

Q&A with Dr. Ken Hughes, CEO of iTP Biomedica bringing to market their Big Data Bioinformatics-Driven BladderPredict[®] Genomics Diagnostics Test predicting the trajectory of Early Stage Bladder Cancer



Dr. Ken Hughes
Chief Executive Officer

iTP Biomedica
www.iTPBiomedica.com

Contact:
Kenneth Hughes, PhD
hughes@itpbiomedica.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: *Dr. Hughes, what is the idea behind iTP Biomedica?*

Dr. Hughes: iTP Biomedica is a big data bioinformatics-driven diagnostics and prognostics company, which uses the entire transcriptome, which is the functional expression of the human genome, in disease tissue to predict the way that a disease will progress. We use the entire genome to provide a risk score for a disease's potential trajectory to a more dangerous state. It helps to manage an individual's particular disease.

CEOCFO: *With so many possible combinations and outside factors with a disease, how are you able to do this?*

Dr. Hughes: What we do is not what other company's do, which is look towards a few individual genes that may correlate with disease progression. We actually look at the entire genome, all 20,000 genes and non-coding species. Therefore, the multiple dimensions at which we look at the genome, and the tissue itself, lead to an exquisitely accurate understanding of an individual's disease. Our accuracy in disease severity identification can far exceed those that occur with many standard microarray-type approaches that people are familiar with. We provide a true description of personalized medicine, if you like.

CEOCFO: *How can you be predictive for an individual when there are so many personalized factors?*

Dr. Hughes: We are looking at gene-expression patterns associated within an individual's disease. We correlate this with well-characterized clinical cohorts, including outcome data, and we compare to the path that previous diseases had taken. This allows us to correlate an individual who is going down a particular path with those that have happened before. Because we are looking, not just at a few genes but at the entire genome expression itself, the multi-dimensional power associated with the analysis makes the correlation very strong. The consequence of that is a very accurate risk prediction, which is shown in our first product, BladderPredict[®]. This is a prognostic test that helps delineate the clinical trajectory of a patient's early stage bladder cancer. Specifically, whether it will stay in an essentially indolent state or likely progress towards to malignant disease.

CEOCFO: *Why bladder first?*

Dr. Hughes: Happenstance, for one thing. Our CMO is a top uro-oncologist and our CSO was working in that space in his academic pursuits when we founded iTP. It was a natural fit, because there was an unmet medical need. We had the clinical and scientific expertise, and access to clinical specimens at Mount Sinai Hospital in Toronto. It was a great exemplifier of the technical approach and the scientific approach we were taking to the understanding and subsequent management of disease.

CEOCFO: *Is BladderPredict available today? Where is the company right now?*

Dr. Hughes: Bladder Predict has been previously accredited by regulatory authorities for CAP and ISO15189 in collaboration with our seed investment partner Mount Sinai Services Inc. in Toronto. However, we have to transfer the test to a commercial laboratory to fully market the product. That will take a little bit of time and a little more inward investment.

CEOCFO: *How will the results be used? How much interpretation would a doctor need to do or is that all in the result?*

Dr. Hughes: It is all in the results and it really helps describe the risk in the disease. BladderPredict is a laboratory developed test. It will help the physician, who already understands the individual patient, the environment in play and the patient's family history, to better predict the risk of progression of the disease. Therefore, it will enable the physician to get frontline therapy to the patient quickest if necessary or indeed the physician may be able to counsel the patient that their disease is not so bad, and they should relax, which will really improve quality of life. It will not only expedite care in the cases where an unfortunate individual has a very serious disease, but it will also save healthcare dollars by properly targeting frontline therapies to those patients that really need it.

CEOCFO: *How are you able to go to the depth and to take the whole genome when others cannot? Is it the technology? Is it that people have not thought about it? Is it a little of both?*

Dr. Hughes: Our CSO is a world leader in transcriptomics science and network biology. We also have the excellent clinical infrastructure and patient sample availability associated with Mount Sinai Hospital here in Toronto. Therefore, it has really been a marrying of world-leading scientific and clinical expertise to realize practical applications in managing diseases, as shown, in this first case, in bladder cancer. The expertise associated with transcriptomics and bioinformatics data handling, as disease-specific supervised machine learning in these big data applications, is not commonplace. We are just blessed to have it in-house at iTP.

“iTP Biomedica has a revolutionary, proprietary technology that is far beyond what is currently out there in the diagnostics and prognostics space. The normal limitations associated with diagnostics in general do not apply to us and we provide unprecedented accuracy in understanding disease and its consequences.”- Dr. Ken Hughes

CEOCFO: *What is the response from people in the medical community who are aware of what you are doing?*

Dr. Hughes: Many have said “We would love to use it! Can we?”

