diagnostic tests with its proprietary Nucleosomics™ (NuQTM) technology and products. The Company's range of products will continue to expand over the next 5-10 years with both general and specific cancer tests, on increasingly simple formats.

1

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]

2

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

3

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]

4

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]

5

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]

6

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]

Our Products

The Company's existing products, as well as those that are currently in the development pipeline, are described in detail below:

NuQ™ Suite of Epigenetic Cancer Blood Tests

Epigenetics is the science of how genes are switched on or off in the body's cells. A major factor controlling the switching on and off is the structuring of DNA. The DNA in 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.

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 the blood as summarized in Figure 2 below. When cells break up, they end up in the bloodstream to be recycled back into 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 in cancer cells are different in structure from those in healthy cells.¹ The Company has developed tests for some of the major nucleosome varieties and we have shown that we can detect the nucleosome patterns that are specific to cancer in the blood. Furthermore, we have shown that the nucleosome varieties also differ between cancer types (to distinguish for example between cancer of the pancreas, colon or mouth).

1

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

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 but we will also pursue diagnostic opportunities in other disease areas.

The Company's NuQ™ blood test products fall into 4 main types and will complement each other to provide a total solution:

NuQ™: A general test for the detection of the level of all nucleosomes in a patient's blood.

NuQ-X™: We currently have two tests in the NuQ-X™ family. They are tests for the detection of nucleosomes containing specific nucleotides are used as a blood test for the presence of cancer. So far we have tested blood samples from lung, colon, pancreatic and oral cancer patients taken on diagnosis prior to treatment. To date, every blood sample taken from patients with cancer that we have tested is clearly positive in both of the NuQ-X™ tests (100%). All blood samples taken from healthy patients have tested clearly negative in both tests (0%). Further clinical testing is necessary, but NuQ-X™ tests have great potential to fulfil the holy grail of a simple screening blood test for cancer.

NuQ-V™: We currently have four tests in the NuQ-V™ family. These are tests for the detection of nucleosomes containing specific histone variants and are used as a blood test for cancer. Additionally, we have found that the pattern of blood levels of the different types of histone variants in nucleosomes is different for different cancer types. NuQ-V™ test levels are raised in 85% of blood samples taken from patients with cancer that we have tested to date and, as well as detecting cancer, the patterns can distinguish between different cancer types. The Company will develop further NuQ-V™ tests to distinguish all the main cancer types and to increase the cancer detection rate of NuQ-V™ even higher from 85%.

NuQ-M™: We currently have one test in the NuQ-M™ family. This test is for the detection of nucleosomes containing modified histones, the proteins that package and order DNA into nucleosomes, and can be used as a blood

test for cancer. Our development work with this family of tests is at an earlier stage. The Company will develop many more such tests and the intention is to use them in a similar way to that described for the NuQ-V™ tests above.

We believe our products will enable doctors to screen for cancer using a NuQ-X™ test with a high detection rate (we have observed a 100% detection rate to date) and, if cancer is detected, to use NuQ-M™ and NuQ-V™ tests to investigate which cancer is present (up to 85% accuracy of those tested to date).

The Company will bring its suite of NuQ™ blood tests to the market at the end of 2011 to meet the strong need for cancer diagnostics.

NuQ™ Research Products

The Company has already developed a number of NuQ™ tests that it is using for clinical validation. In addition to their application in diagnostics, these products are useful research tools and will be marketed for research use.

The Company is currently organizing the manufacture of its first research use products and will commence sales in late 2011. The research products are semi-manual kits for the simultaneous analysis of 96 blood samples (the usual format for research products). The most expensive component in the manufacture of products are the pairs of antibodies employed. Initially these will be bought in or licensed in at a cost of \$14-\$94 per kit (for the lowest and highest cost pair we are currently using), but the Company has commenced development of its own antibodies which will reduce costs to less than \$10 per kit. Other production costs are less than \$30 per kit. Total initial production costs will be around \$50-\$125 (or \$2-\$4 per test as samples are usually tested in duplicate, so that a 96 well kit can be used to analyze some 48 samples) and we anticipate a subsequent drop in the production price the first year to approximately \$40 per kit. The selling price will be in the region of \$700 - \$1200. A mock-up of a typical kit is shown in Figure 3 below.

