VOLITIONRX LTD Form S-1/A September 13, 2012

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1/A

Amendment No. 1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Commission File Number: 000-30402

VOLITIONRX LIMITED

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

2835 (Primary Standard Industrial Classification Code Number) 91-1949078 (I.R.S. Employer Identification Number)

150 Orchard Road

Orchard Plaza 08-02

Singapore 238841

Telephone: (202) 618-1750

Facsimile: +65 6333 7235

(Address, including zip code, and telephone number, including

area code, of registrant s principal executive offices)

Agents and Corporations, Inc.

1201 Orange Street, Suite 600

Wilmington, DE 19899

(Name, address, including zip code, and telephone number,

including area code, of agent for service)

From time to time after the effective date of this Registration Statement

(Approximate date of commencement of proposed sale to the public)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. X.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

1

EXPLANATORY NOTE:

The purpose of this Amendment No. 1 (the Amendment) to our Registration Statement on Form S-1, which was originally filed with the Securities and Exchange Commission (the SEC) on August 3, 2012, is to update the financial statements of the Company for the quarterly period ended June 30, 2012 and to furnish Exhibit 101 to the Form S-1 in accordance with Rule 405 of Regulation S-T. Exhibit 101 provides the consolidated financial statements and related notes from the Form S-1 formatted in XBRL (eXtensible Business Reporting Language).

Other than the aforementioned, no other changes have been made to the Form S-1. This Amendment to the Form S-1 speaks as of the original filing date of the Form S-1, does not reflect events that may have occurred subsequent to the original filing date, and does not modify or update in any way disclosures made in the original Form S-1.

Pursuant to Rule 406T of Regulation S-T, the interactive data files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

CALCULATION OF REGISTRATION FEE

| Title of Each Class | Amount to be | Proposed | | Amount of | |
|--|--------------|----------------------------------|----------------------------------|--------------|--|
| of Securities to be | Registered | Maximum Offering Price Per | Proposed Maximum Aggregate | Registration | |
| Registered (1) | (2) | Share | Offering Price | Fee | |
| Common stock, \$0.001 par value per share | 688,101 | \$4.00 (3) | \$2,752,404.00 | \$315.43 | |
| Common stock, \$0.001 par value per share, issuable upon exercise of Investor Warrants | 344,059 | \$2.60 (4) | \$894,553.40 | \$102.52 | |
| Common stock, \$0.001 par value per share, issuable upon exercise of Placement | 26,685 | \$1.75 (5) | \$46,698.75 | \$5.35 | |
| Warrants | | | | | |
| Total | 1,058,845 | - | \$3,693,656.15 | \$423.30 | |

(1)

This Registration Statement covers the resale by our selling shareholders (the Selling Shareholders) of: (i) up to 688,101 shares (the Purchased Shares) of common stock previously issued at a price of \$1.75 per share to the Selling

Shareholders in connection with a private placement that closed on May 11, 2012; (ii) up to 344,059 shares (the Investor Warrant Shares) of common stock issuable upon the exercise of outstanding investor s warrants (the Investor Warrants) at an exercise price of \$2.60 that were previously issued to the Selling Shareholders in connection with a private placement that closed on May 11, 2012; and (iii) up to 26,685 shares (the Placement Warrant Shares) of common stock issuable upon the exercise of outstanding placement agent s warrants (the Placement Warrants) at an exercise price of \$1.75 that were previously issued to the placement agent pursuant to an engagement agreement dated May 10, 2012. (The Investor Warrants and Placement Warrants are referred to collectively as the Warrants and the Investor Warrant Shares and Placement Warrant Shares issuable under the Warrants are referred to collectively as the Warrant Shares).

(2)

This Registration Statement includes an indeterminate number of additional shares of common stock issuable for no additional consideration pursuant to any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock. In the event of a stock split, stock dividend or similar transaction involving our common stock, in order to prevent dilution, the number of shares registered shall be automatically increased to cover the additional shares in accordance with Rule 416(a) under the Securities Act of 1933, as amended (the Securities Act).

(3)

Estimated in accordance with Rule 457(c) of the Securities Act, solely for the purposes of calculating the registration fee based upon the average of the high and low prices as reported on the Over the Counter Bulletin Board (OTCBB) as of July 30, 2012.

(4)

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) of the Securities Act. The proposed maximum offering price is determined by the offering price of the common stock in the private placement completed on May 11, 2012.

(5)

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) of the Securities Act. The proposed maximum offering price is determined by the price at which the Warrants may be exercised.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE

REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

| The information in this preliminary prospectus is not complete and may be changed or withdrawn without notice. These securities may not be sold until this registration statement filed with the Securities and Exchange Commission (SEC) is declared effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. | | | |
|---|-------------------------------------|------------------------------|---------------------|
| is not soliciting an offer t | o buy these securthes in any jurisa | iction where the offer or sa | ue is not permutea. |
| | | | |
| | | | |
| | | | |
| | Subject to completion, date | ed, 2012 | |
| | | | |
| | 2 | | |
| | | | |

VOLITIONRX LIMITED

150 Orchard Road

Orchard Plaza 08-02

Singapore 238841

(201) 618-1750

PRELIMINARY PROSPECTUS

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED OR WITHDRAWN WITHOUT NOTICE. THESE SECURITIES MAY NOT BE SOLD UNTIL THIS REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS DECLARED EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY JURISDICTION WHERE THE OFFER OR SALE IS NOT PERMITTED.

1,058,845 SHARES OF COMMON STOCK

This prospectus covers the resale by our selling shareholders (the Selling Shareholders) of: (i) up to 688,101 shares (the Purchased Shares) of common stock previously issued at a price of \$1.75 per share to the Selling Shareholders in connection with a private placement that closed on May 11, 2012; (ii) up to 344,059 shares (the Investor Warrant Shares) of common stock issuable upon the exercise of outstanding investor s warrants (the Investor Warrants) at an exercise price of \$2.60 that were previously issued to the Selling Shareholders in connection with a private placement that closed on May 11, 2012; and (iii) up to 26,685 shares (the Placement Warrant Shares) of common stock issuable upon the exercise of outstanding placement agent s warrants (the Placement Warrants) at an exercise price of \$1.75 that were previously issued to the placement agent pursuant to an engagement agreement dated May 10, 2012. (The Investor Warrants and Placement Warrants are referred to collectively as the Warrants and the Investor Warrant Shares).

We are not selling any shares of our common stock in this offering and, as a result, we will not receive any proceeds from the sale of the common stock covered by this prospectus. All of the net proceeds from the sale of our common stock will go to the Selling Shareholders. Upon exercise of the Investor Warrants and the Placement Warrants, however, we will receive \$2.60 per share and \$1.75 per share, respectively, or such lower price as may result from the

anti-dilution protection features of such Warrants. Any proceeds received from the exercise of such Warrants will be used for general working capital and other corporate purposes.

The Selling Shareholders may sell common stock from time to time at prices established on the Over the Counter Bulletin Board (OTCBB) or as negotiated in private transactions, or as otherwise described under the heading Plan of Distribution. The common stock may be sold directly or through agents or broker-dealers acting as agents on behalf of the Selling Shareholders. The Selling Shareholders may engage brokers, dealers or agents who may receive commissions or discounts from the Selling Shareholders. We will pay all the expenses incident to the registration of the shares; however, we will not pay for sales commissions or other expenses applicable to the sale of our common stock registered hereunder.

VolitionRX Limited is a development stage company and currently has limited operations. Any investment in the shares offered herein involves a high degree of risk. You should only purchase shares if you can afford a loss of your investment. Our independent registered public accountant has issued an audit opinion for VolitionRX Limited, which includes a statement expressing substantial doubt as to our ability to continue as a going concern.

Our common stock is currently quoted on the OTCBB under the symbol VNRX.OB . On July 30, 2012, the closing price of our common stock was \$4.00 per share.