CEOCFO: *What has been the response from the investment community?*

Dr. Hughes: Like everyone else, it is very difficult to get the investment community to focus on an individual area. Diagnostics and prognostics, as you are probably aware, is a challenging area to get attention from the investment community right now. Notwithstanding, we are working diligently on ways to allow us to properly and aggressively provide BladderPredict to the market, and to advance our proprietary pipeline in various diseases, including prostate cancer and diabetic kidney fibrosis. Yes, times are tough in terms of raising money to move forward and it is difficult to get the message out there, particularly when many VCs within the investment community have previously been burned in the diagnostics area. That is a great shame, because bladder cancer is a very large and unserved medical market as we speak today, and we are ready to go.

CEOCFO: *What have you learned as the test has been available, as you have gone through the process of development? What, if anything, might have changed?*

Dr. Hughes: That is a good question. The intention of the test was certainly met in development. Really, we learned more in terms of the communication, particularly in addressing the clinical and market needs, as well as just articulating the brilliance of the science. From a product perspective, I think we understood the medical need quite well and addressed it.

CEOCFO: *Given what the test can do, where does cost come into play?*

Dr. Hughes: It should not, because health economic evaluations actually show that, to the healthcare system, our test will be cost saving. However, it remains to be seen whether the people reviewing the data will move past simple cost and into an appreciation of value.

CEOCFO: *Could you be working with organizations that focus on bladder cancer to push forward what you are able to do or is that just too much of a long way around?*

Dr. Hughes: We have engaged, and want to continue to engage, with patient groups in the area of bladder cancer and elsewhere. However, they tend to - appropriately - fund basic research, and they do not advocate for corporate

positioning. As BladderPredict comes online those avenues of communication will be open. However, it is not a driver. It is a way to communicate the value when it is a reality, rather than up front. Bladder cancer groups and prostate cancer groups support a lot of great research, not only in diagnostics, but in therapeutics and that should continue.

CEOCFO: *Would you re-evaluate at a certain point in time as the disease progresses or as the oncologist might be starting to work or is it not relevant once you have the original idea?*

Dr. Hughes: Obviously, the disease can progress with time, so there may be a need to use it again. However, at least for the considerable period of time, the understanding of the disease will be set and the therapeutics, as a frontline approach and a management approach, can be guided. You are going to have to look at that on a case specific basis. What will be clear is when a patient presents and takes the BladderPredict test, the risk in the clinical trajectory of their disease at that time will be quite clear and will allow appropriate therapy and management.

CEOCFO: *Are you looking at the US market? Are you looking globally as well? Do you need to start with the US?*

Dr. Hughes: Our fundraising is with North American groups and North American applications at this time. You cannot be all things to all people and we are a relatively small company. Clearly, there are opportunities and I have had a number of conversations in Asia and in Europe. After rollout in North America, we will look to partnering in Europe and Asia to take BladderPredict, and indeed all the tests associate with our pipeline, to the global market.

CEOCFO: *What do you understand from past experience about bringing a product to market?*

Dr. Hughes: That it is a lot of work!

CEOCFO: *How do you spend your time as CEO? What are you doing all day at the office?*

Dr. Hughes: Communicating the value of the company to the external community as well as the internal community, making sure that everything is ticking over, that the books are managed and that everything is moving forward. Looking after the development of the pipeline, where new opportunities may be, where new collaborations can come up and making sure that we are connected in a way that we can bring science practically through development into the clinic, and then ultimately to the commercial reality. That is standard in these smaller science-driven companies. We are also looking for new collaborations and new opportunities to apply the technology. We got into kidney fibrosis recently and it makes perfect sense. We are also keeping abreast of developments elsewhere. A number of companies are working in related spaces, if not on related indications, and we need to know what they are doing, what they are not doing, and whether they are potential future competition. There is always a lot to do.

CEOCFO: *Why does iTP Biomedica standout?*

Dr. Hughes: iTP Biomedica has a revolutionary, proprietary technology that is far beyond what is currently out there in the diagnostics and prognostics space. The normal limitations associated with diagnostics in general do not apply to us and we provide unprecedented accuracy in understanding disease and its consequences. Interested parties should have a look with their health economic hats on to better understand the benefits we will bring scientifically, clinically and financially in the healthcare community. BladderPredict is addressing an unmet medical need with a very large market, which is more than half a billion dollars, and iTP has a rich development pipeline following in even bigger markets.