The NuQ™ research use kits are run on simple instrumentation available from a wide range of suppliers and found in every research laboratory and hospital. Our own instrument, on which we develop and run the NuQ™ tests is shown in Figure 4 below.

NuQ™ Clinical Diagnostic Products

There are three main segments to the clinical market addressed by the Company's products, and the NuQ™ tests will be adapted for each of these segments.

Centralized High-Throughput, Hospital Laboratories

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 instruments are used in all major hospital for the analysis of 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. A typical example of an ELISA system is shown below in Figure 5. Our NuQ™ products are all ELISA tests; thus, we anticipate that our tests will be adopted quickly in the

healthcare market because ELISA tests are widely used and well understood by clinicians and laboratory staff.

The patient diagnostics market is much larger than the research use market. However, healthcare providers operate strong cost control policies, and the global diagnostics companies that manufacture random access analyzers (e.g. Abbott) compete on market share and operate on a low price/high volume basis. The analyzers themselves are usually provided at no immediate cost in which the laboratory is given the instrument in return for agreeing to purchase minimum test numbers at given prices for a given time (this is somewhat similar to consumer mobile telephone contracts in which the phone itself is provided free). When the contract is complete the customer gets a free upgrade to the latest instrument upon signing a new contract.

One option open to the Company is to license our NuQ™ technology on a non-exclusive basis to a global diagnostics company, with an estimated revenue on such a license of approximately \$10 per test. The other option, which is the usual way that small innovative companies with high value ELISA products enter the centralized laboratory market, is to sell manual and/or semi-automated 96 well ELISA plates for use by these laboratories. In this way, small ELISA diagnostic companies are able to command prices in the range of \$20-40 per test, dependent on the clinical benefit and health care cost saving benefits of the particular test. We have conducted end user research with the heads of centralized laboratories and we believe the Company's products will command the high end of this price range.

Point-of-Care Devices: These 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 will contract with an instrument manufacturer to produce these instruments for point-of-care NuQ™ testing for the oncologist's office, general doctor's office or at home testing. See Figure 6 for an example of a point-of-care device. The Company expects to enter the point-of-care clinical market in 2013, as the Company will first need to adapt its tests to these small instruments and demonstrate their success in the greater diagnostics market before these products will be adopted by others in the industry.

Disposable Home Use or Doctor's Office Tests: These tests are single shot disposable devices which can be purchased over the counter at any chemist shop that 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 Company will contract with a specialist company to adapt the NuQ™ tests to this doctor office or home use system and contract with their manufacture. The sale of these tests will initially be for professional use only and will likely be released at a later time for non-professional use. 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.

The self-use home testing kit market is massive in size and potentially highly profitable, as the format 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 point-of-care or self-use home testing kit. About 30% of the population in developed countries are over the age of 50 and would be likely candidates for mass cancer screening, were such at home tests available. On a 5-yearly screen basis, the Company estimates this represents some 40 million tests per annum in the U.S. and Europe, for which we would expect to conservatively sell at a price of at least \$30-40 per test. The tests are expected to cost approximately \$5-6 each to manufacture. Given that the price charged to the user should be approximately \$30-\$40, the margin appears very attractive and the cost benefit to the patient compelling. The potential total market size for NuQ™ self-tests is over a billion dollars annually, based on 30 million test sales worldwide per year.

HyperGenomics™

The Company is in the process of developing its HyperGenomics™ tests, which will be administered once cancer has been detected to accurately 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. The Company believes the hypergenomic technology has the potential to be as ground breaking and revolutionary as our NuQ™ suite of tests, as HyperGenomics™-based tests would provide detailed information on the specific cancer and the individual's prognosis, and would help guide treatment.

