--- Closely Held ---

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Tumor Microenvironment[1]

--- OTraces Summary ---

Only blood test to Access TME
(all other known companies use biopsy)

Has achieved 90%+ accuracy
in tumor detection
through TME Access

Enables early tumor detection

Definitive tumor detection
(DNA limited to prognosis)

Real Time IVD Tumor Diagnosis
(for active surveillance monitoring)

Immunotherapy drug
development/patient monitoring

CORPORATE PROFILE

OTraces has developed a patented technology to enhance the accuracy of biomarkers and cancer blood tests that uses math and physics-based noise suppression techniques to remove ambient non-cancer distortions that compromise the performance of all known cancer blood tests. This simple and cost-effective test modality is biomarker agnostic and utilizes ordinary ELISA instrumentation. It is the first test to achieve access to active proteins found in the **tumor microenvironment (TME)** --- well recognized as the prime center of diagnostic content and as the focal point for immunotherapy drug and vaccine development. The TME blood test enables OTraces ***to diagnose tumor status and progression dynamically and in real time, without the need for an expensive and often traumatic biopsy in most cases***

Subject to current funding, OTraces will complete validation trials for its **TME Liquid Biopsy**™ blood test for prostate cancer at Johns Hopkins and launch a U.S. based CLIA lab test for monitoring PCa patients with moderate disease to improve Active Surveillance outcomes. This launch will enable OTraces to start generating U.S. sales within 8 to 10 months of funding --- roughly 18-24 months ahead of the company's original base plan --- and should set the stage for Canadian (and possibly U.S.) clinical

Blood Test Accuracy and Biological/Proteomic Noise

- All known cancer biomarker-based tests are subject to the corrupting influence of proteomic "noise", as seen in the high false positive rates of the PSA prostate test. Industry accuracy (predictive power) currently averages only 70-75% across all tests for even the top companies, and the lack of any significant FDA approvals in the cancer IVD sector for screening tests over the past 3 decades highlights the difficulty of resolving the proteomic noise problem.
- OTraces has filed for extensive patent protection on all known noise suppression and other methods for achieving 90%+ predictive power and for blood test access to the TME –- which it is believed blocks would-be competitors on two fronts both of which are believed critical in the cancer screening field.
- All software used to evaluate chemistry results and exclusively store patient records and data resides in dedicated U.S. resident cloud-based servers fully controlled by OTraces. This MIS system is linked to instruments in the field or in CLIA labs, as well as to other users in the U.S. and abroad seeking improved test performance by utilizing the OTraces software.
- Unlike DNA liquid biopsy, exotic and expensive equipment is not required to implement the OTraces test; it is a true diagnostic test (not a prognosis), and it is highly scalable and inherently high-margin/low cost (i.e., key requirements for screening test success).

[1] Scientific and other technical terms are referenced in the Glossary on pages 16-17. *See page for applicable disclosures.*

Accuracy Track Record

--- Predictive Power---

Prostate, Breast, Lung, Ovarian and Melanoma

(Unpublished)

Condition	Status	Cohort Size	% Correct	Test Location
Prostate Cancer Screening	Cancer	60	95.0%	Johns Hopkins Lab[1]
	Not Cancer	180	87.0%	
	Cancer	111	96.4%	OTraces Lab
	Not Cancer	148	96.6%	
Prostate Cancer Aggressive Vs. Non Aggressive Surveilance	High Gleason Score	160	96.0%	OTraces Lab
	Low Gleason score	111	89.0%	
Breast Cancer	Cancer	200	97.0%	Gertsen Inst. Moscow[2]
	Not Cancer	207	96.6%	
	Cancer	651	96.9%	OTraces Lab
	Not Cancer	529	97.5%	
Ovarian Cancer	Cancer	101	96.0%	OTraces Lab
	Not Cancer	111	99.1%	
Melanoma	Cancer	172	98.3%	OTraces Lab
	Not Cancer	172	97.7%	
Lung Cancer	Cancer	96	100.0%	OTraces Lab
	Not Cancer	96	97.9%	

1. Third party validation trial at JHU under Dr. Kenneth Pienta

2. Third party validation at gertsen Institute, Moscow

Notice

This report contains forward-looking statements that are based on management's expectations and beliefs. These statements are subject to a number of factors which involve known and unknown risks, delays, uncertainties and other factors not under the Company's control which may cause actual results, performance or achievements of the company to be materially different from the results, performance or other expectations implied by these forward-looking statements.

In any forward-looking statement in which the Company expresses an expectation or belief as to future results, such expectations or beliefs are expressed in good faith and are believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will be achieved. These factors include but are not limited to: results of pending or future clinical trials, risks associated with intellectual property protection, financial projections, market projections, and in-licensing of technologies. OTraces does not undertake an obligation to update any forward-looking statements.

OTraces Inc. is a development stage company and as such any investment in OTraces represents a high degree of risk. Potential investors should not invest in the Company unless they meet certain suitability standards and can afford the loss of their entire investment.

EXECUTIVE SUMMARY

OTraces Inc. has developed and filed U.S. and international patents on **cancer detection software technology that applies math/physics-based noise suppression techniques to human biological disease testing for the first time**. This novel blend of math and physics with biology is designed to remove proteomic noise that is believed to corrupt the accuracy of all known cancer blood tests, and it serves to coordinate and rationalize biomarker activity. The result has been a blood test technology which has consistently achieved 90%+ accuracy (as measured by the demanding metric known as predictive power) --- substantially above the current industry average which is only 70-75% and the PSA test for prostate cancer which is less than 60%.

OTraces is also the first blood test to gain access to important diagnostic content of the tumor microenvironment (TME) --- which should facilitate patient monitoring and drug development relative to the rest of drug and biotech industry that still relies on biopsy and other physical TME extraction methods. The TME is a vast storehouse of diagnostic content far surpassing the tumor itself and is the main focus of the industry's search for new immunotherapies and companion diagnostics. An OTraces TME blood test that can track tumor status and progression in real-time is a major accomplishment that has yet to be widely recognized by the industry, which is why the Johns Hopkins final validation trial results for the prostate cancer blood test are regarded as critical.

This technology has potential applications well beyond solid cancer tumors, where preliminary development work diagnosing other diseases, including Alzheimer's, Lyme's Disease and Macular Degeneration, has been encouraging.

In summary, OTraces has:

- Achieved access to biomarker activity in the TME – believed to be an industry first for an IVD blood test.
- Demonstrated 90%+ accuracy in validation trials for prostate cancer (PCa) at Johns Hopkins, versus the current IVD industry average of 70-75% and less than 60% for the PSA test **(which also has 75% false positive rates as compared with less than 10% for OTraces).**
- Detected biomarker surges in the TME during Johns Hopkins validation trials to date, signaling PCa tumor progression from low-grade to potentially life-threatening aggressive cancer, which frequently is undetected by conventional active surveillance methods. **Active surveillance of men with low grade PCa addresses a potential $200 million U.S. market opportunity where the TME test would have minimal competition. Launch of this test is expected 8 to 10 months after funding.**
- Similar biomarker surges were observed in earlier breast cancer validation trials, where the OTraces test detected tumor formation at stage 0.
- Surveyed over 40 active TME proteins with its methods to determine the cancer signal for each one **— a protein TME biomarker library for potential additional blood tests that has no known industry parallel.**

OTraces method is differentiated:

- Based on simple, easily accessible blood analysis techniques that can be run on existing instrumentation.
- Proprietary software and methods, housed on dedicated U.S. cloud-based servers fully controlled by OTraces, evaluate the chemistry results and provide a platform for collaborations with other companies on either a revenue sharing or FFS basis.
- Extensive patents pending protect the access to and evaluation of the TME, giving the company exclusive global rights to this emerging diagnostic pathway.

Unlike DNA liquid biopsy:

- **Exotic and expensive equipment is not required to implement the OTraces test.**
- **It is a true diagnostic test to determine what's occurring now, not a prognosis of potential future.**
- **It is a highly scalable and inherently high-margin/low cost modality ---** compatible with the needs for global deployment as a high-volume screening test.

Company Strengths:

- **Experienced Management with a Strong Track Record** –- Founder and CEO Keith Lingenfelter was previously a senior officer at **IGEN International** which was sold to **Roche Diagnostics** for $1.5 billion, and Chairman and CFO Alain Cappeluti was an original employee and the CFO for **Human Genome Sciences** and **Cogenesys**, which were sold for $400 million to **Teva**. Other key team members have experience in diagnostics and CLIA lab operations.
- **Defensible Patents Pending** – OTraces has filed for patent protection covering both the attainment of 90%+ predictive power and blood test biomarker access to the TME --- two high value claims across the cancer screening spectrum.
- **Large Addressable Markets –** North American available market for prostate and breast cancer screening alone approximate $2 billion for each indication, excluding other potential uses and other international markets.