THE PURCHASE OF THE SECURITIES OFFERED THROUGH THIS PROSPECTUS INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD CAREFULLY READ THIS ENTIRE PROSPECTUS, INCLUDING THE SECTION ENTITLED RISK FACTORS BEGINNING ON PAGE 8 HEREOF BEFORE BUYING ANY SHARES OF VOLITIONRX LIMITED S COMMON STOCK.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

No dealer, salesperson or any other person is authorized to give any information or make any representations in connection with this offering other than those contained in this prospectus and, if given or made, the information or representations must not be relied upon as having been authorized by us. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any security other than the securities offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any securities by anyone in any jurisdiction in which the offer or solicitation is not authorized or is unlawful.

The date of this prospectus is ______, 2012.

TABLE OF CONTENTS

| | Page |
|--|------|
| Prospectus Summary | 5 |
| The Offering | 6 |
| Risk Factors | 7 |
| Determination of Offering Price | 14 |
| Use of Proceeds | 15 |
| Selling Security Holders | 15 |
| Plan of Distribution; Terms of the Offering | 17 |
| Dilution | 18 |
| Description of Property | 18 |
| Description of Securities | 19 |
| Description of Our Business | 20 |
| Management s Discussion and Analysis | 36 |
| Directors, Executive Officers, Promoters and Control Persons | 41 |
| Executive Compensation | 49 |
| Security Ownership of Certain Beneficial Owners and Management | 61 |
| Certain Relationships and Related Transactions | 63 |
| Legal Matters | 65 |
| Experts | 65 |
| Commission Position of Indemnification for Securities Act | |
| Liabilities | 66 |
| Where you can find more Information | 66 |
| Index to Financial Statements | F-1 |

You should rely only on the information contained or incorporated by reference to this prospectus in deciding whether to purchase our common stock. We have not authorized anyone to provide you with information different from that contained or incorporated by reference to this prospectus. Under no circumstances should the delivery to you of this prospectus or any sale made pursuant to this prospectus create any implication that the information contained in this prospectus is correct as of any time after the date of this prospectus. To the extent that any facts or events arising after the date of this prospectus, individually or in the aggregate, represent a fundamental change in the information presented in this prospectus, this prospectus will be updated to the extent required by law.

PROSPECTUS SUMMARY

The following summary highlights material information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. Before making an investment decision, you should read the entire prospectus carefully, including the Risk Factors section, the Management s Discussion and Analysis of Financial Condition and Results of Operations section, the financial statements and the notes to the financial statements. You should also review the other available information referred to in the section entitled Where You Can Find More Information in this prospectus and any amendment or supplement hereto. Unless otherwise indicated, the terms the Company, VolitionRX, VNRX, we, us, and our refer and relate to VolitionRX Limited, together with our wholly owned subsidiary, Singapore Volition Pte Limited, and its two subsidiaries, Belgian Volition SA and HyperGenomics Pte Limited.

The Company Overview

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.

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

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

The Company is a now a development stage life sciences company focused on meeting the need for accurate, fast, inexpensive and scalable tests for detecting and diagnosing cancer and other diseases. We are in the development stage of our operations and are in the process of discovering and developing blood-based diagnostic tests intended for future commercialization through various channels within the United States and eventually throughout the world. We are currently developing six blood test product prototypes. Each product that we are developing can be commercialized for two distinct markets, the clinical in-vitro diagnostics (IVD) market and the research use only (RUO) market. Commercializing products on the RUO market means that we intend to sell our future products to medical schools, universities and commercial research and development departments for research use only. Products placed on the RUO market may be used for any research purpose, even if the products are being studied or tested for uses other than those intended. RUO products, however, are not to be used for patient diagnosis. Commercializing products on the IVD market means that we intend to sell our future products to be used in hospitals, clinics, etc. for patient diagnosis. None of the products that we are currently developing are available on either market.

Currently, there are very few blood tests available to detect cancer. The current blood tests available are primarily the prostate specific antigen (PSA) test for prostate cancer and the septin-9 test for colon cancer. The PSA test has very poor diagnostic accuracy (detects approximately 70% of prostate cancers and misdiagnoses about 30% of healthy men as positive for cancer) but is widely used because it is the best product currently available. The septin-9 colon cancer test has better diagnostic accuracy (detects approximately 70% of colon cancers and misdiagnoses about 10% of healthy people as positive for cancer) but is extremely expensive and technically complex. There are currently no blood tests for detecting lung cancer. Pancreatic cancer is currently not detectable by any means prior to symptomatic presentation of the patient by which time the disease is advanced and the patient life expectancy is short (a matter of a small number of months).

We do not anticipate earning revenues until such time as we able to fully market our intended products on either the RUO or IVD clinical diagnostics market. For these reasons, our auditors stated in their report on our audited financial statements that they have substantial doubt that we will be able to continue as a going concern without further financing. The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish its plan of operations described herein and eventually attain profitable operations.

SUMMARY OF THIS OFFERING

Securities being offered

1,058,845 shares of common stock, which includes: (i) 688,101 shares of common stock; (ii) 344,059 shares of common stock issuable upon the exercise of the outstanding Investor Warrants; and 26,685 shares of common stock issuable upon the exercise of the outstanding Placement Agent Warrants. Our common stock is described in further detail in the section of this prospectus titled DESCRIPTION OF SECURITIES.

Securities being offered by the Company

None.

Number of common shares outstanding Before the Offering (1)

9,879,187 shares of common stock.

Number of common shares outstanding After the Offering (2)

10,249,931 shares of common stock.

Use of Proceeds

We will not receive any of the proceeds from the sale of shares of common stock by the Selling Shareholders. Upon exercise of the Investor Warrants and the Placement Warrants, we will receive \$2.60 per share and \$1.75 per share, respectively, or such lower price as may result from the anti-dilution protection features of such Warrants. Any proceeds from the exercise of such Warrants will be used for general working capital and other corporate purposes.

Terms of Warrants

Each Investor Warrant entitles the holder thereof to purchase one-half common share at an exercise price of \$2.60 per full share, for a four year period ending May 10, 2016. Each Placement Warrant entitles the holder thereof to purchase one common share at an exercise price of \$1.75 per full share, for a three year period ending May 10, 2015. The price per Warrant Share shall be subject to adjustment for stock splits, combinations and similar recapitalization events and anti-dilution protection features.

Risk Factors

An investment in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth under the Risk Factors section hereunder and the other information contained in this prospectus before making an investment decision regarding our common stock. Our common stock should not be purchased by investors who cannot afford the loss of their entire investment.

OTCBB Trading Symbol

(1)

Based on the number of shares issued and outstanding as of August 2, 2012, not including 1,840,744 shares issuable upon exercise of options and warrants to purchase our common stock, including the Warrant Shares being offered for sale under this prospectus.

(2)

Assumes full exercise of the Warrants held by the Selling Shareholders (and excluding all other shares issuable upon exercise of outstanding options and warrants).

6

RISK FACTORS

Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this prospectus, before making an investment decision regarding our common stock. If any of the events or circumstances described in these risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock.

RISKS ASSOCIATED WITH OUR COMPANY

We have not generated any significant revenue since our inception and we may never achieve profitability.

We are a development stage company and since our inception on September 24, 1998, we have not generated any significant revenue. As we continue the discovery and development of our future diagnostic products, our expenses are expected to increase significantly. Accordingly, we will need to generate significant revenue to achieve profitability. Even as we begin to market and sell our intended products, we expect our losses to continue as a result of ongoing research and development expenses, as well as increased manufacturing, sales and marketing expenses. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders—equity. Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and then maintain profitability, our business, financial condition and results of operations will be negatively affected and the market value of our common stock will decline.

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

We believe that our current cash, cash equivalents and marketable securities will be sufficient to meet our anticipated cash requirements to the fourth quarter of 2012. If we incur delays in commencing commercialization of our intended products or in achieving significant product revenue, or if we encounter other unforeseen adverse business developments, we may exhaust our capital resources prior to this time.