The Company estimates that 10 million biopsy tests are performed annually in the U.S. with over a million in prostate cancer alone. Around 240,000 of these are positive and would be suited for hypergenomic profiling. A similar number are performed in Europe and in the rest of the world. Such tests command high prices. For example MammaPrint, a prognostic gene array for predicting breast cancer recurrence, has a list price of \$4250/€2675 with over 14,000 tests carried out since approval by the FDA in 2007. On the reasonable basis that a HyperGenomics™ test would be priced comparatively, the potential annual market size for HyperGenomics™ tests would be in the hundreds of millions of dollars within 5 years.

The Company will spend the fourth quarter of 2011 and the first quarter of 2012 in technical validation of this technology. In parallel, a pre-assembled kit will be developed to service the rapidly expanding life-science/epigenetics research community and will complement the Nu-Q™ range of epigenetics research tools and kits. In addition to continued method refinement of the HyperGenomics™ technology, the Company will develop a robust bioinformatics platform, which shall combine the HyperGenomics™ technology with computer science and information technology, to process and analyze data and store information. The Company expects its HyperGenomics™ products to be rolled out onto the market within the next two years.

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 in June 2011 and the Company is now in the process of developing the test, based on its existing NuQ™ technology. The test will 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 its NuQ™ based endometriosis tests through the fourth quarter of 2011. The Company will review the best ways of commercializing a product in the late first quarter of 2012 if the validations continue to prove its diagnostic potential. If the Company is successful in developing a reliable test, we believe that there would be significant interest from large pharmaceutical companies in partnering with the Company.

Product Development

The Company's first products, the epigenetic cancer blood tests based on our proprietary NuQ™ technology, are in development and will be released for research use by the first quarter of 2012.

The Company will focus its energies in 2012 on bringing its NuQ™, NuQ-X™ and NuQ-V™ products to the market, while secondarily working on the proof of concepts and validations for NuQ-M™, Hypergenomics (NuQ-IHC) and Endometriosis (NuQ Endo) products.

A graphic representation of the developmental stage of each of the Company's product lines at the end of third quarter of 2011 is as follows:

Plan of Operations / Sales and Marketing Strategy

The first use of our NuQ™ products will be for research, as the research market has lower regulatory barriers and is faster to adopt new products than the clinical diagnostics sector. We believe that by selling our products in the research market, we will drive awareness of our Company and our products which in turn, will lead to future sales in both the research and clinical markets. The Company's products will be available for purchase in the first quarter of 2012 to researchers via the Company's product website, <http://www.nucleosomics.com>. Initially, the Company will

provide its products to four carefully chosen opinion leaders to provide further validation and product feedback. The Company intends to choose a sales partner for its NuQ™ research products in the first quarter of 2012, which will further drive sales in this market. Additionally, the Company will manufacture an initial run of 1,000 NuQ™ kits in late fourth quarter of 2011. We expect our first revenues to be generated from the sales of these kits to researchers, closely followed by sales of NuQ-V™ and NuQ-X™ in the research market.

Further, it is expected that the Company will obtain CE Marking for its products in late 2012 which will allow for the NuQ™ tests to be used in a clinical setting in Europe. FDA approval is expected in 2013 which will allow for clinical use of our products in the U.S. Once the products have received the requisite approval from the FDA and CE Marking, the Company will begin selling its products for both research and clinical use, starting in Europe, followed by the U.S. and then the rest of the world, with a focus on Asia. The Company will use the following methods to generate revenues from its NuQ™ products:

Direct Sales: As the Company wants to get its products to market as quickly as possible, direct sales will be the first path to market the suite of NuQ™ products as well as all of the Company's other products when they are first available for sale. Initial sales will be achieved through strong existing contacts, a dedicated product website and a distribution agent to handle the physical logistics.

