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Questioning Market Leaders For Long Term Investors

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COMPANY INTERVIEW

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Response Biomedical Corporation (RBM:TSX)



S. WAYNE KAY, Chief Executive Officer of Response Biomedical Corporation, has more than 25 years of medical devices/biotechnology experience. He is a former President, CEO and Director of Quidel Corporation, a leading global company in the discovery, development, manufacturing and marketing of rapid diagnostic solutions at the point-of-care (POC) in infectious diseases and reproductive health. During his tenure, he designed and managed a strategy responsible

for building and sustaining unprecedented market leadership of rapid influenza testing (from an approximately 2% to 49% market share). He was also responsible for significantly improving the financial performance of the company during his tenure. Since leaving Quidel in 2004, Mr. Kay served as an executive advisor to the management and Boards of several early stage companies, mainly in the San Francisco Bay and San Diego areas. He also served as an executive advisor to one the US's most successful healthcare/life sciences blue chip venture capital funds, Kleiner Perkins Caufield and Byers.

SECTOR - MEDICAL DEVICES

(AJE606) TWST: Please begin with a brief historical sketch of the company and a picture of the things you're doing at the present time.

Mr. Kay: Response Biomedical has been focused on the development of a basic technology platform that can be broadly applied to various point-of-care medical and non-medical diagnostic tests. Much of the work done historically in the company up until this point has been focused on research development and the beginnings of product manufacturing. The company is transitioning as we speak to bring more of these products to market and see the fruition of the sales, marketing, and commercialization of the company blossom as we move into our market expansion phase. Our product focus initially is in the infectious disease areas and in the cardiac marker area that have clinical applications

in the hospitals, the laboratory, physicians' office and other ambulatory sites.

TWST: How do your products that you are bringing to market differ from what exists already?

Mr. Kay: Much of what's been historically available in diagnostic product technology in the form of products that are available either in a central laboratory, or in a reference laboratory. This is where a physician sends a blood specimen out to have multiple tests performed or in a central hospital laboratory where a technician will draw the blood in the emergency room or perhaps a bedside and send it to the laboratory to have the final analysis completed and results reported to the physician. These point-of-care tests are taking the testing from a central lab and offering it right at the bedside or at the point-of-care, whether in the

emergency room, a physician seeing a patient in their exam room in their office, or other ambulatory settings. We're looking to take those tests where a fast, expedient answer may indeed be advantageous to a physician to have a quick turnaround time as in the case of cardiac markers such that they will know what that patient's blood chemistry level is for the various markers and be able to make a clinical decision to move quickly to the therapeutic course of action. What stands us apart from other point-of-care testing is the sensitivity and specificity of our quantitative testing. We get lab-quality results in less than 20 minutes, which is something we're very proud of.

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TWST: Aside from cardiac markers, what are some of the other areas where your product lines will be effective?

Mr. Kay: Essentially in any of the immunoassay, our technology has a very nice affinity. We believe feasibility has been demonstrated beyond cardiac, clearly in infectious diseases, as I said previously. This would be for things like staph infections, diagnosis of infectious influenza, and also issues of other respiratory tract infections for instance, where having a quick answer while a patient is in a physician's office, thereby having the ability to make a differential diagnosis and know which course of therapy to move on with. Our products will lend themselves to adding value

to the healthcare supply chain. There are other areas such as renal or therapeutic drug monitoring, where we could imagine our technology being applied. Also, areas such as tumor markers and testing for early signs and indications of abnormality for various cancers are applications where our technology might be also well applied.

TWST: I understand that at one point you had to suspend your work in the staph infection area.

Mr. Kay: We haven't suspended our work. For the marketing and distribution of all of our infectious disease products, we developed a partnership with 3M Medical. As you know, 3M is a very successful multinational corporation that has a well-established distribution infrastructure in the hospital marketplace and they have a business unit that is focused on hospital infection control and prevention. The first product that they are interested in was staph. As they began to develop this business unit and look at other products that we worked on, the next being a flu product, they realized that staph was a concept of developing a market for testing in the point-of-care in the hospitals where that is not done today. In contrast, flu testing is done quite broadly in emergency room settings especially and in some outpatient clinic areas for the hospital. 3M more recently decided that it would be an exciting market opportunity to take a big, established and fast growing market like flu and put more of their focused promotional effort in that area than it would be to develop the distribution, infrastructure, and resource needed to support a developing market for point-of-care staph testing. 3M made the decision recently to table our commercialization plans in the staph area in favor of accelerating plans for flu and possibly other infectious diseases focused in the upper respiratory tract. We have begun the feasibility research and

development work to identify that next opportunity for our strategic partnerships.

TWST: What are the main items on your strategic agenda as you look out over the next three years or so?

