

VOLITIONRX LTD  
Form S-1  
November 28, 2014

As filed with the Securities and Exchange Commission on November \_\_, 2014

Registration No. 333-\_\_\_\_\_

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**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)

**1 Scotts Road  
#24-05 Shaw Centre  
Singapore 228208  
Telephone: +1 (646) 650-1351  
Facsimile: +32 8172 5651**

*(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)*

Copy of correspondence to:  
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**As soon as practicable after this Registration Statement becomes effective.**

*(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: .

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please 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.

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

**CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities to be Registered</b>	<b>Proposed Maximum Aggregate Offering Price<sup>(1)</sup></b>	<b>Amount of Registration Fee<sup>(2)</sup></b>
Common stock, \$0.001 par value	\$ 11,500,000.00	\$ 1,336.30

(1)

Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended, and includes shares of our common stock that the underwriters have an option to purchase within 30 days of the date of this prospectus to cover overallotments.

(2)

Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

**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 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.*

Subject to Completion

Preliminary Prospectus dated November , 2014

**PRELIMINARY PROSPECTUS**

**Shares**

**Common Stock**

We are offering \_\_\_\_\_ shares of our common stock pursuant to this prospectus.

Our common stock is currently quoted on the OTCQB under the symbol VNRX . On November \_\_\_\_, 2014, the closing price of our common stock was \$\_\_\_\_\_ per share.

We intend to apply to have our shares of common stock listed on the NYSE MKT under the symbol VNRX . No assurance can be given that such application will be approved. In the event the application is not approved, we will not complete this offering.

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 CAREFULLY READ THIS ENTIRE PROSPECTUS, INCLUDING THE SECTION ENTITLED RISK FACTORS BEGINNING ON PAGE 10 HEREOF BEFORE BUYING ANY SHARES OF VOLITIONRX LIMITED S COMMON STOCK. 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.

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.

Public offering price	\$	\$
Underwriting discount <sup>(1)</sup>	\$	\$
Proceeds to us, before expenses	\$	\$

(1)

The underwriters will receive compensation in addition to the underwriting discount described above. See the section entitled Underwriting beginning on page 74 of this prospectus for a description of compensation payable to the underwriters.

We have granted the underwriters an option to purchase up to an additional \_\_\_\_\_ shares of our common stock from us at the public offering price, less the underwriting discounts and commissions, within 30 days from the date of this prospectus, to cover over-allotments of the shares, if any. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable will be \$\_\_\_\_\_, and the total proceeds to us, before expenses, will be \$\_\_\_\_\_. The underwriters expect to deliver the shares against payment therefor on or about \_\_\_\_\_, 2014.

**National Securities Corporation Lake Street Capital Markets**

***Joint Book Running Managers***

The date of this prospectus is \_\_\_\_\_, 2014



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## **ABOUT THIS PROSPECTUS**

In considering whether to purchase shares of common stock in this offering, you should rely only on the information contained in this prospectus and any free writing prospectus we file with the Securities and Exchange Commission, or SEC. We and the underwriters have not authorized anyone to provide any information different from that contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Information contained on, or accessible through, our website is not part of this prospectus. Unless otherwise expressly stated or the context otherwise requires, all information in this prospectus assumes the underwriters have not exercised their overallotment option to purchase additional shares of our common stock.

### **Smaller Reporting Company Scaled Disclosure**

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, as indicated herein, we have elected to comply with the scaled disclosure requirements applicable to smaller reporting companies, including providing two years of audited financial statements. Accordingly, the information contained herein may be different from the information you receive from our competitors that are public companies, or other public companies in which you hold stock.

### **Market Data**

Market data used in this prospectus has been obtained from independent industry sources and publications as well as from research reports prepared for other purposes. Industry publications, surveys and reports generally state that the information contained therein has been obtained from sources believed to be reliable. However, we have not independently verified the data obtained from these sources. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties that apply to the other forward-looking statements that are described in this prospectus. In addition, while we are not aware of any misstatements regarding the market or industry data presented herein, such statements involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading **Risk Factors** beginning on page 10 of this prospectus.

## **Representations and Warranties**

The representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant made to you or for your benefit. Moreover, such representations, warranties or covenants were accurate only as of the date they were made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

## **Trademarks**

Nucleosomics<sup>®</sup>, NuQ<sup>®</sup> and HyperGenomics<sup>®</sup> and their respective logos are trademarks and/or service marks of VolitionRx Limited and its subsidiaries. All other trademarks, service marks and trade names referred to in this prospectus are the property of their respective owners.

## **Financial Information**

Except as otherwise expressly noted, all financial information contained in this prospectus is expressed in United States dollars (USD or \$).

## 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 sections entitled Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations, and 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.*

### Company Overview

We are a clinical stage life sciences company focused on developing blood-based diagnostic tests that meet the need for accurate, fast, inexpensive and scalable tests for detecting and diagnosing cancer and other diseases. We have developed twenty blood assays to date that can be used individually or in combination to generate a profile which forms the basis of a blood test for a particular cancer or disease. We intend to commercialize our products in the future through various channels within the European Union, the United States and eventually throughout the rest of the world.

Currently, there are very few blood tests for diagnosis of cancer in common clinical use. The only commonly used blood screening test for any cancer is the PSA test for prostate cancer. We consider the PSA test to have relatively poor diagnostic accuracy (detecting approximately 70% of prostate cancers and misdiagnoses about 30% of healthy men as positive for cancer) but is widely used because it is the only product currently available.<sup>1</sup> The American Cancer Society recommends that prostate cancer screening should not occur without an informed decision making process regarding risks.<sup>2</sup> In 2012, the U.S. Preventative Services Task Force recommended against PSA-based screening for healthy men because of a moderate or high certainty that the service has no benefit or that the harms outweigh the benefits.<sup>3</sup> The test is still used to monitor patients after definitive diagnosis or treatment. There are currently no commonly used blood tests for screening for lung cancer or colorectal cancer.

VolitionRx is developing blood-based diagnostics for an array of the most prevalent cancers, beginning with colorectal cancer, using technology based on our Nucleosomics<sup>®</sup> biomarker platform. The platform employs a range of simple NuQ<sup>®</sup> immunoassays on an industry standard ELISA format, which allow rapid quantification of epigenetic changes in-vitro and in biofluids (whole blood, plasma, serum, sputum, urine etc.) compared to other approaches such as bisulfite conversion and polymerase chain reaction, or PCR. NuQ<sup>®</sup> markers can be used alone, in combination or as ratios to generate profiles related to specific conditions. The first tranche of data released from a large independent trial for colorectal cancer could, if carried through into its screening trial, potentially have a positive impact for broad scale, cost effective, cancer diagnostics.

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

We undertook our early trials in Europe because our laboratories are based in Belgium and Hvidovre Hospital in Denmark has given access to 4,800 previously collected samples from patients for our retrospective colorectal trial (the Retrospective CRC Study ) as well as 14,000 samples to be collected over 20-24 months from April 2014, from patients for our prospective colorectal trial (the Prospective CRC Study ). All research and production operations are currently in Belgium due to its favorable environment for small companies including a well-trained technical work force, low cost quality research facilities and access to government support including our funding from the Walloon region.

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<sup>1</sup> National Cancer Institute Fact Sheet: Prostate-Specific Antigen (PSA) Test, [24 July 2012] [online], Available at <http://www.cancer.gov/cancertopics/factsheet/detection/PSA>, [accessed 10.31.2014]

<sup>2</sup> Wolf. A *et. al.* American Cancer Society Guideline for the Early Detection of Prostate Cancer: Update 2010, CA: A Cancer Journal for Clinicians; 3 Mar 2010:60;2:70-98, available at <http://www.ncbi.nlm.nih.gov/pubmed/20200110> [accessed 10.31.2014]

<sup>3</sup> U.S. Preventative Services Task Force, May 2012 [online], available at <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prostate-cancer-screening> [accessed 10.31.2014]

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

The clinical in-vitro diagnostics, or IVD, market, which can only be accessed after the assay has either been approved for clinical use in the United States by the United States Food and Drug administration, or the FDA, or as a Laboratory Developed Test, or LDT, in the United States under a Clinical Laboratory Improvement Amendments, or CLIA, waiver; or by CE Marking in the European Union; and

The research use only, or RUO, market.