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

| It is difficult to forec | ast our future | performance. | , which may | cause our | financial | results to | fluctuate un | predictabl | v |
|--------------------------|----------------|--------------|-------------|-----------|-----------|------------|--------------|------------|---|
| | | | | | | | | | |

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

The demand for our intended products;

Our ability to obtain any necessary financing;

Our ability to market and sell our future products;

Market acceptance of our future products and technology;

Performance of any future strategic business partners;

Our ability to obtain regulatory clearances or approvals;

16

| Changes in technology that may render our future products uncompetitive or obsolete; |
|--|
| |
| Competition with other cancer diagnostics companies; and |
| |
| Adverse changes in the healthcare industry. |
| |
| |
| 7 |
| |

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

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

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

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

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

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

We will rely primarily on a direct sales force to sell our future research and clinical products within the United States and abroad. In order to meet our anticipated sales objectives, we expect to grow our direct sales and marketing organization significantly over the next several years and intend to opportunistically build a direct sales and marketing force in certain international markets. There are significant risks involved in building and managing our sales and marketing organization, including risks related to our ability to:

to our Company or our stockholders.

Our Amended and Restated Certificate of Incorporation exculpates our officers and directors from certain liability

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

Our internal controls may be inadequate, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Exchange Act Rule 13a-15(f), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and/or directors of the Company; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Our internal controls may be inadequate or ineffective, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public. Investors relying upon this misinformation may make an uninformed investment decision.

We have a going concern opinion from our auditors, indicating the possibility that we may not be able to continue to operate.

Our independent registered public accountants have expressed substantial doubt about our ability to continue as a going concern. This opinion could materially limit our ability to raise additional funds by issuing new debt or equity

securities or otherwise. If we fail to raise sufficient capital when needed, we will not be able to complete our proposed business. As a result we may have to liquidate our business and investors may lose their investments. 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. Investors should consider our independent registered public accountant s comments when deciding whether to invest in the Company.

RISKS ASSOCIATED WITH OUR BUSINESS

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

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

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

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

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

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

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

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

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

costs. There can be no assurance that we will be successful in the face of increasing competition from new technologies or products introduced by existing companies in the industry or by new companies entering the market.

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

The market for cancer diagnostics is intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. Our future competitors include large multinational corporations and their operating units, including General Electric, Philips, Siemens, and several others. These companies have substantially greater financial, marketing and other resources than we do. Each of these companies is either publicly traded or a division of a publicly traded company, and enjoys several competitive advantages, including:

Significantly greater name recognition;

Established relationships with healthcare professionals, companies and consumers;

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

Established supply and distribution networks; and

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

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

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

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

Our failure to obtain necessary regulatory clearances or approvals would significantly impair our ability to distribute and market our future products on the clinical in-vitro diagnostics market.

We are subject to regulation and supervision by the FDA in the United States, the Conformité Européenne in Europe and other regulatory bodies in other countries where we intend to sell our future products. Before we are able to place our intended products in the clinical in-vitro diagnostics markets in the U.S. and Europe, we will be required to obtain approval of our future products from the FDA and receive a CE Mark, respectively. Delays in obtaining approvals and clearances could have material adverse effects on the Company and its ability to fully carry out its plan of operations.

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

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

could have a material negative effect on our business.

We will rely on third parties to manufacture and supply our intended products. The manufacture of our intended diagnostic products will require specialized equipment and utilize complicated production processes that would be difficult, time-consuming and costly to duplicate. If the operations of third party manufacturers are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill our future sales orders. Any prolonged disruption in the operations of third party manufacturers could have a significant negative impact on our ability to sell our future products, could harm our reputation and could cause us to seek other third party manufacturing contracts, thereby increasing our anticipated development and commercialization costs. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards required by the FDA and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop products or receive approval of any products in a timely manner. As of the date of this Report, we have not entered into any agreements with third party manufacturers for the manufacture of any of our intended products.

The manufacturing operations of our future third party manufacturers will likely be dependent upon third party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business. The operations of our future third party manufacturers will likely be dependent upon third party suppliers. A supply interruption or an increase in demand beyond a supplier s capabilities could harm the ability of our future manufacturers to manufacture our intended products until new sources of supply are identified and qualified. Reliance on these suppliers could subject the Company to a number of risks that could harm our business, including: Interruption of supply resulting from modifications to or discontinuation of a supplier s operations; Delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier s variation in a component; A lack of long-term supply arrangements for key components with our suppliers; Inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms; Difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner; Production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;

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

| • | | |
|---|--|--|

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

•

Fluctuation in delivery by the suppliers due to changes in demand from us or their other customers.

Any interruption in the supply of components of our future products or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our future customers, which would have an adverse effect on our business.

We will depend on third party distributors in the future to market and sell our future products in markets outside of North America, which will subject us to a number of risks.

We will depend exclusively on third party distributors to sell, market, and service our future products in markets outside of North America. We are subject to a number of risks associated with reliance upon third party distributors including:

.

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

.

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

.

Third party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us; and

.

Disagreements with our future distributors could result in costly and time-consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar.

If we fail to establish and maintain satisfactory relationships with our future third party distributors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which could harm our results of operations and financial condition.

If the patents that we rely on to protect our intellectual property prove inadequate, our ability to successfully commercialize our future products will be harmed and we may never be able to operate our business profitably.

Our success depends, in large part, on our ability to protect proprietary methods, discoveries and technologies that we develop under the patents and intellectual property laws of the United States, European Union and other countries, so that we can seek to prevent others from unlawfully using our inventions and proprietary information. We have exclusive license rights to a number of patent applications related to our diagnostic tests under development, but do not have any issued patents in the United States and only one issued patent in Europe. Additionally, the Company has patent applications authored by both Singapore Volition and Belgian Volition, which are also currently pending. We cannot assure you that any of the pending patent applications will result in patents being issued. In addition, due to technological changes that may affect our future products or judicial interpretation of the scope of our patents, our intended products might not, now or in the future, be adequately covered by our patents.

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

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

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

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

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

In addition to patented technology, we rely upon trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult or impossible to obtain or enforce. We may not be able to protect our trade secrets adequately. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to

competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential information into the public domain or to third parties could allow our future competitors to learn our trade secrets and use the information in competition against us, which could adversely affect our competitive advantage.

RISKS ASSOCIATED WITH OUR COMMON STOCK

The Company s stock price may be volatile.

| The market price of the Company s common stock is likely to be highly volatile and could fluctuate widely in price in response to various potential factors, many of which will be beyond the Company s control, including the following: |
|---|
| |
| |
| competition; |
| |
| additions or departures of key personnel; |
| |
| the Company s ability to execute its business plan; |
| |
| operating results that fall below expectations; |
| |
| loss of any strategic relationship; |
| |
| industry developments; |

| economic and other external factors; and |
|--|
| |
| period-to-period fluctuations in the Company s financial results. |
| |
| In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of the Company s common stock. |
| |
| |
| 13 |
| |

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

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

We may in the future issue additional shares of our common stock which would reduce investors ownership interests in the Company and which may dilute our share value.

Our Certificate of Incorporation and amendments thereto authorize the issuance of 200,000,000 shares of common stock, par value \$0.001 per share. The future issuance of all or part of our remaining authorized common stock may result in substantial dilution in the percentage of our common stock held by our then existing stockholders. We may value any common stock issued in the future on an arbitrary basis. The issuance of common stock for future services or acquisitions or other corporate actions may have the effect of diluting the value of the shares held by our investors, and might have an adverse effect on any trading market for our common stock.

The Company s common stock is currently deemed to be penny stock, which makes it more difficult for investors to sell their shares.

The Company s common stock is currently subject to the penny stock rules adopted under section 15(g) of the Exchange Act. The penny stock rules apply to companies whose common stock is not listed on the NASDAQ Stock Market or other national securities exchange and trades at less than \$5.00 per share or that have tangible net worth of less than \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than established customers complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If the Company remains subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for the Company s securities. If the Company s securities are subject to the penny stock rules, investors will find it more difficult to dispose of the Company s securities.

FINRA sales practice requirements may limit a stockholder s ability to buy and sell our stock.

