VOLITIONRX LTD
Form 8-K/A
January 11, 2012

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K/A

Amendment No. 2

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **October 6, 2011**

VolitionRX Limited

(Exact name of Company as specified in its charter)

Delaware	**0-24707**	**91-1949078**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

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Check the appropriate box below if the Form 8-K/A filing is intended to simultaneously satisfy the filing obligation of the Company under any of the following provisions:

. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

FORWARD LOOKING STATEMENTS

The following discussion, in addition to the other information contained in this Amended Current Report (Report), should be considered carefully in evaluating our prospects. This Report (including without limitation the following factors that may affect operating results) contains forward-looking statements regarding us and our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this Report. Additionally, statements concerning future matters such as revenue projections, projected profitability, growth strategies, possible changes in legislation and other statements regarding matters that are not historical are forward-looking statements.

Forward-looking statements in this Report reflect the good faith judgment of our management and the statements are based on facts and factors as we currently know them. Forward-looking statements are subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, but are not limited to, those discussed in this Report. Readers are urged not to place undue reliance on these forward-looking statements which speak only as of the date of this Report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Report.

As used in this Report and unless otherwise indicated, the terms we , us , our , the Company , SNDC , and VNRX VolitionRX Limited.

ITEM 1.01

ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

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 contains customary representations, warranties and conditions to closing. The Share Exchange Agreement closed on October 6, 2011.

Section 2.3 of the Share Exchange Agreement provides that there are 750,000 outstanding and unexercised warrants of Singapore Volition and Singapore Volition intends to issue an additional 900,000 warrants to its affiliates through a stock incentive plan. As a result of the Share Exchange Agreement, each outstanding and unexercised warrant or option of Singapore Volition, by operation of law, became a warrant or option of the Company. The exercise of these warrants would increase the amount of issued and outstanding shares of the Company s common stock and cause the Company s shareholders to suffer dilution in their ownership interests. Additionally, this may dilute the book value of the common stock, and that dilution may be material. Further, the resulting increase in the issued and outstanding shares of common stock of the Company may make it more difficult for shareholders of the Company to sell their shares on the market at a time and price that the shareholders deem appropriate.

Section 2.4 of the Share Exchange Agreement discloses that Singapore Volition is also a party to a Share Purchase Agreement (Purchase Agreement) with ValiRX PLC, a registered company of England and Wales (ValiRX) dated September 22, 2010 and subsequently amended on June 9, 2011 (the Amendment). Pursuant to that Purchase Agreement and Amendment, Singapore Volition shall purchase all of the shares held by ValiRX in ValiBio SA (ValiBio). In exchange for the ValiBio shares, Singapore Volition shall issue stock with a value of $1,110,000 USD in either Singapore Volition or, following the closing of the Share Exchange Agreement, in the Company, in accordance with the terms and provisions of the Purchase Agreement. On December 6, 2011, the Company issued shares of its common stock with a value of $1,110,000 USD to ValiRX. As a result of the share issuance, existing shareholders of the Company experienced dilution in their ownership interests. The Company cannot predict what effect, if any, the share issuance will have on the market price of its common stock.

Sections 5.2 and 5.3 of the Share Exchange Agreement provide that, prior to the closing of the agreement, a total of 265,000 shares of common stock of the Company shall be cancelled and the Company shall complete a 0.6-for-1 reverse split of the Company s then 2,020,000 issued and outstanding shares of common stock, resulting in 1,212,000 shares of the Company s common stock issued and outstanding following the cancellation and reverse split. Subsequently, the Company and Singapore Volition mutually agreed to modify the condition that the Company complete a reverse split and, in lieu thereof, that the Company shall cancel forty percent (40%) of the 2,020,000 shares of the Company s then issued and outstanding common stock, resulting in 1,212,000 shares of the Company s common stock issued and outstanding following the cancellation. The material effect of the cancellations of shares is that the existing shareholders of the Company now have greater ownership interests in the Company and may have more influence or control and greater ability to delay, defer or prevent any potential changes in control of the Company. However, with a smaller number of issued and outstanding shares of the Company, it may be more difficult for a strong public market for our common stock to develop and if it does not develop, investors may not be able to resell their shares of common stock and may lose all of their investment. Further, a smaller public float may cause our stock price to be very volatile and fluctuate widely.