Given the much larger potential of the clinical IVD market, we have focused our resources on launching our first test for colorectal cancer in the clinical IVD market. We plan to use the results of the 4,800 patient Retrospective CRC Study for submission for European clinical approval. We currently plan to apply for the first of our CE Mark (European) approvals in the second quarter of 2015.

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

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

Our Nucleosomics® biomarker platform is a technology that can be used for a wide variety of cancers. We are currently developing Nucleosomics® tests for a number of major cancers including colorectal, lung and prostate. We have one trial underway in the United States with MD Anderson Cancer Center in Texas, to establish the efficacy of Nucleosomics® to differentiate between the more aggressive anaplastic prostate cancer, and the typical, less-aggressive castration resistant prostate cancer. We are also validating the use of our tests for early diagnosis of endometriosis, a benign but often debilitating condition, and the leading cause of admissions to hospital for abdominal pain. Endometriosis affects approximately 10% of women and is a leading cause of infertility.<sup>4</sup> At present, there are no non-surgical diagnostic tests for endometriosis.

We do not anticipate earning significant revenues until such time as we are able to fully market our intended products on the IVD market. For this reason, our auditors stated in their report on our most recent audited financial statements that our losses and negative cash flow from operations raise substantial doubt that we will be able to continue as a going concern without further financing. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our plan of operations described herein, obtain financing and eventually attain profitable operations.

## Corporate Information

We are a Delaware corporation. Our executive offices are located at 1 Scotts Road, #24-05 Shaw Centre, Singapore 228208, and our telephone number is +1 (646) 650-1351. We maintain a website at [www.volitionrx.com](http://www.volitionrx.com). Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to such reports are available to you free of charge through the Investors section of [www.volitionrx.com](http://www.volitionrx.com) as soon as practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. The information contained on our website is not incorporated by reference into this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

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<sup>4</sup> American Society for Reproductive Medicine Fact sheet: Endometriosis - A Guide for Patients [Online] available at [http://www.asrm.org/BOOKLET\\_Endometriosis/](http://www.asrm.org/BOOKLET_Endometriosis/) [accessed 11.12.2014]

## THE OFFERING

*The following summary of the offering contains basic information about the offering and the common stock and is not intended to be complete. It does not contain all the information that may be important to you. For a more complete understanding of the common stock, please refer to the section of the accompanying prospectus entitled "Description of Securities - Common Stock."*

Common stock being offered \_\_\_\_\_ shares of common stock.  
by us

Common stock outstanding 14,691,332 shares of common stock.  
before this offering<sup>(1)</sup>

Common stock outstanding \_\_\_\_\_ shares of common stock.  
after this offering

Over-allotment option We have granted the underwriter the right to purchase up to \_\_\_\_\_ additional shares of common stock from us at the public offering price less the underwriting discount within 30 days from the date of this prospectus to cover over-allotments.

Use of Proceeds We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately \$\_\_\_\_\_ million, or approximately \$\_\_\_\_ million if the underwriters exercise their over-allotment option in full, after deducting the underwriting discount and estimated offering expenses payable by us.

We intend to use \$1.4 million of the proceeds of this offering to fund our prospective colorectal trials with Hvidovre Hospital, in Denmark and \$0.7 million to fund an ongoing study at University Hospital in Bonn, Germany. We intend to use the remaining proceeds of this offering for general working capital and other corporate purposes. See the section entitled "Use of Proceeds" on page 25 of this prospectus for additional information.

Dividend Policy We have not previously paid cash dividends on our common stock. It is our current intention to invest our cash flow and earnings in the growth of our business and, therefore, we have no plans to pay cash dividends for the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends. For additional information, see the section of this prospectus titled "Dividend Policy."

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.

Lock-up provisions

We, and each of our directors and executive officers, have agreed with the underwriters, subject to specific exceptions, not to sell or transfer any shares of our common stock or securities convertible into or exercisable for shares of our common stock for a period of up to 180 days after the date of this prospectus (subject to extension in certain circumstances). See Underwriting.

Trading Symbol

Our common stock is currently quoted on the OTCQB Marketplace under the symbol VNRX . We intend to apply to have our shares of common stock listed on the NYSE MKT under the same symbol.

(1)

Based on the number of shares issued and outstanding as of November 25, 2014 and excludes:

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3,459,924 shares of our common stock issuable upon the exercise of common stock purchase warrants outstanding as of November 25, 2014, with a weighted average exercise price of approximately \$1.97 per share;

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1,568,300 shares of our common stock issuable upon the exercise of stock options outstanding as of November 25, 2014, with an exercise price of approximately \$3.41 per share; and

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431,700 additional shares of common stock reserved for issuance under our 2011 Equity Incentive Plan, as of November 25, 2014.

## **RISK FACTORS**

*An 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 occurs, our business, financial condition, 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. See the section entitled "Cautionary Note Regarding Forward-Looking Statements" beginning on page 20 of this prospectus.*

### **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, 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 (excluding any proceeds from the proposed offering subject to this prospectus) will be sufficient to meet our anticipated cash requirements to the second quarter of 2015. 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 forecast our future performance, which may cause our financial results to fluctuate unpredictably.*

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:

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Our ability to develop or procure antibodies for clinical use in our future products;

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Our ability to translate preliminary clinical results to larger prospective screening populations;

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The demand for our intended products;

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Our ability to obtain any necessary financing;

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Our ability to market and sell our future products;

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Market acceptance of our future products and technology;

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Performance of any future strategic business partners;

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Our ability to obtain regulatory clearances or approvals;

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Changes in technology that may render our future products uncompetitive or obsolete;

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Competition with other cancer diagnostics companies; and

Adverse changes in the healthcare industry.

***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.*

Our products will require several dynamic and evolving sales models tailored to different worldwide markets, users and products. We have decided to focus our sales strategy on the clinical market in 2015 with the CE Marking of our first product in Europe, and through a technology license for LDT development in a CLIA lab in the United States. We intend to progressively grow to large volumes of tests sold to centralized laboratories and eventually reach the mass diagnostics testing market. The exact nature of the ideal sales strategy will evolve as we continue to develop our intended products and seek entry into the IVD markets. 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.

There are significant risks involved in building and managing our sales and marketing organization, as well as identifying and negotiating deals with the right sales and distribution partners, including risks related to our ability to:

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Identify appropriate partners;

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Negotiate beneficial partnership and distribution agreements;

.

Hire qualified individuals as needed;

.

Generate sufficient leads within our targeted market for our sales force;

.

Provide adequate training for effective sales and marketing;

.

Retain and motivate our direct sales and marketing professionals; and

.

Effectively oversee geographically dispersed sales and marketing teams.

Our failure to adequately address these risks could have a material adverse effect on our ability to increase sales and use of our future products, which would cause our revenues to be lower than expected and harm our results of operations.

***Our Amended and Restated Certificate of Incorporation exculpates our officers and directors from certain liability to our Company or our stockholders.***

Our Amended and Restated Certificate of Incorporation contains 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 our transactions and dispositions of assets;

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

·  
provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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. Additionally, for so long as we remain as a smaller reporting company, under current rules our accounting firm will not be required to provide an opinion regarding our internal controls over financial reporting.