The Financial Industry Regulatory Authority (FINRA) has adopted rules that relate to the application of the SEC s penny stock rules in trading our securities and require that a broker/dealer have reasonable grounds for believing that the investment is suitable for that customer, prior to recommending the investment. Prior to recommending speculative, low priced securities to their non-institutional customers, broker/dealers must make reasonable efforts to obtain information about the customer s financial status, tax status, investment objectives and other information.

Under interpretations of these rules, FINRA believes that there is a high probability that speculative, low priced securities will not be suitable for at least some customers. FINRA s requirements make it more difficult for broker/dealers to recommend that their customers buy our common stock, which may have the effect of reducing the level of trading activity and liquidity of our common stock. Further, many brokers charge higher transactional fees for penny stock transactions. As a result, fewer broker/dealers may be willing to make a market in our common stock, reducing a shareholder s ability to resell shares of our common stock.

DETERMINATION OF OFFERING PRICE

The prices at which the shares of common stock covered by this prospectus may actually be sold will be determined by the prevailing public market price for shares of common stock, by negotiations between the Selling Shareholders and buyers of our common stock in private transactions or as otherwise described in Plan of Distribution.

14

USE OF PROCEEDS

We will not receive any proceeds from the sale of shares of common stock by the Selling Shareholders covered by this prospectus. All proceeds from the sale of shares of common stock offered under this prospectus will be for the account of the Selling Shareholders as described below in the sections entitled Selling Security Holders and Plan of Distribution. We have agreed to bear the expenses relating to the registration of the common stock for the Selling Shareholders.

To the extent the Selling Shareholders exercise all of the Warrants covering the 370,744 shares of common stock issuable upon exercise of all of the Warrants held by such Selling Shareholders, we would receive \$2.60 per share from the exercise of the Investor Warrants and \$1.75 per share from the exercise of the Placement Warrants, or such lower price as may result from the anti-dilution protection features of such Warrants. The Warrants may expire without having been exercised. Even if some or all of these Warrants are exercised, we cannot predict when they will be exercised and when we would receive the proceeds. We intend to use any proceeds we receive upon exercise of the warrants for general working capital and other corporate purposes.

SELLING SECURITY HOLDERS

This prospectus covers the resale by our Selling Shareholders of 1,058,845 shares of common stock, including: (i) up to 688,101 shares (the Purchased Shares) of common stock previously issued at a price of \$1.75 per share to the Selling Shareholders in connection with a private placement that closed on May 11, 2012; (ii) up to 344,059 shares (the Investor Warrant Shares) of common stock issuable upon the exercise of outstanding investor s warrants (the Investor Warrants) at an exercise price of \$2.60 that were previously issued to the Selling Shareholders in connection with a private placement that closed on May 11, 2012; and (iii) up to 26,685 shares (the Placement Warrant Shares) of common stock issuable upon the exercise of outstanding placement agent s warrants (the Placement Warrants) at an exercise price of \$1.75 that were previously issued to the placement agent pursuant to an engagement agreement dated May 10, 2012. (The Investor Warrants and Placement Warrants are referred to collectively as the Warrants and the Investor Warrant Shares and Placement Warrant Shares issuable under the Warrants are referred to collectively as the Warrant Shares).

The following table sets forth, as to each of the Selling Shareholders, the number of shares of our common stock and Warrants held of record as of August 2, 2012, assuming exercise of all of the Warrants held by such Selling Shareholder on that date; the number of shares of our common stock being offered by such Selling Shareholder pursuant to this prospectus; and the number of shares of our common stock beneficially owned upon completion of the offering and the percentage of beneficial ownership upon completion of the offering based upon 10,249,931 shares of

our common stock outstanding as of August 2, 2012, assuming full exercise of all Warrants held by the Selling Shareholders and outstanding on that date. The shares being offered hereby are being registered to permit public secondary trading, and the Selling Shareholders may offer all or part of the shares for resale from time to time. However, the Selling Shareholders are under no obligation to sell all or any portion of such shares nor are the Selling Shareholders obligated to sell any shares immediately upon effectiveness of this prospectus. All information with respect to share ownership has been furnished by the Selling Shareholders.

| | | Shares Beneficially Owned Prior | | Shares Beneficially Owned After | Percentage Beneficially Owned after |
|-------------------------------|---|---------------------------------------|-----------------------|---------------------------------------|---|
| Name of Selling | Position, Office or Other | to the Offering | | the Offering | the Offering |
| Shareholder | Material Relationship | | Offered 39,000 | | |
| Alan Colman | Director of the Company; Director of Singapore | 165,643 | 39,000 | 126,643 | 1.24% |
| | Volition; and Chairman of the | | | | |
| | Scientific Advisory Board of | | | | |
| | Singapore Volition | | | | |
| Andreas Ladurner | Scientific Advisory Board | 11,715 | 7,715 | 4,000 | 0.04% |
| | Member of Singapore | | | | |
| | Volition | | | | |
| Andrews Securities, LLC | Placement Agent | 13,685 | 13,685 | 0 | 0.00% |
| (4) | | | | | |
| Annette Helen Williams | - | 25,000 | 15,000 | 10,000 | 0.10% |
| Appletree Investment | - | 725,780 | 1,668 | 724,112 | 7.06% |
| Management, Inc. (5) | | 256.500 | 256 500 | 0 | 0.000 |
| BOCO Investments, LLC (6) | - | 256,500 | 256,500 | 0 | 0.00% |
| Borlaug Limited (7) | Jake Micallef (Controlling | 15,000 | 15,000 | 0 | 0.00% |
| Dorlang Littled (7) | Director of Borlaug Limited) | 13,000 | 13,000 | O | 0.00 % |
| | is a Director and Science | | | | |
| | Executive of Belgian Volition | | | | |
| Cameron John Reynolds | President, CEO and Director | 223,516 | 3,515 | 220,001 | 2.15% |
| · | of the Company; CEO and | | | | |
| | Director of Singapore | | | | |
| | Volition; Director of Belgian | | | | |
| | Volition; and CEO and | | | | |
| | Director of Hypergenomics | | | | |
| | Pte Limited | 22 207 | 4.205 | 20.000 | 0.07% |
| | Communications Manager of | 32,287 | 4,287 | 28,000 | 0.27% |
| McCubbin | Singapore Volition | 0 572 | 0 572 | 0 | 0.0007 |
| Cleopatra Trading Limited (8) | - | 8,573 | 8,573 | 0 | 0.00% |
| David Archibald Innes | _ | 17,144 | 17,144 | 0 | 0.00% |
| Davina Evelyn | - - | 8,573 | 8,573 | 0 | 0.00% |
| Markiewicz | | 0,273 | 0,575 | 0 | 0.0070 |
| Elizabeth Ann Kunze | - | 17,144 | 17,144 | 0 | 0.00% |
| Farshid Kolahi Zonoozi | - | 12,858 | 12,858 | 0 | 0.00% |
| Guy Archibald Innes | Director of the Company; and | 1,048,747 | 224,460 | 824,287 | 8.04% |
| | Director of Singapore | | | | |
| | Volition | | | | |
| Habib Skaff | Scientific Advisory Board | 13,429 | 9,429 | 4,000 | 0.04% |
| | Member of Singapore | | | | |