The foregoing summary description of the terms of the Share Exchange Agreement may not contain all information that is of interest to the reader. For further information regarding specific terms and conditions of the Share Exchange Agreement, this reference is made to such agreement, which is filed as Exhibit 2.1 to the Company s Current Report on Form 8-K filed with the SEC on September 29, 2011, and incorporated herein by this reference.

ITEM 2.01

COMPLETION OF ACQUISITION OR DISPOSITION OF ASSETS

The information provided in Item 1.01 of this Amended Current Report on Form 8-K/A is incorporated by reference into this Item 2.01.

As a result of the Share Exchange Agreement, (i) our principal business became the business of Singapore Volition, which is more fully described below; and (ii) Singapore Volition became our wholly-owned operating subsidiary. We are currently a development stage company. Since the Volition Shareholders obtained the majority of the outstanding shares of the Company through the acquisition, the acquisition is accounted for as a reverse merger or recapitalization of the Company. As such, Singapore Volition is considered the acquirer for accounting purposes.

As of the date of the Share Exchange Agreement, there were no material relationships between the Company and Singapore Volition or between the Company and any of Singapore Volition s respective affiliates, directors, or officers, or any associates of its respective officers or directors, other than in respect of the Share Exchange Agreement.

ITEM 3.02

UNREGISTERED SHARES OF EQUITY SECURITIES

The information provided in Item 1.01 of this Amended Current Report on Form 8-K/A is incorporated by reference into this Item 3.02.

Exemption from Registration. The shares of common stock referenced herein were issued to the Volition Shareholders in reliance upon an exemption from registration afforded under Section 4(2) of the Securities Act for transactions by an issuer not involving a public offering, or Regulation D promulgated thereunder, or Regulation S for offers and sales of securities outside the U.S. The Share Exchange Agreement is an exempt transaction pursuant to Section 4(2) of the Securities Act as the share issuance to the Volition Shareholders was a private transaction by the Company and did not involve any public offering. Additionally, we relied upon the exemption afforded by Rule 506 of Regulation D of the Securities Act which is a safe harbor for the private offering exemption of Section 4(2) of the Securities Act whereby an issuer may sell its securities to an unlimited number of accredited investors, as ten (10) out of the thirty-eight (38) Volition Shareholders are accredited investors as that term is defined in Rule 501 of Regulation D. Further, we relied upon the safe harbor provision of Rule 903 of Regulation S of the Securities Act which permits offers or sales of securities by the Company outside of the United States that are not made to U.S. persons or for the account or benefit of a U.S. person, as twenty-eight (28) of the thirty-eight (38) Volition Shareholders are not U.S. persons as that term is defined in Rule 902 of Regulation S.

ITEM 5.01

CHANGES IN CONTROL OF REGISTRANT

The information provided in Item 1.01 of this Amended Current Report on Form 8-K/A is incorporated by reference into this Item 5.01.

Immediately following the closing of the Share Exchange Agreement, the Volition Shareholders beneficially owned 85.08% of the voting securities of the Company. The new shares of the Company's capital stock issued to the Volition Shareholders in connection with the Share Exchange Agreement were not registered under the Securities Act but were issued in reliance upon an exemption from registration afforded under Section 4(2) of the Securities Act for transactions by an issuer not involving a public offering, or Regulation D promulgated thereunder, or Regulation S for offers and sales of securities outside the U.S. These securities may not be offered or sold absent registration or an applicable exemption from the registration requirements. Certificates representing these shares contain a legend stating the same.

The Share Exchange Agreement is being accounted for as a "reverse acquisition," as the Volition Shareholders own a majority of the outstanding shares of the Company's capital stock immediately following the closing of the Share Exchange Agreement. The Board of Directors and management, after the Share Exchange Agreement, are comprised of Singapore Volition s management team. Furthermore, the operations of Singapore Volition are the continuing operations of the Company, therefore, Singapore Volition is deemed to be the acquirer in the reverse acquisition.

ITEM 5.02

DEPARTURE OF DIRECTORS OR CERTAIN OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF CERTAIN OFFICERS

On October 6, 2011, Alexander B. Magallano resigned from all positions with the Company, including but not limited to, that of Chief Executive Officer, President and Director. His resignation was not the result of any disagreement with the Company on any matter relating to the Company s operations, policies or practices.