***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. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our plan of operations described herein, obtain financing 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 the clinical market. The successful development and commercialization of our intended products is critical to our future success. Our ability to successfully develop, manufacture, market, and sell our future products 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 United States and in Europe. Delays in obtaining approvals and clearances could have material adverse effects on us and our ability to fully carry out our plan of operations. 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.

***Our failure to obtain necessary regulatory clearances or approvals on a timely basis would significantly impair our ability to distribute and market our future products on the clinical IVD 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 IVD markets in the United States 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 us and our ability to fully carry out our 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 EU.

***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 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 competitors include large multinational corporations and their operating units, including Abbott Laboratories Inc., Cepheid Inc., Philips, GE Healthcare, Siemens, Gen-Probe Incorporated, MDxHealth SA, EpiGenomics AG, Roche Diagnostics, Exact Sciences Corporation, Sequenom, Inc 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:

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Significantly greater name recognition;

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Established relationships with healthcare professionals, companies and consumers;

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

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Established supply and distribution networks; and

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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 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 competitors.

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

Continuing concerns over United States 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 IVD markets for diagnostic tests, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

***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 prospectus, 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 us to a number of risks that could harm our business, including:

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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

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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 which will subject us to a number of risks.*

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

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

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

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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

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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 to be 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, we have 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 United States 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 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 market prices and trading volume of our stock may be volatile.*

The market price of our common stock is likely to be highly volatile and the trading volume may fluctuate and cause significant price variation to occur. We cannot assure you that the market prices of our common stock will not fluctuate or decline significantly in the future. Some of the factors that could negatively affect the prices of our shares or result in fluctuations in those prices or in trading volume of our common stock could include the following, many of which will be beyond our control:

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competition;

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additions or departures of key personnel;

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our ability to execute our business plan;

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operating results that fall below expectations;

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loss of any strategic relationship;

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industry developments;

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economic and other external factors; and

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period-to-period fluctuations in our 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 and trading volume of our common stock.

***Share ownership by our officers and directors make it more difficult for third parties to acquire us or effectuate a change of control that might be viewed favorably by other stockholders.***

As of September 30, 2014, our executive officers and directors owned, in the aggregate, 34.9% of our outstanding shares. As a result, if the officers and directors were to oppose a third party's acquisition proposal for, or a change in control of, the Company, the officers and directors may have sufficient voting power to be able to block or at least delay such an acquisition or change in control from taking place, even if other stockholders would support such a sale or change of control.

***Our corporate governance documents, and certain corporate laws applicable to us, could make a takeover attempt, which may be beneficial to our stockholders, more difficult.***

Our Board of Directors, or Board, has the power, under our articles of incorporation, to issue additional shares of common stock and create and authorize the sale of one or more series of preferred stock without having to obtain stockholder approval for such action. As a result, our Board could authorize the issuance of shares of a series of preferred stock to implement a stockholders rights plan (often referred to as a poison pill) or could sell and issue preferred shares with special voting rights or conversion rights, which could deter or delay attempts by our

stockholders to remove or replace management, and attempts of third parties either to engage in proxy contests or to acquire control of the Company. In addition, our charter documents:

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enable our Board to fill vacant directorships except for vacancies created by the removal of a director;

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enable our Board to amend our bylaws without stockholder approval subject to certain exceptions; and

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require compliance with an advance notice procedure with regard to business to be brought by a stockholder before an annual or special meeting of stockholders and with regard to the nomination by stockholders of candidates for election as directors.

These provisions may discourage potential acquisition proposals and could delay or prevent a change of control, including under circumstances in which our stockholders might otherwise receive a premium over the market price of our common stock.

***Our management will have broad discretion as to the use of proceeds from this offering. You may not agree with the manner in which we use the proceeds, and our use of those proceeds may not yield a favorable return on your investment.***

While we anticipate using \$1.4 million of the offering proceeds to fund our prospective colorectal trials with Hvidovre Hospital, in Denmark and \$0.7 million to fund an ongoing study at University Hospital Bonn, in Germany, we have not formally designated the amount of net proceeds that we will use for any other particular purpose. Accordingly, our management will have broad discretion as to the application of the net proceeds of this offering and could use them for purposes other than those contemplated at the time of this offering. We may not be successful in using the net proceeds from this offering to increase our profitability or market value, and we cannot predict whether the proceeds will be invested to yield a favorable return.

***The shares you purchase in this offering will experience immediate and substantial dilution.***

The public offering price per share of our common stock will be substantially higher than the net tangible book value per share of our common stock immediately after the offering. At the assumed public offering price of \$\_\_\_\_\_ per share (which was the last reported sale price per share of our common stock on the OTCQB on \_\_\_\_\_, 2014), purchasers of our common stock will incur immediate dilution of \$\_\_\_\_\_ per share in the net tangible book value of their purchased shares. Conversely, the shares of our common stock that our existing stockholders currently own will receive an increase in net tangible book value per share. See the section entitled "Dilution" elsewhere in this prospectus.

***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 cause our stock price to decline.***

Our Certificate of Incorporation and amendments thereto authorize the issuance of 100,000,000 shares of common stock, par value \$0.001 per share and 1,000,000 shares of preferred 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 or preferred stock issued in the future on an arbitrary basis. The issuance of common stock or preferred stock for future services or acquisitions or other corporate actions may have the effect of diluting the percentage ownership of our stockholders and, depending upon the prices at which such shares are sold or issued, on their investment in our common stock and, therefore, could have an adverse effect on any trading market for our common stock.

***Future sales of our common stock could depress the market price of our common stock.***

Sales of a substantial number of shares of our common stock in the public market following this offering, or the perception that large sales of our shares could occur, could cause the market price of our common stock to decline or limit our future ability to raise capital through an offering of equity securities.

After completion of this offering, there will be \_\_\_\_\_ shares of our common stock outstanding. All of the shares of common stock sold in this offering will be freely tradable without restriction or further registration under the federal securities laws, other than shares which our directors or executive officers may purchase, which will be subject to the resale limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. Our directors, executive officers and certain other stockholders have agreed to enter into lock-up agreements generally providing, subject to limited exceptions, that they will not, without the prior written consent of National Securities Corporation, directly or indirectly offer to sell, or otherwise dispose of any shares of our common stock during the period ending 180 days after the date of this prospectus.

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

Our 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 a 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 we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

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

The Financial Industry Regulatory Authority, or 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 stockholder s ability to resell shares of our common stock.

***If equity research analysts do not publish research or reports about our business, or if they do publish such reports but issue unfavorable commentary or downgrade our common stock, the price and trading volume of our common stock could decline.***

The trading market for our common stock could be affected by whether and to what extent equity research analysts publish research or reports about us and our business. We cannot predict at this time whether any research analysts will cover us and our common stock or whether they will publish research and reports on us. If one or more equity



analysts cover us and publish research reports about our common stock, the price of our stock could decline if one or more securities analysts downgrade our stock or if those analysts issue other unfavorable commentary or cease publishing reports about us.

If any of the analysts who elect to cover us downgrade their recommendation with respect to our common stock, our stock price could decline rapidly. If any of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our common stock price or trading volume to decline and our common stock to be less liquid.

***We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.***

We are currently a smaller reporting company, meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$75 million and annual revenues of less than \$50 million during the most recently completed fiscal year. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and this prospectus. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains estimates and forward-looking statements that involve risks and uncertainties, principally in the sections entitled Prospectus Summary, Risk Factors, Use of Proceeds, Business, and Management's Discussion and Analysis of Financial Condition and Results of Operations. All statements other than statements of historical fact contained in this prospectus, including statements regarding estimates, future events, our future financial performance, business strategy and plans and objectives of management for future operations, including with respect to us specifically and the cancer diagnostics industry in general are forward-looking statements. We have attempted to identify estimates and forward-looking statements by terminology including anticipates, believes, can, continues, could, estimates, expects, intends, may, plans, potential, predicts, should, or will or the negative or other comparable terminology. Although we do not make estimates or forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Our estimates and forward-looking statements are based on our current assumptions and expectations about future events and trends, which affect or may affect our business, strategy, operations or financial performance. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause our or our industry's actual results, levels of activity, performance or achievements to vary from those expressed or implied by these estimates and forward-looking statements. Before you invest in our securities, you should read this prospectus and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different and worse from what we expect.