| | Volition | | | | |
|---|--|-----------|---------|-----------|--------|
| James Richard McCubbin | | 4,287 | 4,287 | 0 | 0.00% |
| James Young | - | 8,573 | 8,573 | 0 | 0.00% |
| Jeff Andrews | Member of Andrews | 10,000 | 10,000 | 0 | 0.00% |
| Talan Taran XXII. i | Securities, LLC | 26.001 | 12.050 | 12 142 | 0.120/ |
| John Ivan White | - | 26,001 | 12,858 | 13,143 | 0.13% |
| John W.S. Hine | Manchan of Andrews | 42,858 | 42,858 | 0 | 0.00% |
| Luke Nelson | Member of Andrews | 2,000 | 2,000 | 0 | 0.00% |
| Lynn Koczera | Securities, LLC Member of Andrews Securities, LLC | 1,000 | 1,000 | 0 | 0.00% |
| Mark Edward Eccleston | Science Executive of Hypergenomics Pte Limited | 81,000 | 15,000 | 66,000 | 0.64% |
| Martin Charles Faulkes | Chairman and Director of the Company; Chairman and Director of Singapore Volition; and Chairman and | 1,239,101 | 174,101 | 1,065,000 | 10.39% |
| Millennium Trust Company, LLC, Custodian | Director of Belgian Volition - | 8,250 | 8,250 | 0 | 0.00% |
| FBO: Julie Andrews IRA (9) | | | | | |
| MJF Pension Trustees Limited and Dr Farshid Kolahi Zonoozi (10) | - | 12,858 | 12,858 | 0 | 0.00% |
| OncoLytika Ltd (11) | Mark Eccleston (Controlling Director of OncoLytika) is a Science Executive of Hypergenomics Pte Limited | 15,000 | 15,000 | 0 | 0.00% |
| PB Commodities Pte Ltd (12) | - | 119,144 | 17,144 | 102,000 | 1.00% |
| Peter Anton Ninian Grimley | - | 15,000 | 9,000 | 6,000 | 0.06% |
| Philippa Innes | - | 17,144 | 17,144 | 0 | 0.00% |
| Primus International Oy | - | 8,573 | 8,573 | 0 | 0.00% |
| Ltd (13) | | • | , | | |
| Robert Weinzierl | Scientific Advisory Board Member of Singapore Volition | 10,000 | 6,000 | 4,000 | 0.04% |
| Roisin Young | - | 8,573 | 8,573 | 0 | 0.00% |
| Satu Vainikka | Director of the Company | 10,358 | 5,358 | 5,000 | 0.05% |
| Schroder & Co Bank AG (14) | - | 17,144 | 17,144 | 0 | 0.00% |
| US Firangi Trust (15) | - | 8,573 | 8,573 | 0 | 0.00% |

1.

Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Act, and includes any shares as to which the Selling Shareholder has sole or shared voting power or investment power, and also any shares which the Selling Shareholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the stockholder that it is a direct or indirect beneficial owner of those shares. This table includes the Warrant Shares as part of the Selling Shareholder s beneficial ownership prior to the offering. Except as indicated in the footnotes to the table above, each Selling Shareholder has voting and investment power with respect to the shares set forth opposite such Selling Shareholder s name.

2.

This table assumes that each Selling Shareholder will sell all shares offered for sale by it under this registration statement.

3.

Percentages are based upon 10,249,931 shares of our common stock outstanding as of August 2, 2012, assuming full exercise of the Warrants held by the Selling Shareholders outstanding on that date (and excluding all other shares issuable upon exercise of outstanding options and warrants).

4.

Jeff L. Andrews has voting and dispositive control over the common shares beneficially owned by Andrews Securities, LLC.

5.

Robert James Cooles holds investment and voting control over the common shares beneficially owned by Appletree Investment Management, Inc.

6.

Joseph Zimlich has voting and dispositive control over the common shares beneficially owned by BOCO Investments, LLC.

7.

Jake Micallef (Controlling Director) has voting and dispositive control over the common shares beneficially owned by Borlaug Limited.

8.

Farshid Kolahi Zonoozi has voting and dispositive control over the common shares beneficially owned by Cleopatra Trading Limited.

9.

Julie Andrews has voting and dispositive control over the common shares beneficially owned by Millennium Trust Company, LLC, Custodian FBO: Julie Andrews IRA

10.

Karen Lesley King has voting and dispositive control over the common shares beneficially owned by MJF Pension Trustees Limited and Dr Farshid Kolahi Zonoozi.

11.

Mark Eccleston (Controlling Director) has voting and dispositive control over the common shares beneficially owned by OncoLytika Ltd.

12.

Laith Reynolds has sole voting and dispositive control over the common shares beneficially owned by PB Commodities Pte Ltd.

13.

Arja Kuittinen has voting and dispositive control over the common shares beneficially owned by Primus International Oy Ltd.

14.

Thomas Guy (Associate Director) and Justin Kamps (Manager) have voting and dispositive control over the common shares beneficially owned by Schroder & Co Bank AG.

15.

Rahul Harkawat has voting and dispositive control over the common shares beneficially owned by US Firangi Trust.

PLAN OF DISTRIBUTION; TERMS OF THE OFFERING

The Selling Shareholders and any of their pledgees, donees, transferees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or quoted or in private transactions. These sales may be at fixed or negotiated prices. The Selling Shareholders may use any one or more of the following methods when selling shares:

| ordinary brokerage transactions and transactions in which the broker-dealer solicits investors; |
|---|
| block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction; |
| purchases by a broker-dealer as principal and resale by the broker-dealer for its account; |
| an exchange distribution in accordance with the rules of the applicable exchange; |
| privately negotiated transactions; |
| to cover short sales made after the date that this Registration Statement is declared effective by the Commission; |
| broker-dealers may agree with the Selling Shareholders to sell a specified number of such shares at a stipulated price per share; |
| a combination of any such methods of sale; and |
| any other method permitted pursuant to applicable law. |
| The Selling Shareholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. |
| |
| 17 |

Broker-dealers engaged by the Selling Shareholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Shareholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The Selling Shareholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The Selling Shareholders may from time to time pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus.

Upon the Company being notified in writing by a Selling Shareholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such Selling Shareholders and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon the Company being notified in writing by a Selling Shareholder that a donee or pledgee intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

The Selling Shareholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

DILUTION

The Selling Shareholders are offering for resale up to 688,101 shares of common stock and 370,744 Warrant Shares of common stock issuable upon the exercise of the outstanding Warrants. The resale of the current outstanding shares of common stock under this prospectus will not dilute the ownership interests of existing shareholders. To the extent the Warrants are exercised, existing shareholders will experience dilution to their ownership interests in the Company.

DESCRIPTION OF PROPERTY

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

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

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

18

DESCRIPTION OF SECURITIES

Common Stock

Pursuant to the Company's Certificate of Incorporation and amendment(s) thereto, the aggregate number of shares which the Company shall have authority to issue is two hundred million (200,000,000) shares of common stock, par value \$0.001 per share.

Preferred Stock

There are no authorized shares of preferred stock.

Voting Rights

Except as otherwise required by law or as may be provided by the resolutions of the Board of Directors authorizing the issuance of common stock, as hereinabove provided, all rights to vote and all voting power shall be vested in the holders of common stock. Each share of common stock shall entitle the holder thereof to one vote.

No Cumulative Voting

Except as may be provided by the resolutions of the Board of Directors authorizing the issuance of common stock, cumulative voting by any shareholder is hereby expressly denied.

Conversion, Preemption, Preferential Rights, Redemption, Sinking Fund Provisions

No shareholder of the Company shall have, by reason of its holding shares of any class or series of stock of the Company, any conversion, preemptive or preferential rights to purchase or subscribe for any other shares of any class or series of the Company now or hereafter authorized, and any other equity securities, or any notes, debentures, warrants, bonds, or other securities convertible into or carrying options or warrants to purchase shares of any class, now or hereafter authorized whether or not the issuance of any such shares, or such notes, debentures, or bonds or other securities, would adversely affect the dividend or voting rights of such shareholder. There are no redemption or sinking fund provisions applicable to the common stock.

Dividends

The holders of common stock shall be entitled to receive when, as and if declared by the Board of Directors, out of funds legally available therefore, dividends payable in cash, stock or otherwise.

Rights upon Liquidation, Dissolution or Winding-Up of the Company

Upon any liquidation, dissolution or winding-up of the corporation, whether voluntary or involuntary, the remaining net assets of the Company shall be distributed pro rata to the holders of the common stock.

We refer you to our Certificate of Incorporation, any amendments thereto, Bylaws, and the applicable provisions of the Delaware General Corporations Law for a more complete description of the rights and liabilities of holders of our securities.