On October 6, 2011, B. Gordon Brooke resigned from all positions with the Company, including but not limited to, that of Chief Accounting Officer, Chief Financial Officer and Director. His resignation was not the result of any disagreement with the Company on any matter relating to the Company s operations, policies or practices.

On October 6, 2011, Rudy Beloy Perez resigned from all positions with the Company, including but not limited to, that of Secretary and Treasurer. His resignation was not the result of any disagreement with the Company on any matter relating to the Company s operations, policies or practices.

On October 6, 2011, 2011, Cameron Reynolds was appointed as President, Chief Executive Officer and a member of the Board of Directors of the Company to serve until the next annual meeting of the shareholders and until his successor is duly appointed.

On October 6, 2011, 2011, Malcom Lewin was appointed as Chief Financial Officer and Treasurer of the Company to serve until the next annual meeting of the shareholders and until his successor is duly appointed.

On October 6, 2011, 2011, Rodney Gerard Rootsaert was appointed as Secretary of the Company to serve until the next annual meeting of the shareholders and until his successor is duly appointed.

On October 6, 2011, 2011, Dr. Martin Faulkes was appointed as a member of the Board of Directors of the Company to serve until the next annual meeting of the shareholders and until his successor is duly appointed.

On October 6, 2011, Dr. Satu Vainikka was appointed as a member of the Board of Directors of the Company to serve until the next annual meeting of the shareholders and until her successor is duly appointed.

On October 6, 2011, Guy Archibald Innes was appointed as a member of the Board of Directors of the Company to serve until the next annual meeting of the shareholders and until his successor is duly appointed.

On October 6, 2011, Dr. Alan Colman was appointed as a member of the Board of Directors of the Company to serve until the next annual meeting of the shareholders and until his successor is duly appointed.

On October 6, 2011, Kevin John Alexander was appointed as a member of the Board of Directors of the Company to serve until the next annual meeting of the shareholders and until his successor is duly appointed. On December 6, 2011, Kevin John Alexander resigned from all positions with the Company, including but not limited to, that of Director. His resignation was not the result of any disagreement with the Company on any matter relating to the Company s operations, policies or practices.

The biographies for the newly appointed directors and officers are set forth below under the section entitled, DIRECTORS AND EXECUTIVE OFFICERS .

ITEM 5.03

AMENDMENTS TO ARTICLES OF INCORPORATION OR BYLAWS; CHANGE IN FISCAL YEAR

On September 22, 2011, the Company, then 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, which had become forfeited or void for failure to file certain past due annual reports with the Secretary of State of Delaware and for nonpayment of annual franchise taxes. However, subsequent to the Certificate of Incorporation becoming forfeited or void and prior to filing the Certificate for Renewal, another corporation organized under the laws of the State of Delaware had adopted the same name or a name so nearly similar thereto as not to distinguish it from the Company s name of "Standard Capital Corporation". Therefore, pursuant to Section 312(1) of Delaware General Corporation Law, the Company was revived under the new name of "VolitionRX Limited." A copy of the Certificate for Renewal is attached hereto as Exhibit 3.01(b) and is incorporated herein by reference. The name change to VolitionRX Limited was approved by FINRA on October 7, 2011 and became effective on October 11, 2011. As of the date of this Report, the Company is in good standing in the State of Delaware.

Effective December 1, 2011, the Company s Board of Directors approved a change in the Company's fiscal year end from August 31st to December 31st. The Company intends to file a transition report for the four month period from September 1, 2011 to December 31, 2011 on a Form 10-KT on or before March 30, 2011.

ITEM 5.06

CHANGE IN SHELL COMPANY STATUS

As a result of closing the Share Exchange Agreement, the Company is no longer a shell corporation as that term is defined in Rule 405 of the Securities Act and Rule 12b-2 of the Exchange Act.

FORM 10 DISCLOSURE

As disclosed elsewhere in this Report, we completed a Share Exchange Agreement with Singapore Volition. Item 2.01(f) and 5.01(a)(8) of Form 8-K states that if the registrant was a shell company, as we were, immediately before the transaction disclosed under Item 2.01, then the registrant must disclose the information that would be required if the registrant were filing a general form for registration of securities on Form 10 under the Exchange Act.