Our estimates and forward-looking statements may be affected by one or more of the following factors:

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Our inability to generate any significant revenue or achieve profitability;

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Our need to raise additional capital in the future;

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Our expectations to expand our product development, research and sales and marketing capabilities could give rise to difficulties in managing our growth;

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Our limited experience with direct sales and marketing;

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The possibility that we may not be able to continue to operate, as indicated by the going concern opinion from our auditors;

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Our ability to successfully develop, manufacture, market, and sell our future products;

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Our dependency on our ability to successfully develop and commercialize diagnostic products;

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Our ability to obtain necessary regulatory clearances or approvals to distribute and market our future products;

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Our ability to market our future products may be subject to regulatory delays;

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The acceptance by the marketplace of our products;

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The highly competitive and rapid changing nature of the cancer diagnostics market;

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Our ability to develop or procure antibodies for clinical use in our future products;

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Our ability to translate preliminary clinical results to larger prospective screening populations;

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Our reliance on third parties to manufacture and supply our intended products, and such manufacturers' dependence on third party suppliers;

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Our dependence on third party distributors; and

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Protection of our patents, intellectual property, and trade secrets.

Other sections of this prospectus include additional factors that could adversely impact our business, strategy, operating results, financial condition and stock price, including the risks outlined under Risk Factors. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any estimates or forward-looking statements. All estimates and forward-looking statements speak only as of the date they were made, and, except to the extent required by law, we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors. In light of these risks and uncertainties, we cannot assure you that the estimates or forward-looking statements contained in this prospectus will in fact occur. You should not place undue reliance on these estimates and forward-looking statements.

### USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the \_\_\_\_\_ shares of our common stock in this offering at an estimated offering price of \$\_\_\_\_\_ will be approximately \$\_\_\_\_\_, after deducting the underwriting discount and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option to purchase \_\_\_\_\_ additional shares of our common stock, we estimate that the net proceeds to us will be approximately \$\_\_\_\_\_, after deducting the underwriting discount and estimated offering expenses payable by us.

We intend to use \$1.4 million of the net proceeds from this offering to fund our prospective colorectal trials with Hvidovre Hospital, in Denmark, \$0.7 million to fund an ongoing study at University Hospital Bonn, in Germany, and the balance for general working capital and other corporate purposes. We cannot specify with certainty the particular uses of net proceeds that we will receive from this offering. Accordingly, we will have broad discretion in using these proceeds.

### **DIVIDEND POLICY**

We have not previously paid cash dividends on our common stock. It is our current intention to invest our cash flow and earnings in the growth of our business and, therefore, we have no plans to pay cash dividends for the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends.

### **CAPITALIZATION**

The following table sets forth our cash, cash equivalents and capitalization, as of September 30, 2014, as follows:

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on an actual basis;

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on a pro forma as adjusted basis, giving effect to the sale and issuance by us of shares of our common stock in this offering at an assumed public offering price of \$\_\_\_\_\_ per share, after deducting the underwriting discount and estimated offering expenses payable by us.

The pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information together with our consolidated financial statements and related notes that are included elsewhere in this prospectus.

<b>As of September 30, 2014</b>	
<b>Actual</b>	<b>Pro Forma as Adjusted<sup>(1)</sup></b>

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Cash, cash equivalents and short-term investments	\$	2,419,667	\$
Debt obligations	\$	(7,947,666)	\$
Stockholders (Deficit) Equity:	\$	(4,098,212)	\$
Preferred stock, par value \$0.001 per share: 1,000,000 shares authorized; none issued and outstanding, actual or pro forma as adjusted	\$	---	\$
Common stock, par value \$0.001 per share: 100,000,000 shares authorized, 14,308,960 shares issued and outstanding, actual; _____ shares issued and outstanding, pro forma as adjusted	\$	14,309	\$
Additional paid-in capital		14,548,494	
Accumulated other comprehensive loss	\$	(93,526)	\$
Accumulated Deficit	\$	(18,567,489)	\$
Total stockholders (Deficit) Equity	\$	(4,098,212)	\$

(1)

Each \$1.00 increase or decrease in the assumed public offering price of our common stock of \$\_\_\_\_\_ per share would increase or decrease, as applicable, the amount of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately \$\_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us.

In the table above, the number of shares outstanding after this offering is based on \_\_\_\_\_ shares of our common stock outstanding as of \_\_\_\_\_, 2014. The number of shares of our common stock outstanding after this offering excludes the following:

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3,459,924 shares of our common stock issuable upon the exercise of common stock purchase warrants outstanding as of \_\_\_\_\_, 2014, with a weighted average exercise price of approximately \$1.97 per share;

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1,568,300 shares of our common stock issuable upon the exercise of stock options outstanding as of \_\_\_\_\_, 2014, with an exercise price of approximately \$3.41 per share;

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431,700 additional shares of common stock reserved for issuance under our 2011 Equity Incentive Plan, as of \_\_\_\_\_, 2014; and

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any shares issued upon the exercise by the underwriters of the option to purchase up to \_\_\_\_\_ additional shares of common stock from us to cover over-allotments, if any.



## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after completion of this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of our common stock outstanding. Our historical net tangible deficit as of September 30, 2014 was approximately \$\_\_\_\_\_, or \$\_\_\_\_\_ per share, based on \_\_\_\_\_ shares of our common stock outstanding on that date.

After giving effect to the sale by us of \_\_\_\_\_ shares of our common stock in this offering at an assumed public offering price of \$\_\_\_\_\_ per share, and after deducting the underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2014 would have been approximately \$\_\_\_\_\_, or \$\_\_\_\_\_ per share. This represents an immediate increase in pro forma net tangible book value of \$\_\_\_\_\_ per share to our existing stockholders and an immediate dilution of \$\_\_\_\_\_ per share to new investors participating in this offering at the assumed offering price. The following table illustrates this dilution:

Assumed public offering price per share	\$
Net tangible book value (deficit) per share as of September 30, 2014, before this offering	\$ (0.3467)
Increase in pro forma net tangible book value (deficit) per share attributable to new investors in this offering	\$
Pro forma as adjusted net tangible book value (deficit) per share as of September 30, 2014, immediately after this offering	\$
Dilution in pro forma net tangible book value per share to new investors in this offering	\$

The information above is as of September 30, 2014 and excludes the following:

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3,440,924 shares of our common stock issuable upon the exercise of common stock purchase warrants outstanding as of \_\_\_\_\_, 2014, with a weighted average exercise price of approximately \$1.96 per share;

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1,568,300 shares of our common stock issuable upon the exercise of stock options outstanding as of \_\_\_\_\_, 2014, with an exercise price of approximately \$3.41 per share; and

.

431,700 additional shares of common stock reserved for issuance under our 2011 Equity Incentive Plan, as of \_\_\_\_\_, 2014.

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, our pro forma as adjusted net tangible book value (deficit) per share would be \$\_\_\_\_\_ per share, representing an immediate increase in pro forma net tangible book value of \$\_\_\_\_\_ per share to our existing stockholders and an immediate dilution of \$\_\_\_\_\_ per share to new investors. If any shares are issued upon exercise of outstanding options, warrants or convertible notes, new investors will experience further dilution.