INFORMATION WITH RESPECT TO REGISTRANT

THE FOLLOWING DISCUSSION AND ANALYSIS SHOULD BE READ TOGETHER WITH THE CONSOLIDATED FINANCIAL STATEMENTS OF VOLITIONRX LIMITED AND THE NOTES TO CONSOLIDATED FINANCIAL STATEMENTS INCLUDED ELSEWHERE IN THIS REGISTRATION STATEMENT ON FORM S-1. THIS DISCUSSION SUMMARIZES THE SIGNIFICANT FACTORS AFFECTING OUR OPERATING RESULTS, FINANCIAL CONDITIONS AND LIQUIDITY AND CASH-FLOW SINCE INCEPTION.

DESCRIPTION OF OUR BUSINESS

Description of Our Business

The Company was incorporated on September 24, 1998 in the State of Delaware under the name Standard Capital Corporation . On September 22, 2011, the Company filed a Certificate for Renewal and Revival of Charter with Secretary of State of Delaware. Pursuant to Section 312(1) of Delaware General Corporation Law, the Company was revived under the new name of VolitionRX Limited . The name change to VolitionRX Limited was approved by FINRA on October 7, 2011 and became effective on October 11, 2011.

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

The Company is a development stage life sciences company focused on meeting the need for accurate, fast, inexpensive and scalable tests for detecting and diagnosing cancer and other diseases. We are in the development stage of our operations and are in the process of discovering and developing blood-based diagnostic tests intended for future commercialization through various channels within the United States and eventually throughout the world. We are currently developing six blood test product prototypes. Each product that we are developing can be commercialized for two distinct markets, the clinical in-vitro diagnostics (IVD) market and the research use only (RUO) market. Commercializing products on the RUO market means that we intend to sell our future products to medical schools, universities and commercial research and development departments for research use only. Products placed on the RUO market may be used for any research purpose, even if the products are being studied or tested for uses other than those intended. RUO products, however, are not to be used for patient diagnosis. Commercializing products on the IVD market means that we intend to sell our future products to be used in hospitals, clinics, etc. for patient diagnosis. None of the products that we are currently developing are available on either market.

Currently, there are very few blood tests available to detect cancer. The current blood tests available are primarily the prostate specific antigen (PSA) test for prostate cancer and the septin-9 test for colon cancer. The PSA test has very poor diagnostic accuracy (detects approximately 70% of prostate cancers and misdiagnoses about 30% of healthy men as positive for cancer) but is widely used because it is the best product currently available. The septin-9 colon cancer test has better diagnostic accuracy (detects approximately 70% of colon cancers and misdiagnoses about 10% of healthy people as positive for cancer) but is extremely expensive and technically complex. There are currently no blood tests for detecting lung cancer. Pancreatic cancer is currently not detectable by any means prior to symptomatic presentation of the patient by which time the disease is advanced and the patient life expectancy is short (a matter of a small number of months).

We do not anticipate earning significant revenues until such time as we able to fully market our intended products on either the RUO or IVD clinical diagnostics market. For these reasons, our auditors stated in their report on our audited financial statements that they have substantial doubt that we will be able to continue as a going concern without further financing. The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish its plan of operations described herein and eventually attain profitable operations.

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

The Market

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:

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

.

Immunoassays, mostly of blood samples (30% of IVD sales or approximately \$1.5 billion). These are mostly used to monitor for disease progress and relapse. This market segment includes our future NucleosomicsTM products which will be blood immunoassay tests for modified histones for the diagnosis of cancer.

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

Our Intended Products

Each product that we are in the process of developing can be commercialized for two distinct markets, the clinical IVD market and the RUO market. To commercialize our future products on the clinical IVD market requires government approval (CE Marking in Europe and/or FDA approval in the U.S.). Commercializing our future products on the IVD market means that we intend to sell our future products to be used in hospitals, clinics, etc. for patient diagnosis. Commercializing our future products on the RUO market means that we intend to sell our future products to medical schools, universities and commercial research and development departments for RUO and not to be used for patient diagnosis. The RUO market does not require government approval, however, before any of our intended products can be sold on the RUO market, they will need to successfully complete beta-testing. Beta-testing involves providing the products to a few laboratories to identify and correct any problems in the products. None of the products that we are currently developing are available on either the IVD or RUO market. The products that the Company is currently developing are described in detail below:

 $^{^1}$ 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]

²Mariotto AB et al., Projections of the cost of cancer care in the United States: 2010-2020. Jan 19, 2011, JNCI, Vol 103, No.2

³The 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]

⁴Diagnostics: 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]

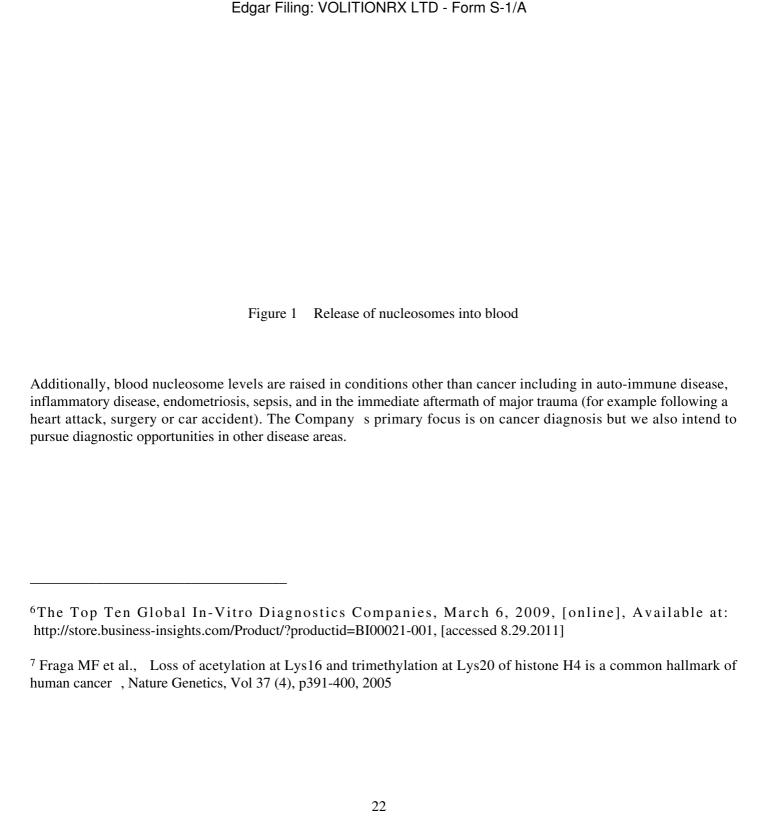
⁵Cancer IVD market expands to meet customer demand, May 1, 2008, [online], Available at: http://www.ivdtechnology.com/article/cancer-ivd-market-expands-meet-customer-demand, [accessed 8.29.2011]

NuQTM Suite of Epigenetic Cancer Blood Tests

We are currently developing six epigenetic cancer blood test product prototypes based on our NuQTM technology which is designed to detect the level of nucleosomes in blood. We are in the development stage of our operations and to date, we have no products available for sale on either the IVD or RUO market. Epigenetics is the science of how genes are switched on or off in the body s cells. A major factor controlling the switching on and off is the struct of DNA. The DNA in every human cell is not a random string but wound around protein complexes in a beads on a string structure. Each individual bead with associated DNA coiled around it is called a nucleosome. These nucleosomes then form additional structures with increasingly dense packing, culminating in chromosomes containing hundreds of thousands of nucleosomes.

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 share⁶. The cancer IVD market also contains many smaller development companies like ours.

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 1 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 cells⁷.



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

.

 $\underline{\text{NuQ-X}^{\text{TM}}}$: We are currently developing one blood test in the NuQ-XTM family to detect the presence of cancer by detecting nucleosomes containing specific nucleotides.

.

<u>NuQ-VTM</u>: We are currently developing four blood tests in the NuQ-VTM family to detect cancer and nucleosomes containing specific histone variants. Through our research, we have found that the pattern of blood levels of the different types of histone variants in nucleosomes is different for different cancer types.

.