Product Sales Partners: When sales volumes increase, the vast majority of sales of diagnostic and research products will be carried out using contracted sales and marketing partners. This will be organized by territory, by region and end user, e.g. clinical vs. research.

Distribution Agreements: 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 will 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.

The Company's NuQ™ 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 research markets in 2012 and develop a flexible strategy for its clinical products through the second and third quarters of 2012.

We predict relatively low sales to researchers initially, but expect rapid growth as our products become standard, progressing to large volumes of tests sold to centralized laboratories and eventually reaching the mass diagnostics testing market. The exact nature of the ideal sales strategy will evolve and be developed by the Company as the list of products and markets grow.

Intellectual Property

The Company holds seven families of patents covering its current product pipeline. Three of these are licensed from world-class research institutions, two are patents authored by Belgian Volition and two are patents authored by Singapore Volition. The Company will continue to apply for patents for further developments. The Company's IP gives it a very strong and varied base from which to protect both its suite of NuQ™ products and other products under development as it continues to make innovative breakthroughs.

Nucleosomics™ IP

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™ tests)

Priority: August 18, 2003

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

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

Priority: July 2, 2009

Status: Pending Worldwide

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

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

Priority: September 1, 2011

Status: Pending Worldwide

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

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

Priority: September 1, 2011

Status: Pending Worldwide

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

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

Priority: September 1, 2011

Status: Pending Worldwide

HyperGenomics™ IP

HyperGenomics Pte Limited holds a worldwide exclusive licence to the following patent application from Imperial College, London:

HyperGenomics WO03004702: Method for Determining Chromatin Structure

Priority: July 5, 2001

Status: Pending in Europe and U.S.

Endometriosis IP

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

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

Priority: July 19, 2011

Status: Pending Worldwide

Future IP Strategy

Both the NuQ™ and HyperGenomics™ technologies will continue to give rise to multiple products in the cancer and other diagnostic fields. 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.

This will provide:

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Ensured 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 product).

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A full 20-year protection for each new product developed (e.g. a NuQ™ product developed in 2010 would continue to be protected in all markets until 2030, beyond expiration of the parent technology patent in 2023).

Trademarks

Singapore Volition has applied for trademarks for the following terms:

-
- Nucleosomics
-
- HyperGenomics
-
- NuQ (covers associated brand names including NuQ-M, NuQ-V, NuQ-Endo, etc.)

The Company is entitled to use TM in association with these terms until final decisions on the registration of the applications are due in early 2012.

Government Approval

All of the Company's NuQTM suite of products are non-invasive, meaning they cannot harm the subject other than through misdiagnosis. As a general principle, to achieve regulatory approval the Company would only need to prove that the products work according to the claims that the Company makes.

The Company's strategy is to begin selling products for research purposes that require minimal regulatory approval, while simultaneously going through the process of obtaining regulatory approval for the products to be used clinically on cancer patients. The Company will first focus on the regulatory process in Europe, due to the granted patent for NuQTM and lighter regulatory requirements for the Company's initial lab products. This will be followed closely by the regulatory process in the U.S. and in the rest of the world. Planning for the rest of the world is being undertaken and will be initiated after CE Marking (described below). In many territories the European CE Mark is sufficient to place products on the market and, where it is not, it often simplifies the regulation processes.

Europe CE Marking

Conformité Européenne (CE) Marking is a rough equivalent of the United States Food and Drug Administration (FDA) approvals process, although is a somewhat lighter regime. 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 standards and follow certain procedures as set forth in the In Vitro Diagnostic Medical Devices Directive which applies to the Company s diagnostic products.

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 EU. 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.

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 and has maintained proper records so that its products can be approved as quickly and simply as possible. The Company has engaged a regulatory consultant to ensure that all of its procedures are fully compliant. Further, the Company is working with EU regulatory professionals to obtain market approval and begin clinical validation.