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MISSION STATEMENT AND GROWTH PLANS

Mission

The company's goal is technological leadership in cancer and disease blood testing for detection and diagnosis through the application of unique, patented noise suppression and related technology. The principal strategic objective is the development and commercialization of prostate, breast and possibly other cancer screening tests in multiple countries, most likely starting in Canada, in order to establish a strong operating and clinical record as needed to attract a major strategic buyer or joint venture partner at a premium valuation. Potential strategic buyers might include large pharmaceutical and medical testing companies, as well as major IT and software companies. The estimated North American market for prostate and breast cancer screening approximates $4 billion in current annual sales.

Other opportunities include special-purpose and Active Surveillance monitoring and other tests, companion diagnostics (immunotherapy drug development), multiple tests in other therapeutic areas and collaborations with other companies and laboratories in the U.S. and abroad that may attract buyout interest from major companies.

Near-Term Growth Plans

OTraces is currently raising $2 million in convertible debentures in order to fund the following programs initiative to accelerate U.S. commercialization.

- **Completion of prostate cancer validation trials at Johns Hopkins**. Results to date have shown the PR Sera Dx blood test has the potential to substantially improve detection of aggressive (high Gleason score) prostate cancer --- the highest risk patients. The final phases will address the diagnosis of:

  i) **Intermediate Grade Prostate Cancer ---** under-diagnosed in the U.S. as it often goes undetected with PSA and other current tests and where improved active surveillance testing to detect tumor progression is a goal; and

  ii) **BPH (benign prostatic hyperplasia, not cancer) ---** a common affliction and primary cause of elevated PSA levels (potentially false positives).

  The JHU validation trial is expected to the most comprehensive clinical review of prostate cancer diagnosis and detection in well over a decade. The fact that the lead clinician, Dr. Kenneth Pienta, is a world authority in both prostate cancer and TME research should add to the trial's eventual impact on the medical and scientific community, and it should accrue to the significant benefit of OTraces where published information and peer review study has heretofore been lacking.

- **Launch a CLIA lab test in the U.S., not requiring FDA approval, to capitalize on the JHU prostate cancer results as they pertain to Active Surveillance.** This is a $200 million U.S. patient monitoring opportunity where the OTraces test is expected to fill an important market need. The product will be called the OTraces' TME Liquid Biopsy™ test.

CORE TECHNOLOGY

What is Predictive Power?

Most Challenging Performance Metric in Blood Testing

Where OTraces Excels Through Noise Suppression

Predictive power (PP), which represents the average of sensitivity (true positive) and specificity (true negative), is one of the most challenging performance metrics in cancer blood testing. **Predictive power scores higher than 75% are rarely achieved, with the notable exception of OTraces, which has consistently recorded 90%+. Accuracy at this level is believed key to obtaining regulatory approval for high-volume screening tests in global markets.**

False results (One minus the predictive power) are an important factor in the cancer blood test screening field. With 90%+ predictive power, the OTraces' test has a substantial advantage because this means false results are in the 0-10% range

This is why it is important that prostate cancer screening continues to be dominated by the PSA test three decades after FDA approval, despite a predictive power score of less than 60% (the average of 90% sensitivity and 25% specificity) and false positive rates as high as 75%. This performance helps to explain why PSA's market penetration in the U.S. male screening population in only 10%, and why Dr. Kenneth Pienta of Johns Hopkins has keen interest in completing the current OTraces prostate cancer validation trials. The cost consequences of high false positives and low accuracy for the PSA test over three decades (i.e. potentially unnecessary and expensive biopsies and other interventions) should boost OTraces ultimate market acceptance and screening potential. In the meantime, authorities in Canada and the U.K. have indicated that the OTraces PR Sera Dx blood test will receive fast track regulatory approval as a lower health care system costs screening alternative to PSA, due to significant reduction in unnecessary biopsies.

Despite its limited performance as a stand-alone test in detecting prostate cancer, PSA can be a versatile and useful test when used in combination with other markers. In fact with our noise suppression technology, it has become an integral part of the OTraces biomarker test panel for both prostate and breast cancer.

Proteomic Noise

Extraneous Distractions Throughout Blood Testing that Corrupt Performance

A major problem in cancer blood testing has been identifying the actions of proteins (or other biomarkers) that are indicative of the disease state (e.g. cancer) from samples whose activity (up or down regulation) may be caused by a multitude of extraneous factors such as other illnesses, medical conditions, alcohol or drugs. Within a large population with known states of disease and not-disease that could serve as the basis of a model to assess the correlation of the protein activity for diagnosis, there exists hundreds, if not thousands, of medical conditions or drug reactions that could affect the up or down regulation of the proteins of choice. ***OTraces has termed these non-disease factors that introduce potential diagnostic error "Proteomic Noise".***

OTraces Predictive Power 90%+
--------- *Proteomic Noise* --------- **e.g. Allergies, Asthma, Zantac, COPD, Influenza, bacterial infections, Rx drugs, Alcohol, Pulmonary hypertension, NSAIDs and other OTC meds, vaccines, etc.**
Industry Predictive Power = 75%

Noise Suppression for Blood Test Accuracy Enhancement

"Removing the Haystack"

This technology is related to the noise suppression techniques used widely in deep space exploration, but its use in cancer detection and diagnosis is more challenging and complex and has been extensively patented. The following illustrates the OTraces approach as it pertains to breast cancer.

Figure 1 presents a scatter-gram of two typical proteins, *VEGF* and *IL6*, important biomarkers in determining cancer status, as measure in 400 patients who have been diagnosed (via mammogram and/or biopsy) as either having breast cancer (red) or being cancer-free (blue). Note the poor discrimination between the disease and not-disease data points. This plot is typical of hundreds of such plots with other biomarkers. ***This poor discrimination is endemic across almost all known biomarkers***[2].

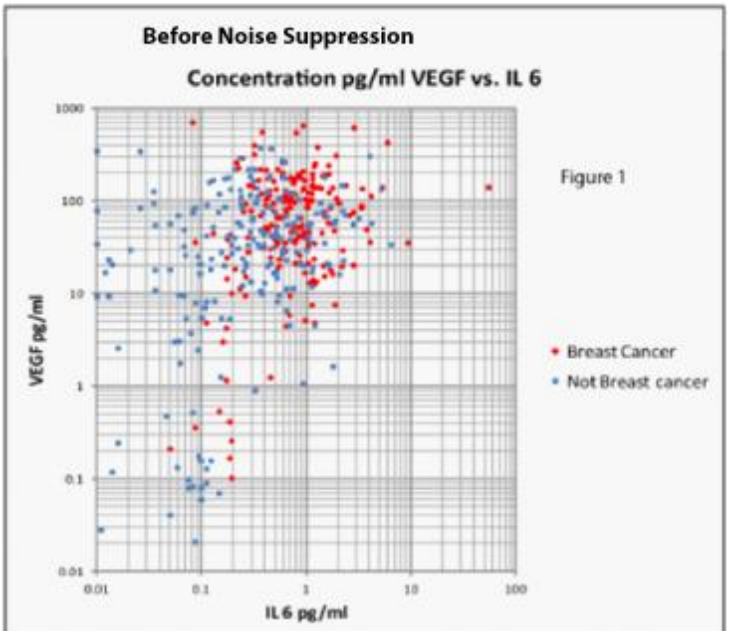


Figure 1

Figure 2 shows the same two biomarkers for the 400 women shown in Figure 1, after the OTraces noise reduction methodology has been applied. The proteomic cancer activity (the "needle") is spatially separated from non-cancer variations **(the "haystack").**

