VOLITIONRX LTD
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February 09, 2015

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Registration No. 333-200628

PROSPECTUS

**2,475,000 Shares**

**Common Stock**

We are offering 2,475,000 shares of our common stock pursuant to this prospectus.

Our common stock is currently quoted on the OTCQB under the symbol VNRX . On February 5, 2015, the closing price of our common stock was $4.10 per share.

Our common stock has been approved for listing on the NYSE MKT under the symbol VNRX .

VOLITIONRX LIMITED IS A CLINICAL 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 4 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.

| | Per Share | Total |
|---|---|---|
| Public offering price | $ 3.75 | $ 9,281,250 |
| Underwriting discount[(1)] | $ 0.30 | $ 742,500 |
| Proceeds to us, before expenses | $ 3.45 | $ 8,538,750 |

(1)

The underwriters will receive compensation in addition to the underwriting discount described above. See the section entitled Underwriting beginning on page 71 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 371,250 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. The underwriters expect to deliver the shares against payment therefor on or about February 11, 2015.

**National Securities Corporation** **Lake Street Capital Markets**

***Joint Book Running Managers***

**The Benchmark Company**

***Co-Manager***

The date of this prospectus is February 5, 2015

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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.

**Investors outside the United States**

Neither we nor any of the underwriters have done anything that would permit this offering or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of shares of our common stock and the distribution of this prospectus outside of the United States.

**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 4 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®, NuQ® and HyperGenomics® 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.[1] The American Cancer Society recommends that prostate cancer screening should not occur without an informed decision making process regarding risks.[2] 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 [3].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® biomarker platform. The platform employs a range of simple NuQ® 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® 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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[1] 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]

[2] 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]

[3] 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:

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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

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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. Pending completion of our review of the regulatory environment in the United States, including the effect of recent pronouncements regarding LDTs by the FDA, we aim initially to enter the United States market through a LDT in 2015, pursuant to a yet to be negotiated relationship with a CLIA lab, while we concurrently seek FDA approval.

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.[4] 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*. 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* 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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[4] American Society for Reproductive Medicine Fact sheet: Endometriosis - A Guide for Patients [Online] available at 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.*

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|---|---|
| Common stock being offered by us | 2,475,000 shares of common stock. |
| Common stock outstanding before this offering[(1)] | 14,691,332 shares of common stock. |
| Common stock outstanding after this offering | 17,166,332 shares of common stock. |
| Over-allotment option | We have granted the underwriter the right to purchase up to 371,250 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 $8.5 million, or approximately $9.7 million if the underwriters exercise their over-allotment option in full, after deducting the underwriting discount and estimated offering expenses payable by us.<br><br>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 15 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 beginning on page 4 and the other information contained in this prospectus before making an |

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|---|---|
| | 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 . Our common stock has been approved for listing on the NYSE MKT under the same symbol. |

(1)

Based on the number of shares issued and outstanding as of February 5, 2015 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 February 5, 2015, 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 February 5, 2015, 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 February 5, 2015.

## 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 14 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 clinical 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

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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.

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***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. Pending completion of our review of the regulatory environment in the United States, including the effect of recent pronouncements regarding LDTs by the FDA, we aim initially to enter the United States market 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;

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Hire qualified individuals as needed;

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

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Provide adequate training for effective sales and marketing;

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Retain and motivate our direct sales and marketing professionals; and

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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:

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

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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

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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.

***Recent announcements from the Federal Food and Drug Administration may impose additional regulatory obligations and costs upon our business.***

On October 3, 2014, the FDA issued draft guidance regarding oversight of laboratory developed tests, or LDTs, titled Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs). According to this guidance, the FDA plans to take a phased-in risk-based approach to regulating LDTs. The FDA plans to phase in enforcement of LTD premarket review, quality system oversight and adverse event reporting over a number of years. The FDA would require that laboratories providing LDTs, subject to certain limited exemptions, within six months after the guidance documents are finalized comply with (i) either a new notification procedure in which the laboratory must provide the FDA with certain basic information about each LDT offered by their laboratory or the FDA s device registration and listing requirements, and (ii) the medical device reporting, or MDR, requirements for LDTs offered by that laboratory. Under this new risk based approach, it is possible that some level of pre-market review may be required for our LDTs-either a 510(k) or PMA-which may require us to obtain additional clinical data.

The draft guidance document was subject to public comment until February 2, 2015. At this time, we do not know what the additional costs and regulatory burdens will be, nor the impact of any final FDA guidance or FDA enforcement of its regulations on our business or operations.

If the FDA requires us to seek clearance or approval for any of our products (as opposed to simply licensing our technology to a CLIA lab), we may not be able to obtain such approvals on a timely basis, or at all. The cost of conducting clinical trials and otherwise developing data and information to support any applications may be significant. Failure to comply with applicable regulatory requirements of the FDA could result in enforcement action, including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

***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;

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Delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier s variation in a component;

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A lack of long-term supply arrangements for key components with our suppliers;

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Inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;

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Difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner;

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Production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;

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

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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.

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***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, 38.5% 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 public offering price of $3.75 per share, purchasers of our common stock will incur immediate dilution of $3.56 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 17,166,332 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 Discussi 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, continu could, estimates, expects, intends, may, plans, potential, predicts, should, or will or the negat 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,