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

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

Early Clinical Studies

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

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

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

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

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

NuQTM Research Kits

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

The selling price will be in the region of \$700 - \$1,200 USD per kit. The NuQTM assay technology is proprietary to the Company so no direct competition exists. However, some competitors manufacture simple generic modified histone ELISA kits which are the closest competitors currently on the market to the Company s intended NuQ-MM products. The generic products offered by competitors do not measure modified histones in intact nucleosomes but require chemical extraction of histones from samples prior to use. Currently, such products sell in the U.S. market for between \$400 - \$475 USD per kit (and even higher in Europe). We intend to sell our NuQTM research kits at a higher market price because:

1.

All of the NuQTM products are protected by multiple patents giving the Company market exclusivity;

2.

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

3.

The NuQ-VTM and NuQ-XTM tests are designed to detect histone variants and other nucleosome structures for which there are no current competitors that the Company is aware of.

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

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

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



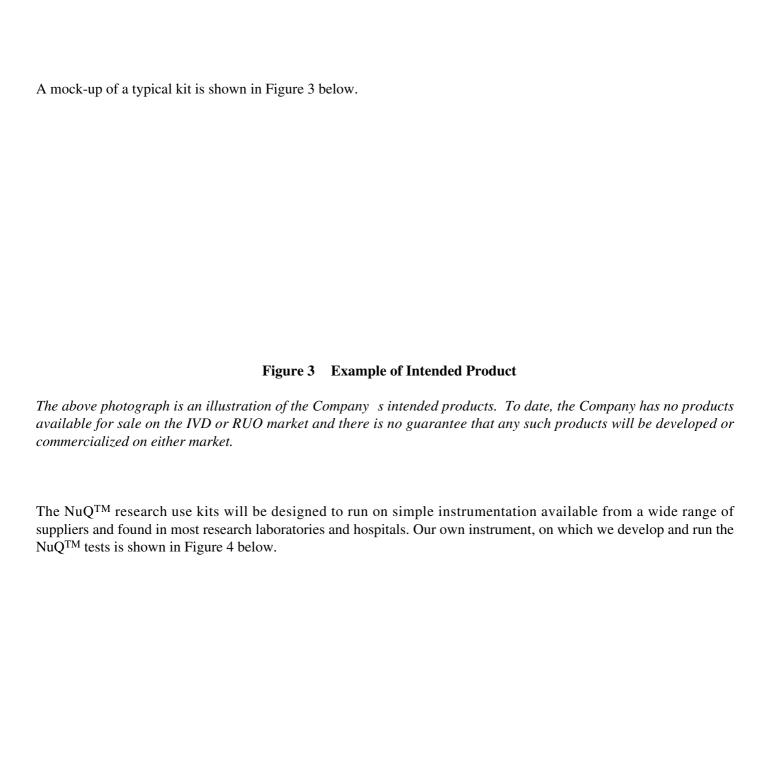


Figure 4 Example of lab instrument for running ELISA tests

NuQTM Clinical Diagnostic Products

There are three main segments of the clinical IVD market that the Company intends to adapt its future NuQ^{TM} products to in the future.

Centralized Laboratory Market

Centralized laboratories test thousands of blood samples taken from patients everyday mostly using fully automated enzyme-linked immunosorbent assay (ELISA) systems, commonly known as random access analyzers, usually supplied by one of the global diagnostics companies. Tests run on ELISA systems use components of the immune system and chemicals to detect immune responses in the body. ELISA systems analyze thousands of blood samples every day and can run dozens of different ELISA tests in any combination on any sample and for many samples simultaneously. The systems are highly automated and rapid (as little as 10 minutes for many tests), and can be run at low costs. Additionally, ELISA instruments are used in all major hospitals throughout the U.S. and Europe and therefore, are well understood by clinicians and laboratory staff. It is more cost-effective and technically simple for hospitals and clinics to run several blood samples simultaneously using ELISA tests compared to non-ELISA tests or alternative methods for screening cancer. All of the NuQTM tests that we are in the process of developing are designed for ELISA systems. A typical example of an ELISA system is shown below in Figure 5.



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

Another option that may be available to the Company is to sell manual and/or semi-automated 96 well ELISA plates for use by these laboratories. As of the date of this Report, the Company has not entered into any discussions or negotiations with diagnostic companies for the sale of ELISA plates.

.

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 NuQTM testing for the oncologist s office, general doctor s office or at home testing. The Company hopes to enter the point-of-care clinical market in Europe in 2014 and in the U.S. in 2015, as the Company will first need to adapt its test prototypes to these small instruments and demonstrate their success in the greater diagnostics market before these products will be adopted by others in the industry. At this stage of its development, the Company cannot accurately predict the costs to manufacture these devices or their selling price. As of the date of this Report, the Company has not entered into any discussions or negotiations regarding the manufacture or sale of these devices. See Figure 6 for an example of a point-of-care device.

| Edgar Filing: | VOLITIONRX LTD | - Form S-1/A |
|---------------|-----------------------|--------------|
|---------------|-----------------------|--------------|

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.

.

Disposable Home Use or Doctor s Office Tests: Disposable home use or doctor s office tests are single shot disposable devices which can be purchased over the counter at any chemist shop or pharmacy and test a drop of blood taken from a finger prick. The test is administered at a doctor s office using a point-of-care device or at home using a home testing kit, neither of which require laboratory involvement. Thus, the patient experiences considerably lower costs using these tests as compared to traditional laboratory tests. The format of the self-use home testing kit is very easy to use and reproduce and does not rely on laboratory processing. There are currently no useful diagnostics tests suitable for mass screening for cancer in general through a simple self-use home testing kit. Figure 7 below shows a basic home use test on the left which displays the results of the test in the two windows, similar to a pregnancy test. The test on the right is more sophisticated and plugs into a meter or the USB port of a computer for analysis and interpretation.

| | | | , |
|--|------|---|-------|
| The above photograph is available for sale on the | | = | _ |

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

The Company intends to contract with a specialist company to adapt the NuQTM test prototypes to the doctor s office or home use system and to contract with a manufacture for the production of these tests. As of the date of this Report, the Company has not entered into any discussions or negotiations with a specialist company or manufacturer. Initially, the Company intends to sell these tests for professional use only (doctor s office) and to sell the tests for non-professional home use at a later time. The Company does not yet have an estimated timeframe for entering into this market. Further, at this early stage of our development, the Company cannot accurately determine the manufacturing costs or selling price of these tests.

<u>HyperGenomicsTM</u>

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

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

For the IVD market, the Company expects to work on the clinical proof of concepts and validations for the HyperGenomicsTM test in 2012. The launch of the HyperGenomicsTM 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 NuQTM technology. The NuQ Endo test is designed to be a simple blood test taken at two stages of a woman s menstrual cycle, during menses and partway through the month. If the two measurements show quantitative differences in total nucleosome level, endometriosis is indicated. Hypothesis-testing and clinical proof of concept work (to demonstrate that the test is feasible or has the potential to be used and effective) on the endometriosis test is currently being carried out in the Company s laboratory. The Company will continue with validation of the NuQ Endo endometriosis test in 2012. The Company will review the best ways of commercializing a product on the IVD market in 2012 if the validations prove its diagnostic potential. If the Company is successful in developing a reliable test, we hope to partner with large pharmaceutical companies to bring these tests to the IVD clinical market. The NuQ Endo test is too early in its development for the Company to accurately determinate the manufacturing costs and sale price of the test. The NuQ Endo test is not currently being developed for the RUO market.