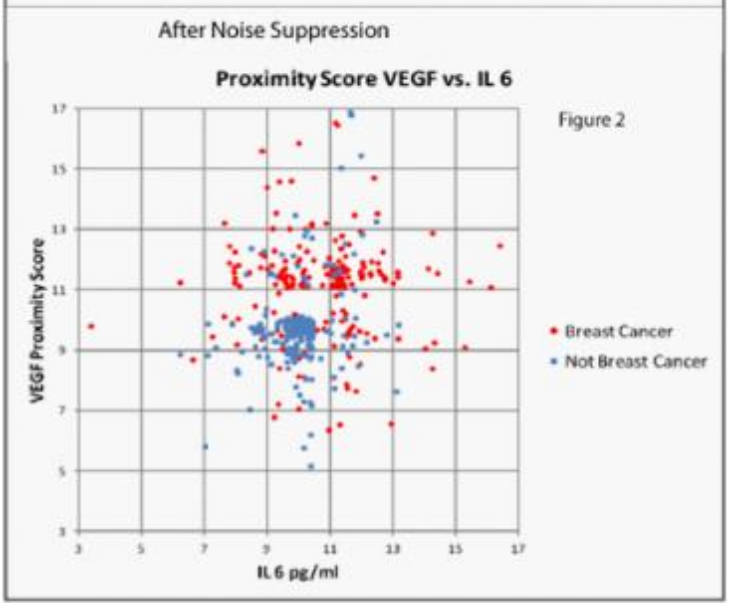


Figure 2

Note:

VEGF *and* ***IL-6*** *are 2 in a 5-protein breast cancer diagnostic panel in the OTraces blood test that uses all of them to generate a 5-dimensional grid.. The spatial separation increases as the additional dimensions are added, producing predictive power of greater than 95% using the proteomic noise suppression methods described herein.*

[2] **The Complexity Paradox** (Kenneth L. Mossman, Oxford University Press, 2014), the challenges faced by Proteomic Investigators are aptly summarized: ***"the nonlinear dynamics inherent in complex biological systems leads to irregular and unpredictable behaviors"***

Breast Cancer Receiver-Operator Curve (ROC)

Acid Test of Biomarker Orchestration and Noise Suppression

Figure 3 uses a classic ***ROC curve*** graph[3] for the same 400 samples shown in Figure 2, half with and half without breast cancer. The blood sample measurements were run on the OTraces CDx Chemistry System, at the Gertsen Institute in Moscow, Russia and analyzed with the proprietary OTraces software (which resides on a U.S. based server) using the spatial proximity and other techniques.

Figure 3 shows the progressive buildup of predictive power as each of the five biomarkers is added, as mentioned above. The most advanced curve (shown in red) depicts what is achieved by the additive combination of the five biomarkers using the OTraces approach. This curve achieves over 98% predictive power. The amplification results directly from the suppression of proteomic noise and the amplification effect from the retention of the "spatial" separation using the spatial proximity correlation method.

The data points on each curve are for computed cancer scores of 0, 20, 40, 60, 80 100(X), 120, 140, 160, 180 and 200. Note that at a score of 100 the true positive rate (sensitivity) and false positive rate 91-specificity) are greater than 95% for the cumulative effect of all five biomarkers (red).

The null line (tan) is that returned for a test with zero value 50/50%.

The Red Curve shows all five biomarkers with complete noise suppression and age mean adjustment correlation. The Green line shows four (less TNFα) and so on, see legend.

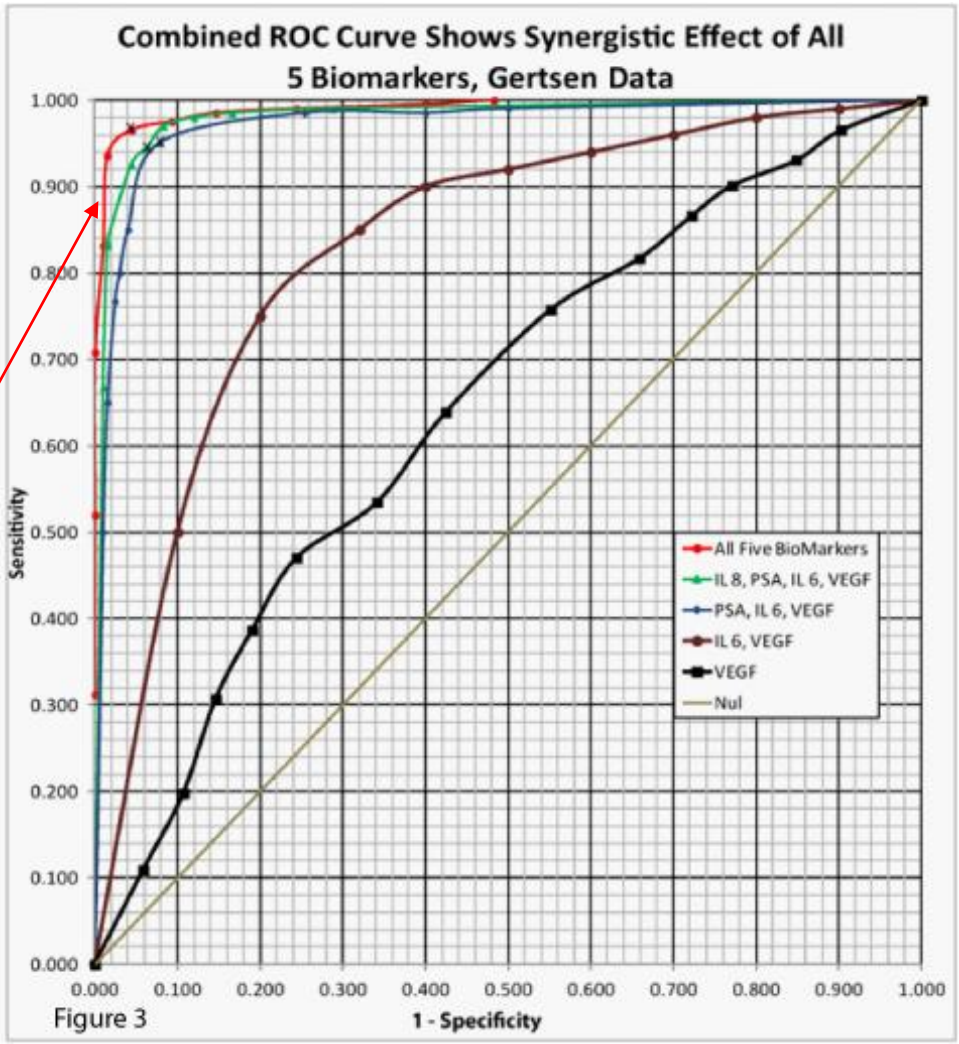


Figure 3

[3] The Receiver-Operator Characteristic (ROC) curve is a common way to graphically compare the Predictive Power of a given test, wherein the true positive rate (Sensitivity) is plotted in function of the false positive rate (1-Specificity) for different cut-off points of a medically relevant parameter.

Prostate Cancer Test Panel for JHU Validation Trials

The Prostate cancer test panel described herein uses the same five biomarkers as the breast cancer panel and demonstrated 90% predictive power when separating aggressive prostate cancer (Gleason score 7(4+3), 8, 9 and 10), from cancer-free samples. The ROC curve for this trial is shown in figure 4, below.

The blinded prostate cancer samples were measured at the Brady Urology Institute at Johns Hopkins. The topmost (blue) curve shows the five-dimensional results using the OTraces method described herein. The can be compared to the green curve, which portray the results from the well-known and currently approved PSA screening test for prostate cancer. The current PSA test achieves 90% sensitivity but sacrifices specificity which is only 57%. The OTraces method described herein achieves 95% sensitivity with a specificity of about 90%, substantially better than the PSA test.

Note that adjustment of the OTraces ROC curve decision point to achieve 98% sensitivity will cause a drop to about 85% specificity, still substantially better than the current screening test. The false negative is cut in half, 10% to 5%, and the false positive rate is cut by a factor of 7.5, 75% to 10%. With the adjustment of the sensitivity to 98% (2% miss called cancers) the false negative rate is still only 15%.

The Blue line shows the ROC curve for OTraces five biomarker panel with full noise suppression. The Green line is the ROC for the current PSA screening test. The Green X is the 4ng/ml diagnosis Set point.