A \$1.00 increase or decrease in the assumed public offering price of \$\_\_\_\_\_ per share would increase or decrease, as applicable, our pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately \$\_\_\_\_\_, and would increase or decrease, as applicable, dilution per share to new investors in this offering by approximately \$\_\_\_\_\_ for an increase of \$1.00, or \$\_\_\_\_\_ for a decrease of \$1.00, after deducting the underwriting discount and estimated offering expenses payable by us.

## BUSINESS

### *Description of Our Business*

We are a clinical-stage life sciences company focused on developing blood-based diagnostic tests that meet the need for accurate, fast, inexpensive and scalable tests for detecting and diagnosing cancer and other diseases. We have developed twenty blood assays to date, using technology based on our Nucleosomics® biomarker platform, that can be used individually or in combination to generate a profile which forms the basis of a blood test for a particular cancer.

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

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

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The RUO market.

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

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

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

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

Our business is subject to certain risks and uncertainties, including those discussed under the heading Risk Factors beginning on page 10 of this prospectus.

## *The Market*

Cancer is one of the leading causes of death worldwide, accounting for around 8.2 million annual deaths globally.<sup>5</sup> In the United States alone, there were an estimated 14 million cancer survivors in 2010.<sup>6</sup> By 2020, this figure is expected to rise to 18.1 million. The American Cancer Society estimated the total health economic burden for cancer (including medical costs and loss of earnings) at approximately \$216 billion for 2009 (\$86 billion in direct medical costs and \$130 billion in lost productivity due to early death).<sup>7</sup> The annualized cost of cancer care in the over 65 age group based on analysis of Medicare payments linked to Surveillance, Epidemiology, and End Results, or SEER, Program data is projected to reach \$158 billion.<sup>8,9</sup> These figures are mirrored across the globe and we expect will continue to grow as populations age. This is a large potential addressable market for which we believe diagnostics will be a significant part. Incidence of, and mortality due to, colorectal cancer in the US have been steadily falling since the mid 1980 s with an acceleration of reduction in both men (3% per annum) and women (2.3% per annum) over the last 15 years. This is largely due to early detection and removal of polyps via colonoscopy.<sup>10</sup> The Pap test has had a similar impact in improving 5 year survival rates in women with precancerous and cancerous cervical lesions.<sup>11</sup>

Statistically, the chances of surviving cancer are greatly improved by early detection and treatment. However, there is currently no screening test for cancer in general, and very few effective blood tests for specific cancers in common clinical use. The only commonly used blood-screening test for any cancer is the PSA test for prostate cancer. We consider the PSA test to have relatively poor diagnostic accuracy (detecting approximately 70% of prostate cancers and misdiagnoses about 30% of healthy men as positive for cancer) but is widely used because it is the best product currently available.<sup>12</sup> The American Cancer Society recommends that prostate cancer screening should not occur without an informed decision making process regarding risks.<sup>13</sup> In 2012, the U.S. Preventative Services Task Force recommended against PSA-based screening for healthy men because of a moderate or high certainty that the service has no benefit or that the harms outweigh the benefits.<sup>14</sup> The test is still used to monitor patients after definitive diagnosis or treatment. There are currently no commonly used blood tests for screening for lung cancer or colorectal cancer.

Further, current methods of cancer diagnosis are either invasive, not cost effective, have low acceptance or cannot provide accurate results. The inadequacy of existing diagnostic products means that most cancers are only diagnosed once the patient experiences symptoms and the cancer is well established. By this stage, it will often have spread beyond the primary tumor (metastatic cancers), making it substantially more difficult to treat. For example colorectal cancer is one of the more survivable diseases if caught early: it has an observed five-year survival rate of 92% in stage I, but only 11% in stage IV.<sup>15</sup> Early, non-invasive, accurate cancer diagnosis remains a significant unmet medical need and a huge commercial opportunity. For these reasons, cancer diagnostics is an active field of research and development both academically and commercially.

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

<sup>6</sup> Mariotto AB et al., Projections of the cost of cancer care in the United States: 2010-2020. Jan 19, 2011, JNCI, Vol 103, No.2, Available at <http://www.ncbi.nlm.nih.gov/pubmed/21228314> [will begin testing the first cohort of retrospective samples in Q1 2015 10.31.2014]

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

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

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

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

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

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

<sup>13</sup> Wolf. A *et. al.* American Cancer Society Guideline for the Early Detection of Prostate Cancer: Update 2010, CA: A Cancer Journal for Clinicians; 3 Mar 2010;60;2:70-98, available at <http://www.ncbi.nlm.nih.gov/pubmed/20200110> [accessed 10.31.2014]

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

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

The global IVD market is forecast to reach \$65 billion in 2018,<sup>16</sup> driven by the increasing health care demands of an aging population. In the United States,<sup>17</sup> the IVD market is made up of:

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Histology, immunohistochemistry and cytology of tissue samples (expected to grow 6.8% per annum from 2011-2018, with an expected value of \$25.5 billion by 2018).<sup>18</sup> These are mostly used to confirm cancer diagnosis post-surgery and to determine cancer sub-type;

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Immunoassay (chemical tests used to detect a substance in blood or body fluid), which will be the second largest market with a value of more than US\$19.1 billion by 2018.<sup>19</sup> These tests are mostly used to monitor for disease progress and relapse. This market segment includes our future Nucleosomics<sup>®</sup> products, which will be blood immunoassay tests for modified histones for the diagnosis of cancer.

Testing is carried out at three principal locations:<sup>20</sup>

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Testing at hospital laboratories: \$30 billion annual revenue for eight billion tests in 2011;

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Testing at CLIA laboratories: \$20 billion annual revenue for 3 billion tests in 2011; and

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Testing at physician office laboratories: \$3 billion annual revenue for 1.2 billion tests in 2011.

We are focused on responding to the need for early, accurate diagnostic tests through the development of our proprietary technologies and product prototypes. We intend to develop a range of products over the next 5-10 years. For the year ended December 31, 2012, we spent approximately \$2.8 million on research and development activities. For the year ended December 31, 2013, we spent approximately \$2.5 million on research and development activities. None of these costs are borne directly by customers as we are in the development stage and do not have any

customers.

### *Our Intended Products*

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

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

<sup>17</sup> Report: The United States Market for In Vitro Diagnostic Tests

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

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

<sup>19</sup> Markets and Markets Report: Immunoassay Market [Technology (Enzyme, Fluorescent, Chemiluminescence, Radioimmunoassay), Analyzers & Reagents, Applications (Infectious Diseases, Cancer, Endocrinology, Cardiology), End Users (Hospitals, Laboratory, Academics)] - Global Forecast to 2018, October, 2013 [online], Available at: <http://www.marketsandmarkets.com/Market-Reports/immunoassay-market-436.html> [accessed 11.04.2014]

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





NuQ® Suite of Epigenetic Cancer Blood Tests

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

Figure 1 A nucleosome

Cancer is characterized by uncontrolled and often rapid cell growth which exceeds the corresponding rate of cell death. When cells die, the DNA fragments into individual nucleosomes which are released into the blood as illustrated in Figure 2 below. The cell debris in the bloodstream is eventually recycled back into the body. When a cancer is present, the number of dying cells can overwhelm the recycling process, leaving the excess fragments, including the nucleosomes, in the blood. Importantly, the structure of nucleosomes is not uniform but subject to immense variety, and nucleosomes in cancer cells have differences in structure from those in healthy cells.<sup>21</sup>

Figure 2 Release of nucleosomes into blood

Blood nucleosome levels can be raised in conditions other than cancer including in auto-immune disease, inflammatory disease, endometriosis, sepsis, and in the immediate aftermath of major trauma (for example following a heart attack, surgery or car accident). Our primary focus is on cancer diagnosis but we also intend to pursue diagnostic opportunities in other disease areas.