Accordingly, we are providing below the information that would be included in a Form 10 if we were to file a Form 10. Please note that the information provided below relates to the combined enterprises of the Company and Singapore Volition after the closing of the Share Exchange Agreement, except that information relating to periods prior to the date of the Share Exchange Agreement relate to Singapore Volition unless otherwise specifically indicated.

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. Copies of the Share Purchase Agreement and Amendment are attached hereto as Exhibits 10.08 and 10.15, respectively. 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 urgent need for accurate, fast, inexpensive and scalable tests for detecting and diagnosing cancer and other diseases. We focus on blood-based tests that we intend to sell through various channels within the United States and throughout the world. We are in the development stage of our operations and are in the process of discovering and developing diagnostic tests intended for future commercialization. We are currently developing seven 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 our products on the RUO market means that we intend to sell our products to medical schools, universities and commercial research and development departments for RUO, not to be used for patient diagnosis. Commercializing our products on the IVD market means that we intend to sell our products to be used for 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 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). Our early pilot clinical studies have demonstrated a high rate of detecting cancer, including in a small number (19) of patients, the ability to detect pancreatic, lung and colon cancer. Whilst these small pilot

studies must be confirmed in larger clinical studies, these are promising findings. Due to the current unavailability of simple, accurate or affordable blood tests to detect cancer, we believe that our tests will be able to detect and characterize cancer and other disease states better than existing methods based on the outcomes we have received from our studies conducted to date. Better detection and characterization of cancer and other disease states will provide better patient outcomes and contain healthcare costs.

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 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. [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 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.[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 our Nucleosomics ™ products which are blood immunoassay tests for modified histones for the diagnosis 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 like ours, developing novel products.

The Company is responding to the need for early, accurate diagnostic tests with its proprietary Nucleosomics™ (NuQ™) technology and other products. The Company intends to expand its 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 $79,126 on research and development activities. For the nine month period ended September 30, 2011, the Company spent $506,218 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.

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[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 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 products on the clinical IVD market requires government approval (CE Marking in Europe and/or FDA approval in the U.S.). Commercializing our products on the IVD market means that we intend to sell our products to be used for in hospitals, clinics, etc. for patient diagnosis. Commercializing our products on the RUO market means that we intend to sell our 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. This 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™ Suite of Epigenetic Cancer Blood Tests

We are currently developing seven epigenetic cancer blood test product prototypes based on our NuQ™ technology which detects the level of nucleosomes in blood. Epigenetics is the science of how genes are switched on or off in the body s cells. A major factor controlling the switching on and off is the structuring of DNA. The DNA in 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 is developing tests for some of the major nucleosome varieties and our early clinical tests have shown that we can detect the nucleosome patterns that are specific to cancer in the blood. Furthermore, our early clinical tests have shown that the nucleosome varieties also differ between cancer types (to distinguish for example between cancer of the pancreas, colon or lung).

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 is developing the following NuQ™ 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:

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NuQ-X™: We currently have two blood tests in the NuQ-X™ family that are used to detect the presence of cancer by detect ing nucleosomes containing specific nucleotides. Thus 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 be a simple screening blood test for cancer.

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NuQ-V™: We currently have four blood tests in the NuQ-V™ family. These are tests used for the detection of cancer and the detection of nucleosomes containing specific histone variants. 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 were 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%.

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NuQ-M™: We currently have one blood 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 test to detect 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.

Generally, one of the Company s basic NuQ-X™ tests is used as a frontline test for the presence of nucleosomes in the blood for the detection of cancer. If this test is negative, there is no cancer and further testing is unnecessary. If the frontline NuQ-X™ test is 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 other NuQ-X™ test, three of the NuQ-V™ tests and the NuQ-M™ test in conjunction (collectively called the NuQ™ panel).