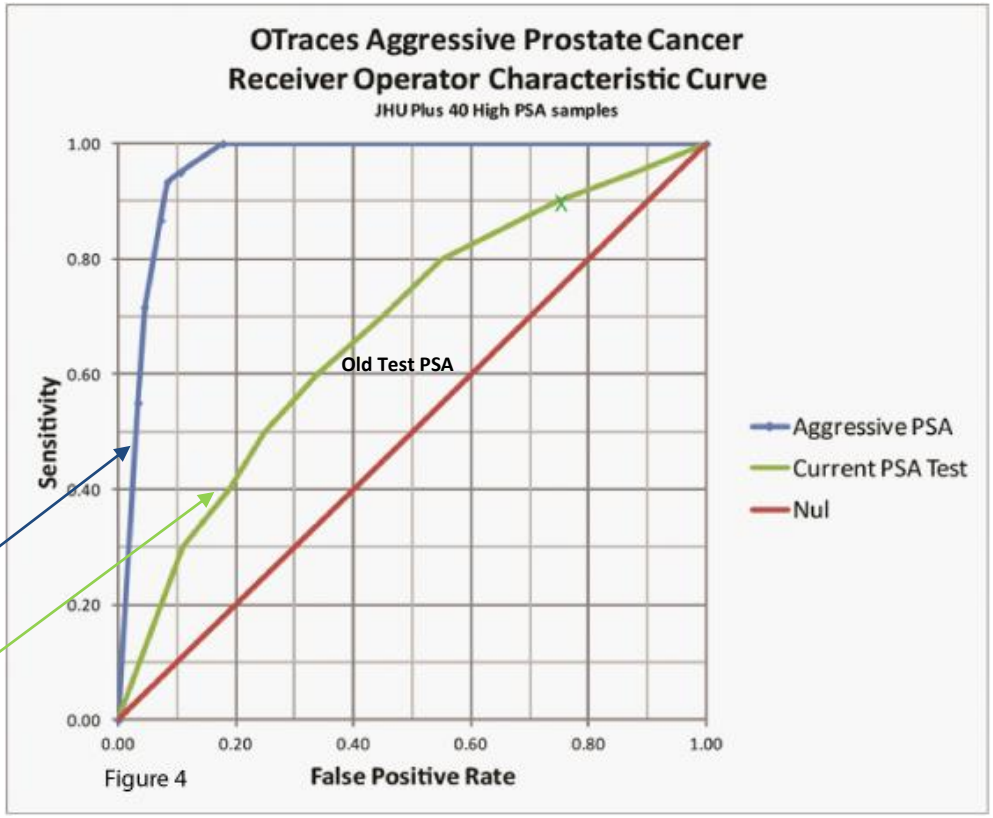
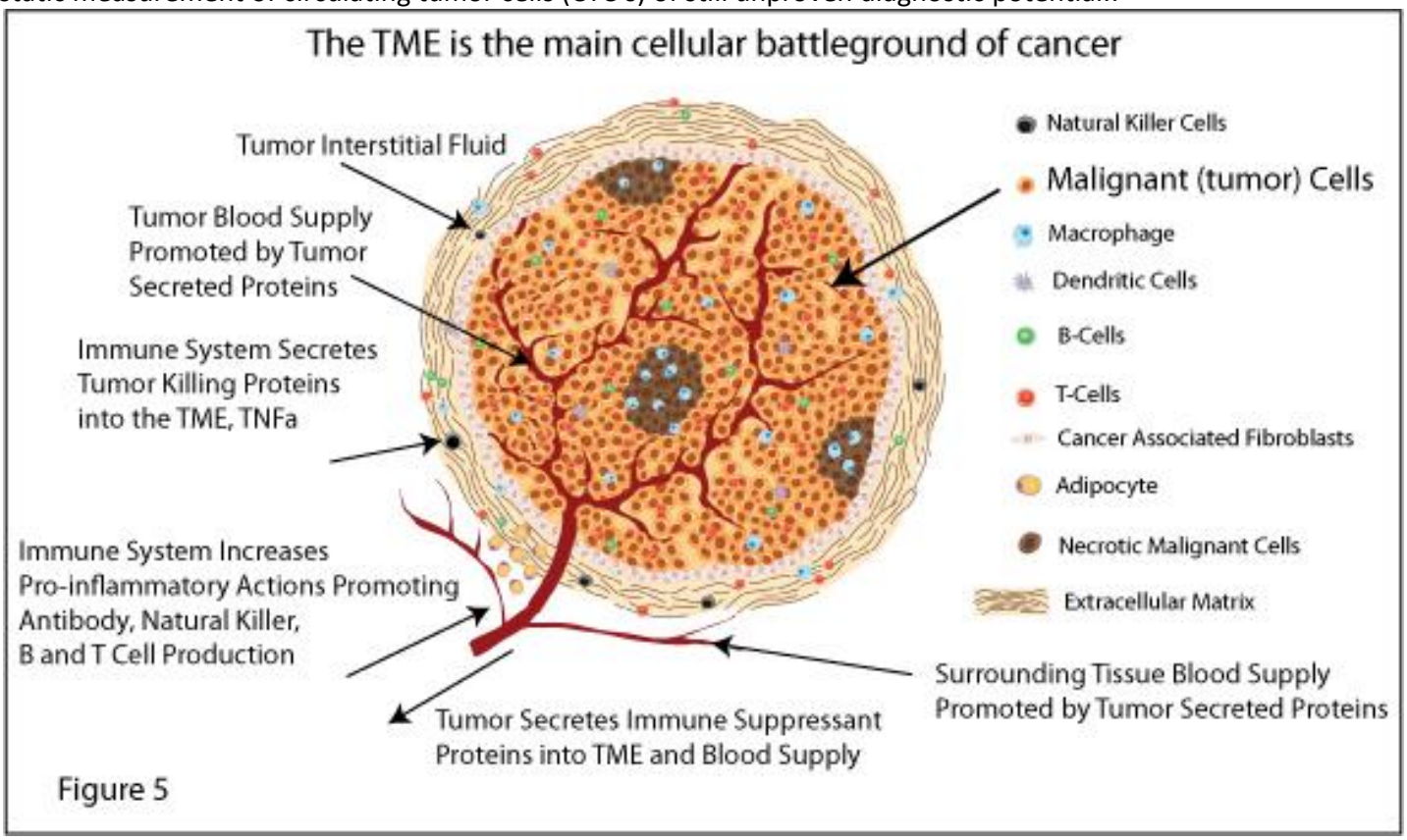


Figure 4

THE TUMOR MICROENVIROMENT

The cellular network that surrounds the tumor, the TME, is now widely recognized in science as far more important diagnostically than the tumor itself or tumor-centric tests like DNA liquid biopsy --- as it defines many aspects of the cancer disease process where the tumor is believed to be only partially involved.

The TME has become the main focus of drug research and the development and the search for broader spectrum T-cell and related compounds. The potential impact of the TME in cancer detection and diagnosis is believed equally substantial; utilizing the OTraces blood test approach, it could enable real-time and dynamic diagnosis of tumor status and progression without biopsy --- a large contrast relative to DNA liquid biopsy, which is, in our opinion, a static measurement of circulating tumor cells (CTC's) of still unproven diagnostic potential..



Protein activity within the TME reflects the conflict between the immune system and the tumor that is the principal center of immunotherapy and drug research at this time, as the research community searches for way to expand the efficacy spectrum of new treatments and to develop others.

A small portion of the complex struggle between the immune system and the tumor is captured in the activity of a number of cytokines measured by the OTraces process:

- **IL-6 and TNFα**. The immune system increases circulating interleukin 6 (IL 6) and tumor necrosis factor alpha (TNFα). These are attempting to suppress the tumor. IL 6 increase concentrations of natural killer cells, T and B cells both in the blood stream and within the TME. These proteins are systemically secreted into the blood stream and these actions are reflected within the TME.
- **IL-8 and VEGF.** The tumor itself secretes Interleukin 8 (IL 8) to promote blood vessel growth in surrounding tissues and vascular endothelial factor (VEGF) to promote blood vessel growth within the tumor bulk. The tumor also secretes immune suppressive factors such as interleukin 10 (IL 10) Into the TME.

All of these proteins are ultimately carried into the systemic blood stream and their activity is detectable via a simple serum concentration measurement using simple highly automatable immunoassays. The problem has been that the serum level concentration is contaminated by other factors, as discussed above. We term this problem "proteomic noise", which the OTraces noise suppression method addresses. Therefore, ***measuring the TME active proteins requires a unique approach to assessing their actions***. Directly sampling the TME interstitial fluid is not practical for two reasons:

i) Accessing these proteins is as complicated and invasive as a biopsy.

ii) As the TME occurs only when a tumor is present, no TME exists in patients who do not have cancer.

OTraces noise suppression technology allows using serum as a proxy for the TME.

The OTraces methodology allows using serum as a proxy for the TME. The serum characteristics (or signal) of the general population with and without an active TME is determined, a priori, via large cohort sampling. A compression methodology is applied to the sample that substantially suppresses the noise caused by extraneous conditions, allowing the protein activity caused by cancer to be measured. This compression method is tested for accuracy by its ability to differentiate cancer from non-cancerous activity in both a training set and a blind validation sample set. This method will accurately determine if a blind sample has an active TME or not. This same methodology is applied to differentiate different tumor conditions (aggressive/non-aggressiveness or tumor stage), as the activity of the measured proteins varies as the tumor condition changes.