Intellectual Property

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

NucleosomicsTM Intellectual Property

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

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

Application Date: 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 |
| Application Date: July 2, 2009 |
| Status: Pending Worldwide |
| |
| Belgian Volition authored the following patent application covering its total NuQ TM assay technology: |
| NuQ Patent UK1115099.2 and U.S. 61530300: Method for Detecting Nucleosomes |
| Application Date: September 1, 2011 |
| Status: Pending Worldwide |
| |
| Belgian Volition authored the following patent application covering its NuQ-V TM 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

28

| . Singapore Volition authored the following patent application covering its $NuQ-X^{TM}$ technology: |
|--|
| NuQ-X Patent UK1115095.0 and U.S. 61530295: Method for detecting Nucleosomes containing Nucleotides |
| Application Date: September 1, 2011 |
| Status: Pending Worldwide |
| Singapore Volition authored the following patent application covering a NuQ-A TM blood test for detecting nucleosome adducts of cancer origin that circulate in the blood of cancer patients. The patent application covers both the use of these adducts as biomarkers and the methods for their detection. As of the date of this Report, the Company has no immediate plans for the development of a blood test under this patent. |
| NuQ-A Patent UK1121040.8 and U.S. 61568090: Method for detecting Nucleosome Adducts |
| Application Date: December 7, 2011 |
| Status: Pending Worldwide |
| HyperGenomics TM Intellectual Property |
| |

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. |
| Endometriosis Intellectual Property |
| |
| 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 |
| Future Intellectual Property Strategy |
| The Company intends to continue its development of the NuQ TM and HyperGenomics TM technologies and will continue to apply for patents for future product developments. The Company s strategy is to protect the <i>technologies</i> |

with patents in Europe and the U.S. Following product development, each product, based on the technologies, will be

further protected individually by new patent filings worldwide.

We believe that this will provide:

70

| Market exclusivity through a double layer of patent protection (primarily the protection of the underlying technology on which all the tests are based and, secondarily, specific patent protection for each future product). |
|--|
| A full 20-year protection for each new product developed (e.g. a NuQ TM product developed in 2010 would continue to be protected in all markets until 2030, beyond expiration of the parent technology patent in 2023). |
| 29 |

Trademarks

•

Europe Granted Trademarks

0

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

0

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

0

Nucleosomics

European Community Trade Mark Application No. 009979551

Registration Date: March 27, 2012

Classes 01, 05, 10. 42

Application Date: May 19, 2011

•

United States Trademark Application Pending

0

NuQ

Application Date: May 20, 2011

United States Trade Mark Application No. 85/326467

Classes 01, 05, 10 and 42

o

Hypergenomics

Application Date: May 20, 2011

United States Trade Mark Application No. 85/326495

Classes 01, 05, 10 and 42

0

Nucleosomics

Application Date: May 20, 2011

United States Trade Mark Application No. 85/326500

Classes 01, 05, 10 and 42

30

Government Approval

All of the Company's intended products are designed to be non-invasive, meaning they cannot harm the subject other than through misdiagnosis. The Company's strategy is to begin selling its future products for RUO purposes, which requires no regulatory approval, while simultaneously going through the process of obtaining regulatory approval for IVD products to be used clinically on cancer patients. Conformité Européenne (CE) Marking is a rough equivalent of the United States. Food and Drug Administration (FDA) approvals process, although it is a somewhat lighter regime. The Company will first focus on the regulatory process in Europe (CE Marking), due to the grant of the NuQTM patent in Europe and due to the lighter regulatory requirements to obtain CE Marking than to obtain FDA approval in the U.S. This will be followed closely by the regulatory process in the U.S. and in the rest of the world. In many territories, the European CE Mark is sufficient to place products on the clinical market and, where it is not, it often simplifies the regulation processes. To date, the Company has not begun the CE Marking or FDA approval process for any of its tests currently under development.

Europe CE Marking

Manufacturers in the European Union (EU) and abroad must meet CE Marking requirements, where applicable, in order to market their products in Europe. The CE Mark certifies that a product has met EU health, safety, and environmental requirements which ensure consumer safety.

To receive the CE Mark, the Company must meet certain requirements as set forth in the In-Vitro Diagnostic Medical Devices Directive, which applies to the Company s diagnostic products. The requirements to procure CE Marking for In-Vitro Diagnostic Medical products are: (i) analytical validation of the products; (ii) clinical validation of the products (which can be retrospective clinical studies using biobank patient samples, i.e. blood samples from historic patients); (iii) implementation of regulatory compliant manufacture; and (iv) certification from the International Organization for Standardization (this last requirement is not technically required but will aid the regulatory approval process in Europe and the U.S.).

The Company is currently engaged in requirements (i) and (ii) for the NuQ-XTM test and the NuQTM panel. Requirements (iii) and (iv) are general requirements that apply to all of the Company s intended products. In compliance with the In-Vitro Diagnostic Medical Devices Directive and the CE Marking process, the Company has ensured that all development and validation is carried out in a manner consistent with regulatory approval. Additionally, the Company has maintained proper records so that its future products can be approved as quickly and simply as possible. The Company has engaged a regulatory advisor to lead in requirement (iv) for all of its future products. All of these requirements must be completed prior to the submission of an application for CE Marking. The

Company will submit applications, which will contain a dossier of all relevant analytical, clinical and manufacturing data following retrospective clinical studies which will require a total of approximately six (6) months to complete. We estimate the cost of obtaining CE Marking will be approximately \$500,000 USD per test. The Company expects that CE Marking for the NuQ-XTM test and NuQTM panel products will be applied for by the end of 2012 or the first half of 2013. Sales of our clinical products can occur in Europe once CE Marking has been granted.

In Europe, IVD companies are able to self-certify that they meet the appropriate regulatory requirements and are subject to inspection for enforcement. European national agencies, such as Customs authorities and/or the Departments of Health, Industry and Labor, conduct market surveillance to ensure the provisions of the applicable Directive have been met for products marketed within the European Union. In pursuit of this goal, surveillance authorities will: i) visit commercial, industrial and storage premises on a regular basis; ii) visit work places and other premises where products are put into service and used; iii) organize random checks; and iv) take samples of products for examination and testing. If a product is found to be noncompliant, corrective action will depend on and be appropriate to the level of noncompliance. Others responsible for the noncompliance of the product will be held accountable as well. Penalties, which may include imprisonment, are determined by national law.

U.S. FDA Approval

The Company s diagnostic products are designated as medical devices by the FDA. Among other things, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the U.S. to ensure that medical devices distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the U.S. to international markets. We estimate the cost of obtaining FDA approval to be approximately \$825,000 USD per product. FDA approval is more expensive and will take at least twice as long as CE Marking in Europe.

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

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

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

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

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

| Product Devel | opment and | Plan of | Operations |
|---------------|------------|---------|-------------------|
| | | | |

NuQ-XTM Test:

•

Research Use Only Market

o

The Company s first intended product, the NuQ- \mathbb{X}^M test for the presence of circulating nucleosomes based on our proprietary NuQTM technology is developed and the first beta-testing is complete. However, this testing has led to some production and formulation improvements which the Company is now implementing and the Company will start beta-testing on this improved test in the third quarter of 2012. If beta-testing is successful, the test will be released into the RUO market as a research kit in the U.S. and Europe in the fourth quarter of 2012.

In-Vitro Diagnostics Market

0

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

0

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.

NuOTM Panel Tests:

Research Use Only Market

o

The NuQTM panel of tests are in the final stages of development for the RUO market. Beta-testing of the NuQTM panel tests is expected to begin in 2012 and shall take approximately one month to complete. The expected costs of beta-testing of the NuQTM panel tests total less than \$20,000 USD. If beta-testing is successful, the Company intends to bring its NuQTM panel products to the research market during 2012 or the first quarter of 2013 by selling the tests as research kits.

•

In-Vitro Diagnostics Market

0

CE Marking (Europe): The NuQTM panel of tests have undergone the initial research phase and are in final stages of development and initial validation data for colon, lung and pancreatic cancers. The NuQTM panel tests are expected to undergo large scale retrospective clinical validations in colon, lung, and pancreatic cancers during 2012 and take approximately nine (9) months to complete. Once the retrospective validations are completed, the tests will be submitted for CE Mark approval. We estimate the cost of obtaining CE Marking will be approximately \$500,000 USD.

0

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

In parallel with the large scale clinical validation studies for colon, lung, and pancreatic cancers, the Company will commence initial testing on further cancers in 2012 based on the Company s NuQM 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 fourth 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.

HypergenomicsTM Test:

•

Research Use Only Market