Early efficacy clinical studies of the frontline NuQ-X™ test and the NuQ™ panel used in conjunction for the presence of circulating nucleosomes in the blood and for the determination of nucleosome structure have been carried out on 19 cancer patients (including lung, colon and pancreatic cancers), 20 healthy patient controls and 12 other disease patient controls (inflammatory bowel disease). Of these samples, the tests for the presence of circulating nucleosomes were positive for all 19 cancer patients tested and negative for all 20 healthy patients. For the 12 other disease patient controls, some patients were positive for nucleosomes, however, the NuQ™ panel was able to distinguish those nucleosomes from cancer nucleosomes. The test results have shown that the NuQ™ panel can distinguish between different nucleosome structures and can distinguish nucleosomes present due to cancer from those due to other diseases tested (if any such nucleosomes are present).

In these studies, a result was deemed positive if it met two criteria: (i) 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 ± 2 standard deviations of the mean which statistically includes 95% of normal people); and (ii) the structure of the nucleosomes differed to those of healthy nucleosomes or of other diseases for which we have tested nucleosome structure to date. All tests were performed in duplicate and a positive result was obtained in both tests in all cases. The studies were carried out by the Company s scientists at its laboratory in Belgium using 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 published in a peer reviewed journal, although the Company intends to do so in 2012.

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[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

NuQ™ Research Kits

The Company is currently planning the manufacture of its first RUO products and intends to commence sales in the first quarter of 2012. The research products are semi-manual kits of the frontline NuQ-X™ test and NuQ™ panel tests for the simultaneous analysis of 96 blood samples, the usual format for research products (a 96 well kit can be used to analyze some 48 samples). Initially, the research kits will be developed for colon, lung and pancreatic cancers. The most expensive component in the manufacture of products is the pairs of antibodies employed. Initially these will be purchased or licensed at a cost of $14 - $94 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 will reduce costs to less than $10 USD per kit. Other production costs are less than $30 USD per kit. Total initial production costs will be around $50-$125 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 intends to develop its own antibodies in the future. The selling price will be in the region of $700 - $1,200 USD per kit. Initially, we intend to manufacture 1,000 kits and expect to launch our first research kits containing our NuQ-X™ test and NuQ™ panel of tests in the first quarter of 2012 at a total cost of approximately $50,000 - $125,000 USD. As of the date of this Report, the Company has not finalized any agreements for the manufacture of the kits. A mock-up of a typical kit is shown in Figure 3 below.

Figure 3 Example of Intended Product

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 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.

Figure 4 Example of lab instrument for running ELISA tests

NuQ™ Clinical Diagnostic Products

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

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Centralized Laboratory Market

Centralized laboratories test thousands of blood samples taken from patients everyday mostly using fully automated enzyme-linked immunosorbent assay (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 hospitals 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. We anticipate that our tests will be adopted quickly in the healthcare market because all of our NuQ™ products are ELISA tests. ELISA tests are widely used throughout the U.S. and Europe and are well understood by clinicians and laboratory staff. Thus, it is more cost-effective and technically simple for hospitals and clinics to run several blood samples simultaneously using our tests as compared to non-ELISA tests or alternative methods for screening cancer. A typical example of an ELISA system is shown below in Figure 5.

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 USD per test, based on our initial market research. 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™ technology.

Another option available to the Company, 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 USD per test, depend ing 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 future products will command the high end of this price range because of their cost-effectiveness, ease of use, mass screening potential, non-invasiveness, advanced technology, and accuracy. 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: 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™ testing for the oncologist s office, general doctor s office or at home testing. The Company expects 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 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. Based on general market research, the Company expects to sell these devices for approximately $250 USD each. The approximate manufacturing cost 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. See Figure 6 for an example of a point-of-care device.

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: These 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 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. Further, there are currently no useful diagnostics tests suitable for mass screening for cancer in general through a simple self-use home testing kit.

The Company intends to contract with a specialist company to adapt the NuQ™ tests to the doctor s office or home use system and contract with their manufacture for the production of these tests. The sale of these tests will initially be for professional use only (doctor s office) and will likely be released at a later time for non-professional home use. We expect the market will support a price of approximately $33 USD per test for these proprietary cancer diagnostic products as this is similar to the price of the non-proprietary generic PSA tests for prostate cancer. The tests are expected to cost approximately $5-6 USD each to manufacture. Given that the price charged to the user should be approximately $33 USD, the margin appears very attractive and the cost benefit to the patient compelling. 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. 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 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.*

HyperGenomics™

The Company is in the process of developing HyperGenomics™ tissue 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 HyperGenomics™ 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. We believe this HyperGenomics™ technology has the potential to be groundbreaking because it has the potential to characterize individual tumors by epigenetic profiling at a very detailed and deep level in a cost effective way to facilitate personalized medicine in a manner that exceeds all current possibilities. 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. For example, in the U.S. only 20% of biopsies taken to confirm breast cancer are positive (American Cancer Society; 2011). Thus, there is a large potential market for the HyperGenomics™ based test.