Cancer Detection and Diagnosis

OTraces effectively appears to control this opportunity as it is the only TME blood test with extensive patent-pending IP. No other blood test has been able to penetrate the biological and chemical barriers in the tumor interstitial fluid that have made the TME off-limits to conventional blood test methods.

The OTraces TME blood test uses a panel of five well-known and well-characterized cytokines already in broad industry use but uniquely combined in such a way that each contributes to maximizing predictive power. **The use of the underlying math/physics-based technology is key because the TME in inherently extremely "noisy"**.

Biomarker Surge in the TME

(as measured in the Serum Proxy)

This graph shows biomarker (immune) surges in breast cancer -- recorded from serum "signature" measurements. Note dramatic surge during the transition for healthy (-1) to at Stage 0 tumor formation as seen in the yellow line (composite of all biomarkers

This shows how the cytokine patterns can track impact of immunotherapy and thus have a potentially important role in companion diagnostics.

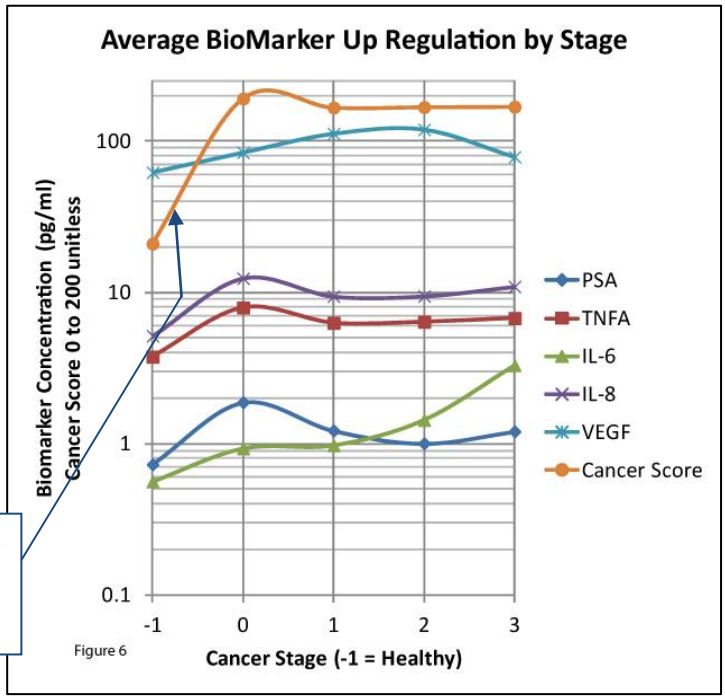


Figure 6

Note that the **Cancer Score** surges from an average 20 to 190 in the transition from "healthy" to stage 0 breast cancers (a very small 2mm tumor) mostly missed by mammography).

Figure 6 above shows the actions of four of these functional cytokines (and one tumor marker) for about 400 women with breast cancer. The graph shows average actions of IL 6, IL 8, TNFα, VEGF and a tumor marker, PSA, versus a scale of cancer stage for these 400 women[4]. On the horizontal axis, **-1 means women without cancer** (putatively healthy). The follow-on stages for women with cancer (stage 0, 1, 2, and 3) are also plotted on the horizontal axis. As can be seen, three of the measured biomarkers up-regulate sharply at stage 0 breast cancer then subside as the tumor stage progresses. **The average cancer score for each cancer stage is shown as the tan line --- it progresses from an average of 20 for the Stage -1 (not cancer) women and spikes over 300% to an average of 190 for stage 0.** The cancer scoring is an arbitrary range of 0 to 200 with 100 being the midpoint and 100 to 200 being cancer positive.

Active Surveillance Monitoring for Men with Low Grade Prostate Cancer

Detecting Tumor Progression That Other Tests Like PSA Often Miss

The protein activity observed in the TME caused by breast cancer ("Immune Surge") is also seen in prostate cancer. Men with low grade tumors are at risk of converting to high grade or aggressive PCa in the future; the problem with current Active Surveillance monitoring tests, including PSA, is that the tests often miss this life-threatening transition.

OTraces' TME-based method resolves this problem. Our studies to date show that these TME-active proteins, with noise suppression, tell the story about what the tumor is doing. For example, the conversion from low grade to aggressive PCa is accompanied by a dramatic increase in VEGF secretion by the tumor, as well as the aggressive secretion of an immune suppressing protein (**IL 10**). This results in the active immune system controlling protein, **IL 6**, being suppressed to below what would be seen in normal or men without any PCa at all. That is, the tumor's activity is suppressing the immune system so deeply that its activity is less than normal and can be measured with the OTraces test.

Utilizing the OTraces **TME Liquid Biopsy™** blood test in the active surveillance protocol (testing every 6 months) could well make active surveillance the preferred treatment modality for these men due to the high predictive power (90%+) of this test.

The OTraces test is expected to be implemented under the FDA Clinical Laboratory Improvement Amendment (CLIA) which provides an exemption for a Laboratory Developed Test (LDT) and which can be launched without a formal clinical trial. It requires only the approval of the physicians at the medical facility where deployed. A similar test already has a diagnostic reimbursement code (DRG) for $600 per test, which the OTraces test can utilize. As the OTraces test costs about $60 per sample to run, the margins would appear to be strong.

Our plan is to initially place all 1,800 men currently in active surveillance at JHU into the OTraces test protocol. JHU also believes that an additional 2,000 men with low grade PCa who are currently electing surgery each year rather than surveillance, will opt for surveillance instead. Expanding the test to other institutions (e.g., M.D. Anderson, Memorial Sloan Kettering, Mayo Clinic) also simply requires approval of the practicing physicians at these facilities (JHU would recommend the test). This total available market appears to be about $200 million annual.

OTraces manage expects revenue from this test will partially fund future clinical trials for screening tests and it will propel the company valuation such that such fund raising will significantly lower dilution. The forecast shows revenues can reach $3, $8, $13.7 and $19 million for years 1, 2, 3, 4 respectively, and EBITDA of $8 million in year 4.

PRODUCTS, SERVICES AND POTENTIAL

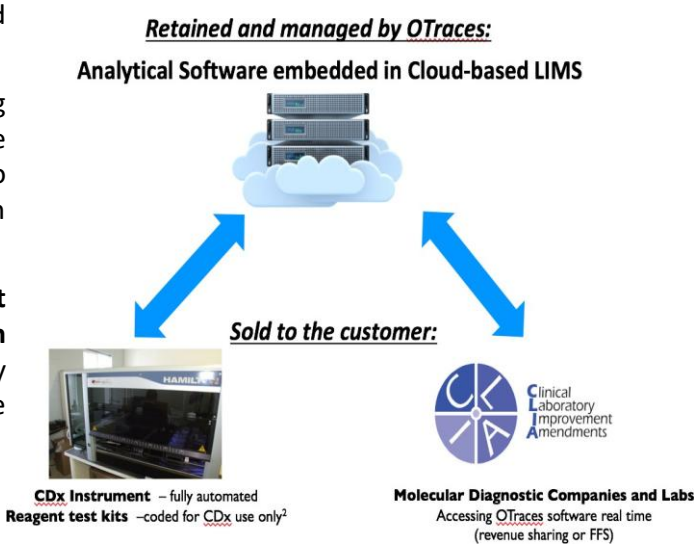
Instruments and the Laboratory Information System

The OTraces methodology is software driven, with all software domiciled exclusively in a U.S. resident **proprietary cloud-based laboratory information management system** ("LIMS") under OTraces control that uses FDA-compliant archival software. Accordingly, all data from the company's instruments in the field can be collected and stored on the OTraces' servers in the U.S. While the blood sampling and immunoassay is performed in the field, results are transmitted back to OTraces in Maryland for evaluation and interpretation by the software. The immunoassay reagents are OTraces specific and coded so that field analytical instrument will only run these reagents.

As a result, this critical analytical element is always under OTraces complete control. The test output from the algorithm, known as the Cancer Score, which is also captured in LIMS, is transmitted back to the originating physician.

OTraces is also a cancer diagnostics service company making available special purpose CLIA-lab tests such as prostate cancer patient monitoring and accuracy enhancement to companies and labs worldwide through collaboration with OTraces.

The company's fully automated **CDx Instrument** and **reagent test kit** are manufactured to specifications by **The Hamilton Company** and **Maxim Biomedical,** respectively --- widely regarded as among the leading contract suppliers in the medical device/testing field with global capabilities.