Mr. Kay: The company has done a great job, as I said, in developing the product. Now that we've developed the product, we really need to move on to providing the support for commercial partners like 3M in the infectious diseases area and similarly with another major leading diagnostic partner, which we're seeking for the cardiac markers. Another interesting development in our ongoing partnering discussions related to our cardiac line is that we now have indications that potential partners would like to explore opportunities beyond infectious diseases and cardiology and we'll be exploring those opportunities, as well, in the coming months. Also, in order for us to succeed at Response Biomedical, we must make certain that we have built a world-class capability in manufacturing and in high-volume production of the devices for the tens of millions of tests that will be needed ultimately for the various segments that we will attempt to serve.

One of our major strategic priorities is to build and expand into a world-class, high-speed, high-volume manufacturing facility. We are building a facility out currently, which we'll move into at the end of this month. This new state-of-the-art facility is a 50% expansion beyond the 30,000 square feet of space that we currently occupy and will have the capability to manufacture up to 15 million devices on a three shift operation in that initial facility expansion. We further need to get on with identifying other product areas beyond infectious diseases and cardiac markers, where we can apply the technology, strategically. As we identify those areas — and tumor markers was one area I

mentioned as an example, where we find a good alliance with a major corporate partner to commercialize those products — we would look to develop the capabilities of product development, manufacturing, quality support for those activities as well. Further, we really want to look at globalizing the business. Much of our product thinking is focused in North America, but clearly there are huge market opportunities not only in Europe, but also in key markets in Asia, such as Japan, where we already have a partnership with Shionogi & Company Ltd. There are also very high hopes and expectations that companies have for opportunity to have commercial success in big markets, such as China, India and other large populations of the Far East. Those are among our key strategic priorities, looking forward, as well as clearly strengthening the strong supportive team that we have today. We want to look at planning for building and succession planning and the human capital that we employ in the company in order to bring the skill and expertise that we'll need to succeed.

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TWST: What do you need to do regarding human resources over the next couple of years?

Mr. Kay: We are a small emerging company, but we have very strong leads at the top and we have very strong middle managers throughout the company. We need to make certain that the

senior middle management level of knowledge that we have and then the tiers of management support beneath them will develop in time in an appropriate phased approach to building out the human resource need. One thing that we are finding is that by selecting leading blue chip players as our commercial partners, many of them have a wealth of resources in areas that if we collaborate with them we will find a way to indeed have a very enhanced overall team behind the management. I think on the commercial side we won't have to worry about focusing on resource development as much as we will on the internal technical operation and efficiency side with which we are able to build a business of sustainable growth in the marketplace.

TWST: Would you tell us about your own background and expertise and the same for one or two of your colleagues?

Mr. Kay: I have spent my entire career, spanning more than 30 years, in the medical device industry. I began with SmithKline Beckman and held a number of sales and marketing international operations roles and then was the President of one of SmithKline's division before moving into an entrepreneurial medical device startup company, taking the company public after raising three rounds of venture capital, and then eventually selling the company. I also was the CEO of the industry's medical distribution and wholesaler business trade association in Washington for seven years, and prior to coming to Response Biomedical, I was the CEO of Quidel Corporation, which is a leading point-of-care diagnostic player with whom we expect to compete in some areas and exceed the capability of their technology in other areas by the quantification capability of our technology platform. We are very fortunate to have a very accomplished senior team to ensure we achieve these goals.

Our Chief Operating Officer, Duane Morris, has a very accomplished background in the pharma area, some biotech, and diagnostic areas before coming to Response Biomedical about a year ago. Duane is an outstanding technical operation manager who manages all of the day-to-day internal operations of the business and is a strong partner to me in managing the activities of the business as we move forward. We have a very accomplished Chief Financial Officer in Rob Pilz who serves as the CFO and Vice President of Finance. Beyond the top three senior officers of the company, we are rich in the knowledge and expertise skill sets of our senior leads of research and development led by Dr. Paul Harris, manufacturing and engineering led by Reed Simmons, Human Resources led by Lori Maida, and other areas throughout the business. We think of ourselves as having quite an accomplished executive team of leadership for a relatively small and emerging company.

TWST: What occupies your own attention most on a day-by-day basis?

Mr. Kay: One is in deep planning for our growth and expansion. As we are moving into a commercial phase of the business, we need a broader exposure and acknowledgement of what we are doing and how we intend to compete effectively in the marketplace among the investor community. Much of my time is spent with key, leading partner relationships, negotiating new corporate partnerships, spending time with leading customer groups and indeed spending the time to develop and strengthen our current investor base and expanding our investor interest in other sectors in North America outside of the Canadian market as we look forward.

TWST: Would you describe your current investor base?