Currently, the HyperGenomics™ product is in the prototype development stage. The Company expects to work on the clinical proof of concepts and validations for the HyperGenomics™ test in 2012. Once the proof of concepts and validations are 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. The Company expects its HyperGenomics™ test to be rolled out onto the RUO market in Europe and in the U.S. in 2013. The Company intends to sell its HyperGenomics™ based test for a similar price as Mammaprint, a molecular diagnostic tissue test for predicting breast cancer recurrence which has a list price of $3,200 USD. The launch of our HyperGenomics™ 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™ technology. The NuQ Endo 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 Endo endometriosis tests in 2012. 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 hope to partner with large pharmaceutical companies to bring these tests to the RUO and IVD clinical market. The NuQ Endo test is too early in its development for the Company to determinate the manufacturing costs and sale price of the test.

Intellectual Property

The Company holds eight families of patents covering its current product pipeline. Three of these are licensed form world-class research institutions, two are patents authored by Belgian Volition and three are patents authored by Singapore Volition. The Company will continue to apply for patents for further product developments. The Company s intellectual property 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™ Intellectual Property

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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)

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 hereto.

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

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

Application Date : July 2, 2009

Status: Pending Worldwide

For more information, see the section entitled Material Contracts of Singapore Volition and its Subsidiaries and Exhibit 10.14 hereto.

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

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

Application Date : September 1, 2011

Status: Pending Worldwide

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

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

Application Date : September 1, 2011

Status: Pending 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

Application Date : September 1, 2011

Status: Pending Worldwide

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Singapore Volition authored the following patent application covering a NuQ-A™ blood test for detecting nucleosome adducts of cancer origin that circulate in the blood of cancer patients. The patent application covers both the use of these adducts as biomarkers and the methods for their detection. As of the date of this Report, there is no product associated with this patent and the Company has no immediate plans for its development.

NuQ-A Patent UK1121040.8 and U.S. 61568090: Method for detecting Nucleosome Adducts

Application Date: December 7, 2011

Status: Pending Worldwide

HyperGenomics™ Intellectual Property

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

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* and *Exhibits 10.01, 10.02, 10.03, 10.16 and 10.17 hereto.*

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 and Exhibits 10.08 and 10.15 hereto.

Future Intellectual Property 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

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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

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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 NuQ™ suite of products are non-invasive, meaning they cannot harm the subject other than through misdiagnosis. The Company s strategy is to begin selling 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™ patent in Europe a nd 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 products.

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 (which can be retrospective clinical studies using biobank patient samples, i.e. blood samples from historic patients); (ii) clinical validation of the products; (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 Company s frontline NuQ-X™ test and the NuQ™ panel. Requirements (iii) and (iv) are general requirements that apply to all of the Company s 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 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 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 Mark approval for the Company s frontline NuQ-X™ test and NuQ™ panel products will be achieved by the end of 2012, at which point the first sales of our clinical products could occur in Europe.

In Europe, IVD companies are able to self-certify that they meet the appropriate regulatory requirements and are subject to inspection for enforcement. Eu ropean 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 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 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 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.

Product Development and Plan of Operations

Frontline NuQ-X™ Test:

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Research Use Only Market

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The Company s first product, the frontline NuQ-X™ test for the presence of circulating nucleosomes based on our proprietary NuQ™ technology is developed, beta-testing is complete, and the test is ready to be released into the RUO

market in the U.S. and Europe by the first quarter of 2012 as part of a research kit along with the NuQ™ Panel tests. Total initial production costs will be around $50-$125 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 intends to develop its own antibodies for the kits in the future. The selling price will be in the region of $700 - $1,200 USD per kit. Initially, we intend to manufacture 1,000 kits at a total cost of approximately $50,000 - $125,000 USD.

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In-Vitro Diagnostics Market

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CE Marking (Europe) : In preparation for release into the IVD market in Europe, the frontline NuQ-X™ 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.