Prostate Cancer Assay – the PR Sera Dx Test

Using the same approach and methods as with the earlier-developed breast cancer assay, OTraces has achieved high predictive power in prostate cancer trials. Dr. Kenneth Pienta, a Professor of Urology/Oncology and a leading expert in prostate cancer at Johns Hopkins University Medical Center is conducting the first prostate cancer test validation trial in North America using serum samples banked in the JHU repository. Results of the recently concluded study at JHU demonstrate that the PR Sera Dx blood test has the potential to substantially improve detection of aggressive (high Gleason score) prostate cancer --- the highest risk patients where an accurate blood test could save lives. The next phases of the JHU trial (subject to funding) will address:

- **Intermediate Grade Prostate Cancer** --- under-diagnosed in the U.S. due to marginal accuracy and unpopularity of the PSA screening test (only 10% market penetration 30 years after its FDA approval), and;
- **BPH (benign prostatic hyperplasia**; not cancer) --- common affliction especially in older males and primary cause of elevated PSA levels (potentially false positives).

OTraces expects these next phases will be equally as successful as the first phase study. Dr. Pienta sees these trials as an opportunity to publish the first comprehensive review of the main diagnostic issues surrounding prostate cancer detection in at least a decade, which is expected to be completed within 60-80 days of receipt of funding. This will provide the platform for the launch of the LDT for active surveillance of at-risk prostate cancer patients via a CLIA lab that OTraces will establish or joint venture with an established CLIA lab operator.

Plans to begin the next phase of prostate cancer validation trials in the Russian Federation have been deferred, while in Canada interest in encouraging development of new prostate screening technologies has led to a significant reduction in Canadian regulatory approval requirements for a prostate cancer test in that country. Management estimates the entire anticipated Canadian approval process could be completed in 12-18 months at a cost of less than $3 million. (This initiative would be financed separately in the future and is not included in the financial projections included herein).

Phase I JHU Prostate Cancer Validation Results:
For Aggressive Prostate Cancer (Completed)

As compared to the current PSA test, the results are significantly better for the OTraces PR Sera Dx test. The current PSA test for prostate cancer (at the medically accepted cut-off point of 4 ng/ml PSA concentration) yields 90% sensitivity (10% false negative rate) and 25% specificity (~75% false positive rate) **which yields an overall predictive power of 57%**.

The sensitivity and the false positive rate of the standard PSA test is shown on the ROC curve, see figure 4 above, as the "X" on the green curve. Plotted in blue are the results of the OTraces test. At 95% sensitivity (or 5% false negative rate, ½ that of the PSA test) this test produced 87% specificity (13% false positive rate). **If a ROC curve cutoff is chosen at a lower specificity, about 84% (slightly higher false positive rate, 16%) the sensitivity is near 100% (1% or less false negatives) a very solid medical outcome**.

The findings of the blinded trial are compared to the standard PSA test in the following table:

Johns Hopkins University – High Gleason Score Samples **Validation (Blinded) Sample Results**			
	Current PSA Test*	**OTraces Trial**	**OTraces better than PSA by:**
Predictive Power	57%	89%	significant
Sensitivity	90%	95%	
% False Negatives	10%	5%	2X
Specificity	25%	87%	
% False Positives	75%	13%	3.5X

*at the ROC curve cutoff of 4ng/ml

It is apparent that the OTraces test is a significantly better predictor of prostate cancer than the current PSA test, with the added benefit that improvement in both the false negative and false positive rates could reduce the number of unneeded biopsies.

Breast Cancer Assay – the BC Sera Dx Test

OTraces has been conducting breast cancer detection trials at the Gertsen Institute in Moscow. While further development has been deferred pending the completion of this offering, the results of the OTraces trials to date have been impressive.

MANAGEMENT

Keith Lingenfelter
Founder, CEO and Member of the Board of Directors

Mr. Lingenfelter was VP & General Manager, Diagnostics for **IGEN International** where he managed the development of a breakthrough luminescent immunoassay technology for measuring the concentration of proteins and DNA in biological fluids[5] that was eventually sold to **Roche** for $1.5 billion in 2003.

Prior to IGEN, he Mr. held several management positions at **Abbott Laboratories** where he was primarily involved in strategic marketing and management of large R&D programs that developed chemistry instrumentation and reagents for clinical assays for the in-vitro diagnostic market. Mr. Lingenfelter has a Masters degree in engineering from California State University.

Alain Cappeluti
Chief Financial Officer and Member of Board of Directors

Mr. Cappeluti has more than 30 years of experience in finance and public accounting, and has participated in $4 billion of corporate financing transactions. His management experience in the biotech industry includes **BioReliance**, **Human Genome Sciences** (HGS), and **CoGenesys**. He joined HGS in 1992 at its founding and served for many years as VP of Finance. He was part of the team that spun Cogenesys out from HGS in 2006 and was its' CFO until it was sold to **Teva** Pharmaceuticals in 2008. Mr. Cappeluti serves on the Board of Directors and is currently the company's largest shareholder. It is the Company's intention to recruit a full-time CFO in the future as warranted by business activity.

Dr. Richard Saul
VP, Research and Development

Dr. Saul brings skill and in-depth experience in the R&D and technical support of diagnostic products in the areas of clinical chemistry and rapid microbiology. He was a founder of Axo Diagnostics, VP Product Development at Celsis-Lumac plc, Director of Assay Development at **IGEN International** and Director - Chemistry R&D, **Dade Stratus, and Baxter Diagnostics.**

Suzana Radulovich, M.D., PhD
Vice President and CLIA Laboratory Medical Director

Dr. Radulovich has over 20 years of experience in laboratory medicine as well as the development of diagnostic methods, bacterial pathogenesis and molecular biology, and was formerly the medical director of **20/20 GeneSystems, Inc.** Since 2009, she is Medical Direct of a high complexity Clinical Laboratory and owner of a family care/urgent care practice in Bel Air, MD. She is author of 33 peer reviewed publications and has been the principal investigator on numerous NIH grants.

Additional Management

The Company has been operating with a group of long-time business associates of Mr. Lingenfelter who are acting in a consulting capacity in order to keep expenses low. These consultants perform functions such as engineering, software development, immunoassay development, clinical laboratory product development, regulatory affairs coordination, Clinical Research Officer function, etc.

Scientific Advisory Board

[5] Use of noise suppression by OTraces, like luminescence by IGEN, reflects his multi-disciplinary approach to product development.

The company is planning on establishing a SAB in the near future that will include Dr. Richard Saul and others and is expected to include distinguished specialists including **Dr. Kenneth Pienta** who is the Donald S. Coffey Professor of Urology at the Brady Urological Institute of Johns Hopkins School of Medicine and as Professor of the Departments of Oncology and Pharmacology and Molecular Science at JHU.

FINANCIAL BACKGROUND

Unlike many development stage biotech companies that raise equity capital at premium valuations, OTraces lacks big name sponsorship and peer reviewed published articles on the technology are not yet available which is why the results from the Johns Hopkins validation trials for prostate cancer are expected to be a game-changer for OTraces in terms of industry profile recognition and stock the valuation. The current $2 million convertible debenture offering is priced at a pre-money valuation of $10 million (excluding the State of Maryland Biotechnology Investment Tax Credit, see below) which compares with $50-70 million for comparable situations in DNA liquid biopsy.

The total investment in OTraces since the company's founding in 2008 has been under $3 million, including clinical validation and development work for breast cancer at the Gertsen Institute in Moscow which was mostly subsidized by business partners. Investors are mainly from company officers and other insiders including Messrs. Cappeluti and Lingenfelter, (Founders and CFO, CEO respectively) and others with extensive experience in the biotechnology and immunodiagnostics field.

The Maryland Biotechnology Investment Incentive Tax Credit ("BIITC") is available to investors both inside and outside Maryland as well as internationally. TBIITC is a refundable credit, meaning that if no tax is due in Maryland, the BIITC is paid to the investor in cash. The credit is 50% of the amount invested in equity, up to a maximum of $500,000 of investment per investor, subject to certain restrictions. In addition, Montgomery County, where OTraces is located, has a supplemental incentive plan that can add up to an estimated additional 8% to the credit. Convertible debt is eligible upon conversion.

Investors in the current offering may be able to take advantage of the BIITC. The state utilizes a "first come, first served" queuing system to prioritize the allocation of the credits. Applications for the queue are taken beginning in June of year for the following fiscal year. While the potential exists for investors to qualify for the BIITC in FY2018, the Convertible Notes should be eligible for FY2019, beginning July 1, 2018.