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<sup>21</sup> Fraga MF et al., Loss of acetylation at Lys16 and trimethylation at Lys20 of histone H4 is a common hallmark of human cancer , Nature Genetics, Vol 37 (4), p391-400, 2005

To date we have developed 20 NuQ<sup>®</sup> blood assays that fall into the five main types set forth below and are intended to complement each other and, together, to provide a total solution. To date, we do not have any products available for sale on the IVD market.

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

NuQ<sup>®</sup>-V: We are currently developing three blood assays in the NuQ<sup>®</sup>-V family to detect cancer by detecting nucleosomes containing specific histone variants. Through our research, we have found that the pattern of blood levels of the different types of histone variants in nucleosomes is different for different cancer types.

NuQ<sup>®</sup>-M: We are currently developing nine blood assays in the NuQ<sup>®</sup>-M family to detect cancer by detecting nucleosomes containing modified histones, the proteins that package and order DNA into nucleosomes.

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

NuQ<sup>®</sup>-T: We are currently developing a NuQ<sup>®</sup>-T assay to detect cancer by detecting total blood nucleosome levels.

Generally, the tests described above are being developed to work in combination, collectively called the NuQ<sup>®</sup> panel, for the IVD market. In our biggest independent clinical trial to date, we have used the NuQ<sup>®</sup> panel prototypes to test approximately 938 samples from patients with symptoms associated with colorectal cancer (the Denmark Trial ). Additionally the NuQ<sup>®</sup> panel prototypes have been used to test a small number of blood samples from lung and prostate cancer patients.

### NuQ® Research Kits

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

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

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

Figure 3 Example of lab instrument for running ELISA tests



## NuQ® Clinical Diagnostic Products

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

### Centralized Laboratory Market

Centralized laboratories test thousands of blood samples taken from patients everyday mostly using fully automated enzyme-linked immunosorbent assay, or ELISA, systems, commonly known as random access analyzers, usually supplied by one of the global diagnostics companies. Tests run on ELISA systems use components of the immune system and chemicals to detect immune responses in the body. ELISA systems analyze thousands of blood samples every day and can run dozens of different ELISA tests in any combination on any sample and for many samples simultaneously. The systems are highly automated and rapid (as little as 10 minutes for many tests), and can be run at low costs. Additionally, ELISA instruments are used in all major hospitals throughout the United States and Europe and therefore, are well understood by clinicians and laboratory staff. It is more cost-effective and technically simple for hospitals and clinics to run several blood samples simultaneously using ELISA tests compared to non-ELISA tests or alternative methods for screening cancer. All of the NuQ® tests that we are in the process of developing are designed for ELISA systems. A typical example of an automated ELISA system is shown below in Figure 4.

Figure 4 Example of an Automated ELISA System

One option that may be available to us in the future is to license our Nucleosomics® technology to a global diagnostics company. As of the date of this prospectus, we do not have an anticipated timeframe for licensing our Nucleosomics® technology.



Another option that may be available to us is to sell manual and/or semi-automated 96 well ELISA plates for use by these laboratories. As of the date of this prospectus, we have 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 implemented in any oncology clinic and tests can be performed during patient consultations. We intend to contract with an instrument manufacturer to produce these instruments for point-of-care NuQ<sup>®</sup> testing for the oncologist's office, general doctor's office or at home testing. We aim to enter the point-of-care clinical market in Europe in 2017 and in the United States in 2018, as we will first need to adapt test prototypes to these small instruments and demonstrate their success in the greater diagnostics market before these products will be adopted by others in the industry. At this stage of its development, we cannot accurately predict the costs to manufacture these devices or their selling price. As of the date of this prospectus, we have not entered into any discussions or negotiations regarding the manufacture or sale of these devices. See Figure 5 for an example of a point-of-care device.

Figure 5 Example of a Point-of-Care Device

*The above photograph is an illustration of our intended products. To date, we have no products available for sale on the IVD market and there is no guarantee that any such products will be developed or commercialized on such market.*

**Disposable Tests for Doctor's Office or Home Use:** Disposable tests for use in a doctor's office or at home are single shot disposable devices which can be provided by a clinician as part of a screening program or purchased over the counter at any chemist shop or pharmacy and test a drop of blood taken from a finger prick. The test can be administered at a doctor's office using a point-of-care device or performed at home using a home testing kit, neither of



which require laboratory involvement. Thus, the patient experiences considerably lower costs using these tests as compared to traditional laboratory tests. The format of the self-use home testing kit is very easy to use and reproduce and does not rely on laboratory processing. There are currently no useful diagnostics tests suitable for mass screening for cancer in general through a simple self-use home testing kit. Figure 6 below shows a basic home use test on the left which displays the results of the test in the two windows, similar to a pregnancy test. The test on the right is more sophisticated and plugs into a meter or the USB port of a computer for analysis and interpretation allowing results to be sent directly to a clinician.

Figure 6 Examples of Disposable Doctor's Office or Home Use Tests

*The above photograph is an illustration of our intended products. To date, we have no products available for sale on the IVD market and there is no guarantee that any such products will be developed or commercialized on such market.*

We intend to contract with a specialist company to adapt the NuQ<sup>®</sup> test prototypes to the doctor's office or home use system and to contract with a manufacturer for the production of these tests beginning in 2017. As of the date of this prospectus, we have not entered into any agreements or contracts with a specialist company or manufacturer. Initially, we intend to sell these tests for professional use only (doctor's office) and to sell the tests for non-professional home use at a later time. We do not yet have an estimated timeframe for entering into this market. Further, at this early stage of our development, we cannot accurately determine the manufacturing costs or selling price of these tests.

#### NuQ<sup>®</sup> tests for non-cancer conditions

Blood nucleosome levels can be raised in conditions other than cancer including in auto-immune disease, inflammatory disease, endometriosis, sepsis, and in the immediate aftermath of major trauma (for example following a heart attack, surgery or car accident). Our primary focus is on cancer diagnosis but we also intend to pursue diagnostic opportunities in other disease areas. Our primary non-cancer focus is the development of a test for endometriosis.

Endometriosis is a progressive gynecological condition that affects one in ten women of childbearing age and approximately 176 million women worldwide. The disease is the leading cause of infertility in women, with up to 40% of all infertile women suffering from endometriosis. At present, there is currently no existing non-surgical diagnostic test for endometriosis. Diagnosis is typically made via invasive and expensive laparoscopy, followed by a histological examination of any lesions found to confirm the diagnosis. Time to diagnosis can take up to 9 years from when the symptoms appear. The lack of a suitable screening test has also held up development of a cure for the disease.

Singapore Volition acquired the patent application for an endometriosis test in June 2011 and we are now in the process of developing the test based on our existing Nucleosomics® technology. We designed the test to be a simple blood test taken at two stages of a woman's menstrual cycle, during menses and partway through the month. If the two measurements show quantitative differences in total nucleosome level, endometriosis is indicated. We are currently conducting hypothesis-testing and clinical proof of concept work (to demonstrate that the test is feasible and is effective) on the endometriosis test in our laboratory. We completed pilot studies of the test in 2012 and will receive the first samples from The University of Oxford in the fourth quarter of 2014 as part of a larger endometriosis study. The University of Oxford will provide serum and plasma samples from approximately 350 patients with endometriosis and 150 control patients over a period of two years. The test is too early in its development for us to accurately determinate the manufacturing costs and sale price of the test. The test is not currently being developed for the RUO market.

#### HyperGenomics®

We are in the process of developing HyperGenomics® tissue and blood-based tests to determine disease subtype following initial diagnosis and to help decide the most appropriate therapy. Although as with the Nucleosomics® RUO kits, we have decided to focus on our clinical Nucleosomics® products in 2015, and only continue with background work in HyperGenomics® until we have the capital and management resources to do multiple programs concurrently.