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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.

NuQ™ Panel Tests (for Colon, Lung and Pancreatic Cancers):

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Research Use Only Market

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The NuQ™ Panel tests have undergone the initial research phase and are in final stages of development and initial validation for colon, lung and pancreatic cancers. Beta-testing of the NuQ™ panel tests is expected to begin the first quarter of 2012 and shall take approximately one month to complete. The expected costs of beta-testing of the NuQ™ panel tests total less than $20,000 USD. The Company intends to bring its NuQ™ panel products to the research market during 2012 as part of a research kit along with the frontline NuQ-X™ test. Total initial production costs will be around $50-$125 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 intends to develop its own antibodies for the kits in the future. The selling price will be in the region of $700 - $1,200 USD per kit. Initially, we intend to manufacture 1,000 kits at a total cost of approximately $50,000 - $125,000 USD.

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In-Vitro Diagnostics Market

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CE Marking (Europe) : The NuQ™ 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 product 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 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.

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™ 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.

Hypergenomics™ Test:

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Research Use Only Market

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Currently, the HyperGenomics™ product is in the prototype development stage. The Company expects to work on the clinical proof of concepts and validations for the HyperGenomics™ test in 2012. Once the proof of concepts and validations are 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. The Company expects its HyperGenomics™ test to be rolled out onto the RUO market in Europe and in the U.S. in 2013. The Company intends to sell its HyperGenomics™ based test for a similar price as Mammaprint, a molecular diagnostic tissue test for predicting breast cancer recurrence which has a list price of $3,200 USD.

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In-Vitro Diagnostics Market

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The launch of our HyperGenomics™ 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™ Endometriosis Test :

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Research Use Only Market

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Currently, the NuQ Endo™ product is undergoing hypothesis-testing and clinical proof of concept work. The Company expects to continue with validations for the NuQ Endo™ 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 RUO market.

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In-Vitro Diagnostics Market

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The launch of our NuQ Endo™ 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 ™ Clinical Diagnostic Products:

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Centralized Laboratory Market

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License of NuQ™ technology to a global diagnostics company: The Company may license our NuQ™ technology on a non-exclusive basis to a global diagnostics company with an estimated anticipated revenue on such a license of

approximately $10 USD per test, based on our initial market research. 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™ 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 and expects to sell the plates at approximately $20-40 USD per test (48 tests per plate). 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. Based on general market research, the Company expects to sell these devices for approximately $250 USD each. The approximate manufacturing cost 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™ tests to the doctor s office or home use system and contract with their manufacture. We expect the market will support a price of approximately $33 USD per test. 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. 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 funding required to bring our current pipeline of products to the RUO market is in place and a lack of funding will not affect our anticipated timeframes. However, delays in funding would lead to delays in the clinical studies of our current product pipeline for the IVD market. In the event we lack sufficient funds to bring all of our current pipeline products to the IVD market, the Company will prioritize the development, clinical validation studies and regulatory approval processes of its products for colon cancer and delay the studies, regulatory submissions and development of its products in other disease areas include lung and pancreatic cancer.

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. Additional funding would likely be in the form of debt financing or equity financing from the sale of our common stock or sales of convertible promissory notes that are convertible into shares of our common stock. We will seek out additional funds from friends, family, and business acquaintances; however, there is no guarantee that such funds will be available as we have not received any firm commitments or indications of interest from our friends, family members, or business acquaintances regarding potential investments in our Company. The Company and its management are committed to the foregoing plan of operations and will use all reasonable means to effectuate it.

Sales and Marketing Strategy

The first use of our NuQ™ 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 products will be available for purchase 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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Direct Sales : As the Company desires to launch its products into both the RUO and IVD markets 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 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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Product Sales Partners : When sales volumes increase, the vast majority of the Company s 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. We estimate such partners will take approximately 30% to 40% of the sales prices of the products sold through these channels. While initial discussions have been commenced, the Company has not finalized any formal partnerships.

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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. We estimate such distributors will take approximately 30% of the sales prices of the 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 IVD products through the later part of 2012. We predict relatively low sales to researchers initially, but expect rapid growth if and when our products gain acceptance. We hope to progressing grow 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 our products and markets grow.

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.

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