PATENTS AND INTELLECTUAL PROPERTY

Predictive Power Enhancement Drives Product Development and Most IP

The omnibus patent filed by OTraces on January 22, 2016 **(Publication Patent Number WO2014158287) covers**:

- All known routes to the achievement of 90%+ predictive power.
- Combining physics, measurement science and new proteomic tools with functional classes of biomarkers utilizing a unique correlation method, and;
- Combining non-concentration physiological patient data with proteomics, and methods for normalizing age drift in disease transition;
- Use of protein markers that measure the microenvironment around the tumor (TME) and using the same data to predict cancer stage and tumor aggressiveness.

Management believes that OTraces has most if not all of these methods covered under current patent submissions and that this portfolio constitutes "blocking patents". Some of these patents may be combined in the patent prosecution process but all concepts have been validated and will be included in the patents prosecuted through to issuance. OTraces' patent strategy is to continue to patent methods it discovers that will improve predictive power of the correlation methods used in the OTraces method. Instead of patenting equations or "algorithms", OTraces employs a complex layering of "method patents" that involves eleven (11) claims which are necessary to compute the blind sample score. On top of the method patents are new novel "use patents" for the TME active proteins.

The biomarkers in the TME are related to the action of the immune system to kill the tumor and actions by the tumor to survive and grow. Typically, these are immune system pro-inflammatory and cell apoptosis (tumor cell killing) cytokines, tumor source circulatory signaling proteins, and others that the tumor secretes into the circulatory system to promote its growth (circulatory) as well as suppress the immune system and finally only one tumor marker.

Patented Methods and Procedures: First Level of Patent Methods

- **Use of protein markers that measure the microenvironment around the tumor.** These markers are related to the action of the immune system to kill the tumor and actions by the tumor to survive and grow. Typically, these are immune system pro-inflammatory, and cell apoptosis (tumor cell killing) cytokines, tumor source circulatory signaling proteins, etc. that the tumor secretes into the circulatory system to promote its growth, and finally only one tumor marker.
- **In order to fully extract predictive power from these proteins, a specialized spatial proximity correlation method is used that retains the orthogonal actions of these biomarkers as cancer progresses.** Regression methods do not retain this information. These markers up-regulate in the transition from "healthy" to cancer in patterns or clumps. OTraces predictive model is developed to properly represent these actions of the immune system and tumor in multi-dimensional space. Non-malignant up regulating conditions that do not follow these patterns are correctly called not-cancer.

Secondary level of Patent Methods

- OTraces incorporates inherent measurement uncertainties as they vary over the measured concentration range by adjusting influences on the computed cancer scores.
- OTraces uses specialized compression and expansion of the concentration to pseudo- concentration transition to reduce what is called spatial density bias in the "Spatial Proximity Correlation Method".
- The Spatial Proximity Correlation method is a topology-based method where the individual sample points are plotted in multi-dimensional space. These methods suffer from stability errors due to individual sample data

points sitting on topologically unstable areas (e.g. tips of steep cone shaped topology in three dimensions). These errors can be found and corrected (both training set and blind samples), by using the patented method incorporating a topologically different algorithm (incongruent).

The OTraces patented predictive power enhancement process:

On training set model	PP Increase
▪ Use of Orthogonally Functional Biomarkers with the Spatial Proximity Correlation method	~10%
▪ Meta-variable method (normalize age cancer transition drift)	~5%
▪ Upgraded influence by degree of non-linear up regulation	~+1%
▪ Reduced influence of assay noise space	~+1%
▪ Reduced influence of topology instabilities	~+1%
Fixing the blind data sets	
▪ Use of 2nd incongruent training set to arbitrate unstable points	~2%

Special Prostate Cancer Patent

During the JHU prostate cancer detection trials, VEGF and TNFα exhibited certain actions that indicated very strong predictive power on their own and in conjunction with PSA. A review of the scientific literature and the patent data base did not turn up any research or patent activity related to the use of these biomarkers in detecting aggressive prostate cancer, nor any evidence that this action had been previously observed.

Additionally, the findings indicate that the aggressive form of prostate cancer secretes strong immune suppressive proteins to promote its growth. Accordingly, OTraces has filed for a special patent relating to the observed actions of these biomarkers for detection of aggressive prostate cancer as a defensive measure. OTraces clinical assay will not likely use just these biomarkers as the other cytokines will be needed to separate non-aggressive from aggressive prostate cancer. A particular strength of this method will be the ability to distinguish the various stages of tumor growth as the disease progresses.

MARKETS AND COMPETITION

Market Size

Prostate Cancer Testing.

An estimated $4 billion is spent on screening and diagnosis of prostate cancer annually --- importantly due to the high incidence of physical biopsies and similar procedures which are typically priced at $3,000-4,000 each, rather than by PSA tests that are relatively inexpensive. The PSA test is still the most widely used cancer screening test which has become a hollow claim for cancer blood screening in general since PSA's market share now stands at only about 10-12% of adult males in the screening population.

Newer blood tests have been launched in recent years and sold at premium prices but predictive power of even the best remains in the mid 60% range --- better than PSA but well below the OTraces' 90%+ level.

- **OPKO Health's 4K Score Test**. This lab developed test launched in 2015 has effectively paved the way for strong interest in the OTraces' TME Liquid Biopsy Test™ for active surveillance by building physician and market interest in detecting tumor progression before it reaches the aggressive stage and recently obtaining Medicare reimbursement in the $600/test range which is less than the $1,000+ some DNA liquid biopsy tests are still receiving but an attractive level from OTraces' standpoint.

  The 4Kscore® Test was designed to identify a man's risk for aggressive prostate cancer. While the literature seems to say that the 4K Score test is better than PSA alone, OTraces has determined that the overall results are as follow: 93% sensitivity but specificity of only 45% would puts 4K in the 69% predictive power range.

- **Beckman Coulter's Prostate Health Index (or phi) Test.** Co-developed by the Mayo Clinic, the phi test claims to reduce biopsies by 30A%. The *phi* is a mathematical formula that provides the probability of prostate cancer on biopsy by combining three tests (prostate-specific antigen [PSA], free PSA, and p2PSA) into a single score. The score is tailored to each patient, aiding in the diagnosis of prostate cancer. Essentially, the test fills the diagnostic gap between a prostate blood screening and prostate biopsy

  Phi is similar to 4K Score but again it has low specificity. Reducing "unneeded" biopsies by 30% still implies a lot of inherent inaccuracy relative to what the OTraces' test typically achieves..

Breast Cancer Testing.

The market for non-invasive breast cancer testing (primarily screening mammography) is estimated to be $850 million annually in the United States and $1.8 billion annually worldwide, and presents a major opportunity for the OTraces breast cancer blood test to substantially impact medical practice and expand the market.

Laboratory Developed Tests

In-vitro diagnostics ("IVD") is estimated to approximate at least a $10 billion market and, according to Toronto-based MaRS Research, **over 90% of sales are not FDA approved owing to exemptions from FDA statutes for laboratory developed tests (LDTs or CLIA lab tests).** One of the fastest growing sectors is DNA-based liquid biopsy tests which have been a boon to companion diagnostics and drug development, but where the track record in early and accurate tumor detection has yet to be well established may be difficult and expensive to clinically validate.

OTraces plans to enter the LDT field on a selective and opportunistic basis, as seen by the planned launch of a prostate cancer Active Surveillance CLIA lab test which will put the company in a $200 million market niche with a

highly promising test that may substantially outperform current diagnostic alternatives.

Breast Cancer Detection

Screening mammography is not without its limitations and management believes that predictive power averages roughly 80%. This can be small comfort to women who test positive in genetic screening tests, which has given to a rise in an increasing incidence of prophylactic surgical intervention -- sometimes still known as the "Angelina Jolie Effect". In early 2014, the Swiss Medical Board published a report recommending that no new systematic mammography screening programs be established in that country. The board reported becoming "increasingly concerned" about the widely-believed notion that mammograms were safe and capable of saving lives, but concluded that statistics clearly indicated that mammograms appeared to be preventing only 1 death per 1,000 women screened, and actually caused harm to many more.

More on DNA Liquid Biopsy

Grail, Inc. has raised over $1 billion to develop a simple and accurate cancer blood test for screening and appears to be at least 2 years away from clinical proof of concept which would put them well behind the OTraces' development plans clinically, not to mention the inherently high costs and limited scalability of the Grail approach which we think makes high-volume screening appear problematical. (See comparison with TME in table below)..

The DNA liquid biopsy approach involves scanning the blood for circulating tumor cells ("CTC's"), "floating" cancer tumor cells and/or tumor DNA that are released into the bloodstream as part of the metastatic process. A recent development in liquid biopsy research is the detection of exosomes wherein particles of DNA may be theoretically detectable at an earlier stage.