Selecting the correct treatment approach can significantly improve outcome, reduce side effects and deliver cost savings. The HyperGenomics® tests will be performed on cancer tissue obtained either by biopsy or during surgical resection to determine the cancer subtype and to determine optimal treatment regimens. The HyperGenomics® profiling tests are being developed to provide detailed epigenetic characterization of tumors in a cost effective way. A new protocol for analyzing white blood cells – a precursor to applications in leukemia - was developed in 2012. We commenced development of a bioinformatics pipeline to analyze the complex data sets generated from the biological samples in 2012 and continued development of the algorithms in 2013. We aim to file new in house methodology patents for HyperGenomics® in 2015.

We realized our first revenue of \$50,000 from contract research in 2012. We will allocate resources to the HyperGenomics® research kit as soon as is practical given our focus on the Nucleosomics® clinical products in 2015, Beta-testing is expected to take approximately six (6) months to complete once initiated and we expect it to cost approximately \$50,000. If beta-testing is successful, we expect to launch HyperGenomics® research kits into the RUO market in Europe and in the United States.

The launch of the HyperGenomics® test into the IVD market in Europe and the United States will follow the commercialization of the test into the RUO market. The estimated timeframe for its launch into the IVD market has not yet been determined and will depend upon the speed of clinical trials and market approval. The HyperGenomics® test is too early in its development for us to accurately determinate the manufacturing costs and sale price of the test.

### ***Validation Studies***

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

A retrospective symptomatic study with Hvidovre Hospital in Denmark with full access to all Danish national registries and databases analyzing approximately 4,800 previously collected samples from patients with colorectal cancer, polyps or adenomas, benign bowel diseases, or other malignancies, all of whom have undergone a colonoscopy (the Retrospective CRC Trial ).

The Retrospective CRC Trial is designed to (i) establish a NuQ® profile for the detection of colorectal cancer in an initially blinded cohort ( Phase I ); and (ii) validate that profile in a second blind cohort ( Phase II ). As part of Phase I, at the end of the third quarter 2014, approximately 20% of the Retrospective CRC Trial samples have been analyzed with a combination of NuQ® assays. Additional NuQ® assays are currently being tested on these Phase I samples. Phase II will commence using the best NuQ® assays on the blind sample cohort in 2015 with the results intended to be used to support CE marking of specific NuQ® assays.

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A prospective colorectal cancer study with Hvidovre Hospital in Denmark with 14,000 samples to be collected over 20-24 months from April 2014 from patients who have had a fecal occult blood test ( FIT Test ). Patients who tested positive following the FIT Test will additionally have a colonoscopy and we have full access to these results and the patient s medical history. It is anticipated that 8,000 samples will be collected from patients who tested positive following a FIT Test and 6,000 samples from patients tested negative. The Prospective CRC Study is designed to evaluate the performance of the validated NuQ<sup>®</sup> panel from the Retrospective CRC Trial in a large non-symptomatic cohort. The samples will be analyzed in batches throughout the collection period.

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

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A retrospective study to evaluate NuQ<sup>®</sup> assays in a treatment selection setting to distinguish anaplastic cancer, a particularly aggressive form of prostate cancer, from typical castration resistant prostate cancer (CRPC), the less aggressive form.

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

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

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

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

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

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

October 9, 2014: Additional analysis performed on 830 of the 938 samples tested from patients aged over 50 years with symptoms indicative of CRC the results of which were first announced on September 11, 2014. Among the 830

subjects, a total of 59 CRC cases were identified by colonoscopy, including 35 colon cancer and 24 rectal cancer cases. Of the 59 CRC cases, the NuQ<sup>®</sup> blood test was able to detect both early (I or II) and late (III or IV) stage cases as summarized in the following table:

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

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

November 24, 2014: Pilot lung cancer study tested both sputum (airway secretions, or mucus coughed up from the lower respiratory tract) and blood samples from the same 46 patients with either non-small cell lung cancer, chronic obstructive pulmonary disease (COPD) or with no disease (healthy) across various NuQ<sup>®</sup> assay panels. In sputum samples, our NuQ<sup>®</sup> test was able to detect 18 of 21 lung cancer cases (85%) with no false positive results for healthy subjects (0 of 13) and discriminate lung cancer from COPD. The sputum assay data is age and smoking independent. In blood the NuQ<sup>®</sup> assays were able to detect 16 of the 21 patients with cancer (76%) with a single false positive result from a healthy subject (1 of 13) and also able to discriminate lung cancer from COPD. The blood assay data is adjusted for age and smoking risk. *Presented at the the Science for Business BioWin Day 2014 in Louvain-la-Neuve, Belgium.*

***Intellectual Property***

We hold or have applied for nine families of patents covering the products currently being developed. One is licensed from a world-class research institution, one is licensed from a pharmaceutical company and seven are authored by our subsidiaries.

Nucleosomics® Intellectual Property

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

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

Application Date: August 18, 2003

Status: Granted in Europe; Pending in United States

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



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Status: Granted in Australia and China; Pending in Europe, United States, Canada, South Africa, India, Brazil, Japan, Singapore

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

**NuQ<sup>®</sup> Patent UK1115099.2 and U.S. 61530300:** Method for Detecting Nucleosomes

Application Date: September 1, 2011

Status: Pending in Europe, United States

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Belgian Volition authored the following patent application covering its NuQ<sup>®</sup>-V technology:

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

Application Date: September 1, 2011

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

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Singapore Volition authored the following patent application covering its NuQ<sup>®</sup>-X technology:

**NuQ<sup>®</sup>-X Patent UK1115095.0 and U.S. 61530295:** Method for detecting Nucleosomes containing Nucleotides

Application Date: September 1, 2011

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

Singapore Volition authored the following patent application covering a NuQ<sup>®</sup>-A blood test for detecting nucleosome adducts of cancer origin that circulate in the blood of cancer patients. The patent application covers both the use of these adducts as biomarkers and the methods for their detection.

**NuQ<sup>®</sup>-A Patent UK112130.5 and U.S. 61568090:** Method for detecting Nucleosome Adducts

Application Date: December 7, 2011

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

Singapore Volition authored the following patent application covering NuQ<sup>®</sup>-M blood tests for detecting nucleosomes containing modified histones of cancer origin that circulate in the blood of cancer patients. The patent application covers methods for their detection.

**NuQ<sup>®</sup>-M US1770893:** Method for detecting Histone Modifications in Nucleosomes

Application Date: February 28<sup>th</sup>, 2013

Status: Pending Worldwide

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

**US61770922:** Method for Predicting Therapy Efficacy using Nucleosome Structure Biomarkers

Application Date: February 28<sup>th</sup>, 2013

Status: Pending Worldwide

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 in United States, Canada, Australia, Europe

Future Intellectual Property Strategy

We intend to continue our development of the Nucleosomics<sup>®</sup> and HyperGenomics<sup>®</sup> technologies and will continue to apply for patents for future product developments. Our strategy is to protect the technologies with patents in Europe and the U.S. The protection of the technologies underlying products will then provide multiple cover for each product. We believe that this will provide:

Market exclusivity through multiple protection for each future product.

Full protection reaching at least to 2031 for each new product developed using the NuQ<sup>®</sup>-X, NuQ<sup>®</sup>-V and NuQ<sup>®</sup>-A technologies.