The Company expects that CE Mark approval for the Company s first clinical products will be achieved by the end of 2012, at which point the first sales of our clinical products can occur in Europe. Further, the Company expects that FDA approval in the U.S. will follow approximately 9 months later in 2013. FDA approval is more expensive and will take at least twice as long as CE Marking in Europe.

U.S. FDA Approval

The Company's diagnostic products are considered by the FDA to be medical devices. 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.

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 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 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 manufacturing processes and those of our suppliers are 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 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 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 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.

Planned Clinical Validations / Clinical Trials

The Company has commenced background work to prepare for clinical validations and trials for the approvals process in Europe and North America.

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 must also comply with numerous other federal, state, and local laws relating to such matters as safe working conditions, environmental protection, industrial safety, and hazardous substance disposal. 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 face competition in the cancer diagnostic market primarily from 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 believe that our products compete with those offered by our competitors primarily on the basis of their cost-effectiveness, ease of use, mass screening potential, non-invasiveness, advanced technology, compatibility with ELISA systems, accuracy and strong IP position.

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

WHERE YOU CAN GET ADDITIONAL INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy our reports or other filings made with the SEC at the SEC's Public Reference Room, located at 100 F Street, N.E., Washington, DC 20549. You can obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You can also access these reports and other filings electronically on the SEC's web site, www.sec.gov.

ITEM 1A. RISK FACTORS

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive office is located at 150 Orchard Road, Orchard Plaza 08-02, Singapore 238841. We currently rent this space for approximately \$1,500 a month. Currently, this space is sufficient to meet our needs, however, once we expand our business to a significant degree, we will have to find a larger space. We do not currently own any real estate.

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. [REMOVED AND RESERVED]

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.

Fiscal Quarter	High	Low
First Fiscal Quarter (Sept. 1, 2010 – Nov. 30, 2010)	--	--
Second Fiscal Quarter (Dec. 1, 2010 – Feb. 28, 2011)	--	--
Third Fiscal Quarter (Mar. 1, 2011 – May 31, 2011)	--	--
Fourth Fiscal Quarter (June 1, 2011 – Aug. 31, 2011)	--	--
First Fiscal Quarter (Sept. 1, 2011 – Nov. 30, 2011)	3.00	1.50

Record Holders

As at November 28, 2011, an aggregate of 8,120,652 shares of our common stock were issued and outstanding and were owned by approximately 81 holders of record, based on information provided by our transfer agent.

Recent Sales of Unregistered Securities

Other than as previously disclosed, 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, 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

At the Annual General Meeting held on February 20, 2004, the shareholders approved a Stock Option Plan (the Option 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 Option Plan will be determined using the Black-Scholes valuation model. No stock options have been granted under this Plan. On October 6, 2011, the Company terminated the Option Plan.

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.

ITEM 6. SELECTED FINANCIAL DATA

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

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

This Annual Report on Form 10-K contains forward-looking statements 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 at August 31, 2011, the Company had cash of \$139 and liabilities of \$127,449. The liabilities of \$55,572 owed to general creditors are as follows: independent accountants \$3,900 for preparation and edgarizing financial statements and other reports, \$49,672 owed to a former director of the Company and \$2,000 for other payables. The amount owed to related parties of \$71,877 is non-interest bearing and has not fixed terms of repayment. During the current year ended August 31, 2011, the Company has incurred the following expenses as compared to the prior year as of August 31, 2010:

<u>Expenditure</u>		August 31,	August 31,
		2011	2010
Accounting and audit	i	\$ 9,700	\$ 5,450
Bank charges		102	105
Edgar filings	ii	1,350	750
Filing fees	iii	1,243	-
Management fees	iv	-	2,400
Office	v	333	292
Rent	iv	-	1,200
Telephone	iv	-	600
Transfer agent's fees and interest	vi	295	150
Total expenses		\$	