Mr. Kay: It's a large and somewhat disparate group of investors across Canada. As you know, we are listed on the Toronto Stock Exchange; we further are an OTC Bulletin Board Stock listed in the US, and we have a good strength of supporters from the US who are investors, though it is not nearly as broad as we would like looking forward. Rather than the somewhat spotty representation of institutional investors institutionally in the US, we would like a longer more enduring breadth of investor interest. Currently, quite a large consumer retail base of investors supports us.

TWST: What is your burn rate now?

Mr. Kay: Our burn rate is approximately \$1 million a month and it will be that for the next foreseeable couple of quarters.

TWST: What about actual problems? What might you worry about over the next few years?

Mr. Kay: Clearly that growth and expansion of a world-class product development and manufacturing facility and capabilities is what we are dependent upon today. We clearly need to execute flawlessly in those areas in order to be successful and to realize the kind of operating performance metrics that we've established for ourselves. The ability to indeed successfully apply the technology base to the breadth of other product applications that I've mentioned are critical areas of focus as well. The last is probably ensuring that we do the right job in the selection of the best corporate partners. We're not going to spend the time as a small emerging company to develop all of the commercial sales, marketing and distribution infrastructure ourselves. We will be highly leveraged and dependent upon the relationships of a few key partnerships like that which we have with 3M. Making certain that we have done a good job of selecting the partnership

and then working to develop these partnerships optimally in their performance to satisfy the needs of the stakeholders at Response Biomedical will be a critical focus area of success that we need to ensure.

TWST: Regarding other product applications, I understand there are possibilities regarding biodefense and West Nile virus.

Mr. Kay: The company, opportunistically when it developed its RAMP® technology platform, focused on areas that were actually in the biodefense area such as an anthrax test, a test for West Nile virus, and others. While not our focus today, they did importantly demonstrate proof of concept. These are non-clinical applications that have served the company well from a commercial perspective of revenue and supported the company in part to this point. However, there are limitations. Demand in the biodefense area is quite difficult to forecast and predict. We have decided that the clinical markets are much bigger markets moving forward, with more attractive growth areas of opportunity. That being said, we will continue to serve and opportunistically look for those opportunities of commercial exploitation of the biodefense and West Nile virus test areas, but not dedicate major new resources in those areas, but mostly favor the larger, more attractive clinical market applications instead.

TWST: What might be some upcoming year-by-year milestones that investors could look for?

Mr. Kay: As we continue to roll out the selection of our corporate partner for the cardiac product area, that's one thing that has clearly a few milestones that will demonstrate major investor interest and appreciation of value to the company. Secondly, is the commercial rollout of product in the 3M partnership for infectious dis-

eases. We are currently awaiting FDA clearance of our Flu A+B test that will be used with our new RAMP® 200 Reader. We will also be making a subsequent 510(k) submission for the use of our new RAMP 200 Reader with all other analytes. We'll also be expanding our current FDA submissions in the cardiac space and the infectious diseases area in the coming years and these are all key milestones. Looking to our successful move into our new facility and expansion there, and the subsequent manufacturing scale-up are all key and important milestones. The partnership for the cardiac business will clearly be one that brings cash to the company not only in product revenue, but also in either some form of upfront or equity investment or other forms of shared income to the company as was the case in the 3M partnership for infectious diseases. 3M, a little more than a year ago when being awarded the exclusive distribution for infectious diseases, made an \$8 million equity investment in Response Biomedical.

TWST: What would you reasonably expect the company to look like in about three years?

Mr. Kay: I would expect that we will be clearly recognized as a point-of-care diagnostics leader in one or two select areas. I hope it's going to be the cardiac product area and in the infectious diseases area, our first few areas where we've taken a quantified platform for testing to what has existed. I think you're going to see a significantly improved clinical and analytical performance enhancement to the user as well as other broader applications, strengths, and success and what we have to offer as we look to the future.

TWST: What would be the two or three best reasons for the long-term investor to look very closely at Response Biomedical?

Mr. Kay: The strength of the successful team that is planning to build a large, rapidly growing market where there is a strong market need expressed and the support of leading technology players as our commercial partners is paramount. The feasibility of the technology platform for future applications and with time seeing the rolled out commercial success of a revenue base that builds and grows attractively over the next three to four years would be of keen interest to our long-term investors.

TWST: Is there anything that you would like to add, especially regarding strategies, long-term objectives and reasons for an investor to look at the company?

Mr. Kay: The fact that we have a strong and unique proprietary quantitative platform for unique point-of-care testing where the assay performance significantly yields outstanding clinical and analytical results, and world-class strategic business commercial partnerships that we are developing with the enviable breadth of product applications that come from our technology. As we expand globally, we are looking at a very accomplished executive leadership team from which to build the needs of the company to make a thriving, enviable business that investors will be pleased to have as a part of their portfolio.

TWST: Thank you. (MC)

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