## Trademarks

We also own a number of trademarks that protect our marks including NuQ<sup>®</sup>, Nucleosom<sup>®</sup>cs and HyperGenom<sup>®</sup>cs

## ***Government Approval***

All of our intended products are designed to be non-invasive, meaning they cannot harm the subject other than through misdiagnosis. Our strategy is to go through the process of obtaining regulatory approval for IVD products to be used clinically on cancer patients. Conformité Européenne, or CE Marking, is a mandatory conformity mark for certain products placed on market in the European Union including, medical devices and IVD tests. CE Marking ensures that the manufacturer's product conforms to the essential requirements of the relevant European health, safety and environmental protection legislation. We intend to first focus on obtaining regulatory approval in Europe (CE Marking), and on licensing to CLIA labs for a LDT in the United States, due to the grant of the NuQ<sup>®</sup> patent in Europe and the relatively fast European CE Marking process. We anticipate this will be followed closely by regulatory submissions in the United States and in the rest of the world. In many territories, the European CE Mark is sufficient to place products on the clinical market and, where it is not, it often simplifies the regulation processes. To date, we have not begun the CE Marking or FDA approval process for any of our tests currently under development.

## Europe CE Marking

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

To receive the CE Mark, our diagnostic products must meet certain requirements as set forth in the In-Vitro Diagnostic Medical Devices Directive. The requirements to procure CE Marking for In-Vitro Diagnostic Medical products are:

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analytical validation of the products;

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clinical validation of the products (which can be retrospective clinical studies using biobank patient samples, i.e. blood samples from historic patients);

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implementation of regulatory compliant manufacture;

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implementation of a Quality System; and

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certification from the International Organization for Standardization (this last requirement is not technically required but will aid the regulatory approval process in Europe and the United States).

We are currently engaged in the first two requirements listed above for the first NuQ<sup>®</sup>-X assay. The remaining requirements listed above are general requirements that apply to all of our intended products. In compliance with the In-Vitro Diagnostic Medical Devices Directive and the CE Marking process, we have ensured that all development and validation is carried out in a manner consistent with regulatory approval. Additionally, we have maintained proper records so that our future products can be approved as quickly and simply as possible. We have engaged a regulatory advisor to lead the Company in meeting the last requirement for all of our future products. All of these requirements must be completed prior to the submission of an application for CE Marking. We will submit applications, which will contain a dossier of all relevant analytical, clinical and manufacturing data following retrospective clinical studies which we expect will require a total of approximately six (6) months to complete. We estimate the cost of obtaining CE Marking will be approximately \$500,000 per NuQ<sup>®</sup> panel. We expect to apply for CE Marking for the NuQ<sup>®</sup>-X assay in 2015. Sales of our clinical products can occur in Europe once CE Marking has been granted.

In Europe, IVD companies are able to self-certify that they meet the appropriate regulatory requirements and are subject to inspection for enforcement. European agencies, conduct market surveillance to ensure the provisions of the applicable Directive have been met for products marketed within the European Union. In pursuit of this goal, surveillance authorities will:

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audit commercial, industrial and storage premises;

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visit work places and other premises where products are put into service and used;

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organize random checks; and

take samples of products for examination and testing.

If a product is found to be noncompliant, corrective action will depend on and be appropriate to the level of noncompliance. Others responsible for the noncompliance of the product will be held accountable as well. Penalties, which may include imprisonment, are determined by national law.



U.S. Laboratory Developed Test

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

The FDA has generally not enforced more stringent premarket review and other applicable FDA requirements for relatively simple lab tests that are available on a limited basis. Rather, LDTs are regulated by the Centers for Medicare & Medicaid Services, or the CMS, through the Clinical Laboratory Improvement Amendments, or CLIA. A CLIA certified laboratory is required to determine, validate and submit performance characteristics on around 50 known and 50 unknown samples including:

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Accuracy;

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Precision;

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Analytical sensitivity;

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Analytical specificity to include interfering substances;

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Reportable range of test results for the test system;

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Reference intervals (normal values); and

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Any other performance characteristic required for test performance.

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

We do not intend to establish a CLIA laboratory in the United States due to the costs and time frame associated with this. We will identify a licensing partner for the Nucleosomics® technology for establishment of an LDT for adjunctive diagnostics to aid in colorectal cancer diagnosis.

#### United States FDA Approval

Our diagnostic products are designated as medical devices by the FDA. Among other things, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical devices distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets. We estimate the cost of obtaining FDA approval to be approximately \$2.5 million per product. FDA approval is more expensive and will likely take at least twice as long as CE Marking in Europe.

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



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

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

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

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

### ***Product Development and Plan of Operations***

#### **NuO® Assays (Cancer and Other Conditions):**

Research Use Only Market

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The NuQ<sup>®</sup> suite of assays has been released for the RUO market.

In-Vitro Diagnostics Market

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

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FDA Approval (United States): FDA approval is expected to require longer large scale prospective clinical validation studies and is expected to commence in 2015 and be completed in 2017. When completed, the data will be submitted to the FDA for United States market approval. We estimate the cost of obtaining FDA approval will be approximately \$2.5 million.

We completed initial external testing on a variety of cancers in 2012-2013 based on our Nucleosomics<sup>®</sup> technology. Cancers were selected by medical need and commercial value and large scale retrospective (CE Mark) and prospective (FDA) clinical validation studies for the cancers identified as most promising in the 2012 studies commenced in 2013. We expect to produce a rolling pipeline of products for different types of cancers over the next three (3) to five (5) years.

**NuQ® Clinical Diagnostic Products:**

Centralized Laboratory Market

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*License of Nucleosomics® technology to a global diagnostics company:* We may license our Nucleosomics® technology on a non-exclusive basis to a global diagnostics company. The approximate licensing fees have not yet been determined. As of the date of this prospectus, we have not entered into any agreements with diagnostic companies or established an anticipated timeframe for licensing our Nucleosomics® technology.

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*Sell manual and/or semi-manual ELISA plates to centralized laboratories:* We may sell manual and/or semi-automated 96 well ELISA plates for use by centralized laboratories. The approximate manufacturing costs or sales price have not yet been determined. As of the date of this prospectus, we have not entered into any discussions or negotiations with diagnostic companies or established an anticipated timeframe regarding the sale of ELISA plates.

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*Point-of-Care Devices:* We intend to enter the point-of-care clinical market in Europe in 2017 and in the United States in 2018. The approximate manufacturing costs or sales price per device have not yet been determined. As of the date of this prospectus, we have not entered into any discussions or negotiations regarding the manufacture or sale of these devices.

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*Disposable Tests for Doctor's Office or Home Use:* We intend to contract with a specialist company to adapt the NuQ® tests to the doctor's office or home use system and to contract with a manufacturer for the production of these tests. The sale of these tests will initially be for professional use only (doctors) and will likely be released at a later time for non-professional home use. The approximate manufacturing costs or sales price per test have not yet been determined. As of the date of this prospectus, we have not entered into any discussions or negotiations with a specialist company or manufacturer. We do not yet have an estimated timeframe for the manufacture or sale of these tests.

If we do not have enough funds to fully implement our business plan, we will be forced to scale back our plan of operations and our business activities, increase our anticipated timeframes to complete each milestone or seek additional funding. In the event that additional financing is delayed, we will prioritize the maintenance of its research and development personnel and facilities, primarily in Belgium, and the maintenance of our patent rights. However the development of the current pipeline of intended products for the RUO market would be delayed, as would clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market. In the event of an ongoing lack of financing, we may be obliged to discontinue operations.

### ***Sales and Marketing Strategy***

The first sales of our NuQ<sup>®</sup> products was for the RUO market, as the RUO market does not require government approval, as compared to the clinical IVD market. We have however decided to focus our efforts on launching our first products in the clinical market in the EU and adopt a licensing model to a CLIA laboratory in the United States given our very encouraging results in Denmark, the much larger potential of the IVD market and our limited resources, which require us to focus our efforts. Our RUO products are available for sale to researchers via our product website, <http://www.nucleosomics.com> and through a contracted distributor.

We intend to primarily sell our RUO products through distribution agreements