The challenge for liquid biopsy includes the fact that early stage tumors are generally not metastatic and likely do not show detectable CTC's. Moreover, the methods for finding one or a few tumor cells or extracting tumor DNA from blood is complex and costly and a static DNA determination of a patient's potential future risk would not seem to compete with OTraces TME blood test methods that show real time tumor diagnostic conditions.

The table below compares OTraces TME based method versus liquid biopsy.

Clinical			Economic		
	TME (OTraces)	DNA		TME (OTraces)	DNA
Accuracy	90%+	Unknown	Competitors:	None (patented)	30+ companies
Diagnosis	Real time	Prognosis only	Unit Pricing:	< $100 screening, at 80% plus Gross Margin	$2,000
				$600 monitoring at 80% plus Gross margin	Cannot Screen or Monitor
Over-diagnosis risk	Rare	High	Hi-Volume Screening Scalability:	High	None
Biopsy dependent	No	High	Screening Reimbursement Risk:	Low	Very High

The problems with liquid biopsy are manifold.

- First the presence of mutant tumor DNA does not necessarily indicative of the presence of an active tumor.
- Nor can it determine what proteins are actively being encoded and thus what current TME actions are.
- Finally the method is complex time consuming and not compatible with high volume screening and not compatible with high reimbursement cost pressures. The method simply does not present a business proposition for high volume screening. OTraces method using simple immunoassay protein measurements is compatible with all technical and business needs of the solution.

“Big Data”

Using IBM Watson Data Analytics Machines and Other Approaches

Research is currently proceeding rapidly with respect to “Big Data” which combines data analytics with medical imaging to help reduce the subjectivity in interpreting the images by humans, while also factoring in a person's genetic makeup, lifestyle, and environment. The method attempts to apply artificial intelligence to image analysis by using massive amounts of data to arrive at a diagnosis.

Work on image pattern recognition is not new, but the application of this approach to medical diagnosis has shown consistent problems with consistency and correlation. Typically, the algorithm must be trained by a medical doctor's eye and brain as to what a tumor (or non-tumor) looks like. For very small subjective visual artifacts this has been shown to be very difficult. Doctor-to-doctor differences in interpreting the image leads to this inconsistency. Adding genetics, lifestyle and environment to the equation (all future risk factors) has not been proven to add value to the real-world detection call of “cancer” or “not cancer”.

OTraces' blood-based method tells the physician the state of the patient’s body at the exact time the blood is drawn. Is the immune system reacting to a possible tumor, is the tumor acting on the body to grow and prosper when the blood is taken for analysis? The OTraces method provides an answer to that question.

GLOSSARY

Blind Sample.
A biological sample drawn from a subject without a known diagnosis for a given disease, and for whom determination or prediction of the presence or absence of that disease is desired.

Cohort Study.
An analysis of risk factors for a group of subjects who may or may not have a disease and uses correlation to determine the absolute risk of a subject contracting the disease.

Cytokines.
Low abundance signaling proteins in the immune system that are secreted by immune cells and act on other cells to coordinate appropriate cellular responses. Cytokines include a diverse assortment of interleukins, interferons, and growth factors. The OTraces methodology for prostate and breast cancer screening tests measures and evaluates the following cytokines, that generally fall into two different categories:

Actions of the immune system to destroy the tumor:

- **Interleukin 6 ("IL-6")** – pro-inflammatory, indicating general immune system uptick in action
- **Tumor Necrosis Factor Alpha ("TNFα")** – causes cellular apoptosis (systematic cell death). *Actions of the tumor to grow and survive:*
- **Vascular Endothelial Growth Factor ("VEGF")** – stimulates growth and/or expansion of blood vessels in the tumor.
- **Interleukin 8 ("IL-8")** – indicative of blood vessel growth in nearby or surrounding tissue. **Exosomes.** Exosomes and other extracellular vesicles are released by many cell types, including cancer and cancer-related cells. In cancer, extracellular vesicles can transmit DNA proteins and nucleic acids. Circulating extracellular vesicles may act as biomarkers of cancer, and detection of these biomarkers may be applied to diagnosis or assessment of prognosis in patients with cancer.
- **Interleukin 10 ("IL-10")** – indicative of immune system suppression secreted by late stage tumors to stop immune system actions to kill the tumor.

Gertsen Institute.
Founded in 1898 and based in Moscow, it is the oldest Institute in Russia dedicated to oncology research and cancer treatment, and widely considered an important center for clinical trials in the region. Dr. Sergeeva, who has been directing the OTraces validation trials, is the spokes person for Abbott Labs in the Russian Federation. Gertsen Institute ties with the Russian Ministry of Health are strong.

Low Abundance Proteins.
Proteins with concentration levels of less than 1 picogram/ml. in samples of blood serum or other body fluids.

Predictive Analytics.
A branch of data mining concerned with the prediction of future probabilities that that may eventually have a role in cancer diagnosis, but is unlikely to compete with OTraces in detection and high-volume screening.

Predictive Power ("PP").
The average of sensitivity ("SN") and specificity ("SP") (i.e., 90% SN and 80% SP yields 85% PP). Predictive power is calculated as: one minus false negatives plus total false positives, divided by total number of samples, and will not change as one adjusts sensitivity and specificity of the test. This descriptive method perhaps better indicates a test's effectiveness better than Sensitivity and Specificity (defined below) combined. For example, the PSA test for prostate cancer has a sensitivity of 90%, but its specificity is only 25%, yielding a predictive power of only 57.5%.

Proteomics.
The branch of biochemistry concerned with the structure and analysis of the proteins occurring in living organisms. In diagnostics this usually means the study of a multiplicity of proteins and their actions associated with the transition to disease.

Proteomic Noise Suppression
Proteomics seeks to assess or detect disease presence by measuring multiple proteins associated found into the blood stream (serum) associated with the disease either by function or by proteins sloughed off into the blood by physical presence of disease related structures. The problem with this method is that no protein has been found that is highly specific to any such disease.

The problem is that all known proteins that may have an association with a disease state are also affected by many conditions that exist with the body, known or unknown. Thus, these proteins represent an equivocal answer to the question of the presence of a particular disease. This is termed Proteomic Noise.

The technical method discussed herein uses well known mathematical methods for suppressing this noise. The noise is represented by information in the serum measurements that is not coupled to innate properties of the disease state of interest. These properties are determined by measuring the serum signature of the proteins (mean values) for samples known to have the disease state and comparing this signature to samples known to not have the disease state. This difference in signature is if it exists is said to be the signal of the disease. These determinations can separate unknown samples into two categories --- those with the disease in question and those without.

ROC Curve.
The receiver-operating characteristic (ROC) curve is a common way to compare diagnostic tests. Initially developed in WWII for radar analysis to differentiate incoming enemy planes from flocks of birds and other "false positive" signals, in a ROC curve the true positive rate (Sensitivity) is plotted in function of the false positive rate (100-Specificity) for different cut-off points of a parameter. Each point on the ROC curve represents a sensitivity/specificity pair corresponding to a particular decision threshold, and graphically displays the Predictive Power of a given test.

Sensitivity.
Measures the proportion of actual positives that are correctly identified as such and is complementary to the false negative rate.

Specificity.
Measures the proportion of actual negatives that are correctly identified as such and is complementary to the false positive rate.

Training Sample Set.
A set of biological samples with a known diagnosis of the "disease" or "not- disease" state used for training the mathematical methods to accurately predict the disease diagnosis in the general population. Statistically, OTraces methods require a minimum data set of at least 100 not disease and 100 disease samples.

Tumor Microenvironment ("TME").
The cellular environment immediately surrounding the tumor, composed of surrounding blood vessels, immune cells, fibroblasts, bone marrow-derived inflammatory cells, lymphocytes, signaling molecules and the extracellular matrix. The TME has become recognized as a major factor influencing the growth of cancer, having been implicated in the regulation of cell growth, determining metastatic potential and possibly determining location of metastatic disease, thus impacting the outcome of therapeutic regimens.

Validation Sample Set.
A group of several hundred or more "blind" samples used to validate the "Trained Model" developed using the "Training Sample Set". These samples have the diagnosis (either "disease" or "not-disease") known only to the Regulatory Authority. They are run by a third party reference institution and scored by OTraces method fully "blind".

They are then validated for product claims by the Regulatory Authority. A fully released diagnostic package with market clearance by the Governmental Regulating Authorities (e.g. FDA or Russian Ministry of Health) includes the mathematical model, the Training Sample Set data, the Validation Sample Set data, and scoring results.

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