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BIO:

Kenneth A. Berlin- President and Chief Executive Officer

Prior to his appointment as president and CEO of Rosetta Genomics, Mr. Berlin, served as worldwide General Manager at cellular and molecular cancer diagnostics developer Veridex, LLC, a Johnson & Johnson company. Under his leadership the organization grew to over 100 employees, and he spearheaded the launch of three can-

cer diagnostic products, the acquisition of its cellular diagnostics partner, and delivered significant growth in sales as Veridex transitioned from a research and development entity to a commercial provider of oncology diagnostic products and services. During Mr. Berlin's tenure, Veridex received numerous awards including recognition from the Cleveland Clinic and Prix Galien for the use of its innovative CellSearch® technology in the fight against cancer. Mr. Berlin joined Johnson & Johnson in 1994 and served as corporate counsel for six years. He then held positions of increasing responsibility within Johnson & Johnson and a number of its subsidiary companies. From 2001 until 2004 he served as vice president, licensing and new business development in the pharmaceuticals group, and from 2004 until 2007 was worldwide vice president, franchise development, Ortho-Clinical Diagnostics. Mr. Berlin holds an A.B. degree from Princeton University and a J.D. from the University of California Los Angeles School of Law.

Company Profile:

Rosetta Genomics develops and commercializes a full range of microRNA-based molecular diagnostics. Founded in 2000, the company's integrative research platform combining bioinformatics and state-of-the-art laboratory processes has led to the discovery of hundreds of biologically validated novel human microRNAs. Building on its strong patent position and proprietary platform technologies, Rosetta Genomics is working on the application of these technologies in the development and commercialization of a full range of microRNA-based diagnostic tools. The Company's miRview product line is commercially available through its Phila-

delphia-based CAP-accredited, CLIA-certified lab. To learn more, please visit www.rosettagenomics.com.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Mr. Berlin, what attracted you to Rosetta Genomics?

Mr. Berlin: What attracted me to Rosetta Genomics was that I was looking for a company that had the potential to be the next Genentech or the Genentech of molecular diagnostics. Genentech is regarded as the most successful biopharmaceutical company and with molecular diagnostics entering this new dawn based on personalized medicine and sequencing of the human genome, there are opportunities for transformational potential. I was looking for a company that had a unique platform that has transformational potential. In the area of microRNAs, which is the area that Rosetta Genomics is focused on, they have developed a platform that I believe has the potential to transform healthcare by addressing some of the intractable diagnostic unmet needs that persist in medicine.

CEOCFO: Would you explain the Rosetta Genomics platform?

Mr. Berlin: The platform really centers around microRNAs. MicroRNAs are small, non-coding genes in the genome that play a very important, if not the most important regulatory role. By that I mean some genes are made to produce proteins which are the mechanisms through which all cells operate. The way microRNAs work is they regulate whether or not proteins get made. So they are directly involved in the key cellular processes such that when these go awry it causes problems that can lead

to disease. By looking at microRNAs, we get a very high-resolution picture of what is going on in the cell and therefore we think they are optimal biomarkers for telling us what is going on in a particular person in the case of disease.

CEOCFO: What is it that Rosetta Genomics knows about or are able to look at that others cannot?

Mr. Berlin: We have been working in this area exclusively for the last eleven years. In that time, we have learned the “tricks of the trade” on how these newly discovered entities work. These are certain tricks to make sure you get the right level of information and you understand that information. We have optimized our ability to discover microRNA signatures and associate those with different disease states. We use both our molecular biology capabilities and our bioinformatics capabilities. Together we have two very strong groups that work very closely to generate cutting edge products. We expect to have eight products on the market by the end of next year. It is the process, it is the platform, and together we are able to generate a steady stream of products.

CEOCFO: What are the areas disease on which Rosetta is focused?

Mr. Berlin: That is probably the most important question. Once you optimize your platform, you need to pick carefully where you play. What we have done is look at several different facets. We have looked at things like; what does the literature say about the role of microRNAs in different disease areas? What is the intellectual property landscape like? What are the big unmet needs? There are some very important unmet needs that people have been trying to address through other means but those means have not yet been successful. Those really translate into, how big is the commercial opportunity, and is it something that we can go after as a company given our size and resources? Therefore, we look at those different factors and they basically function as filters to screen out opportunities and allow us

to focus in on things that meet these different criteria. With that, our initial thrust was in oncology, so the first eight products are all in the oncology area. They examine the microRNA expression levels in tumor tissue. By definition, if you are working on tumor tissue you are working on a patient that has cancer and trying to inform the clinician what type of cancer do they have. If it is a lung cancer patient, it is what type of lung cancer does this patient have. If it is a metastatic cancer patient and you do not know what the primary tumor is, we try to identify that primary tumor so the clinician can determine how best to treat that patient. Those are our initial products. Oncology is the low hanging fruit for molecular diagnostics, but we are now moving beyond looking at tumor tissue and we are able to find microRNAs in different

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body fluids, such as blood, saliva and urine. In any kind of body fluid you can find microRNAs. You can associate the signature of that body fluid with a certain pathological state or physiological state. In other words, you can associate that signature with disease. What we have decided is to take a number of indications through that filter process that I described earlier and have picked several new areas outside of oncology to focus on; namely, cardiovascular disease, neurodegenerative disease, women’s health, and cancer screening.

CEOCFO: Will these be used preventatively as a diagnostic tool?

Mr. Berlin: Early is the key and ultimately, you could get into preventative care. You could get into screening or prediction of disease, but really where we want to go next is early identification because one of the is-

ues in healthcare is we are finding these patients too late to get them off the chronic disease pathway. If you do not get patients off this chronic disease pathway, you spend a lot of money during the rest of that patient’s lifetime administering healthcare to this patient as they deal with this chronic disease. Obviously, it is not good for the patient or for the health care system. Therefore, if we can find these people earlier and get them off this chronic disease path, it is good for patients and good for health economics. One example is heart failure. One of the issues is that we do not find those patients soon enough. Now, you are not necessarily going to get a heart failure patient off the chronic disease pathway, but if you find them soon enough, you can keep them off the later stages of that dreaded disease longer. This will lead to better

quality of care, better quality of life and probably better health economics. One of the indications we are going after is early identification and stratification of patients that are at risk for heart failure.

CEOCFO: Are there many players in this arena?

Mr. Berlin: There are not a lot of players that are as invested in this area as we

are in terms of the time and money spent and the number of publications and products produced. There are other small players out there, but it is hard to gauge how well they are doing; we can only point to the publications. We had eleven publications last year on studies that we have done. We have launched four products and expect to launch one additional product in July, one more at the end of the year and two more by the end of next year. So I think those results speak to our capability and I do not think anybody can really come close to that level of productivity at this point. We are pretty expert at it, and, importantly, we have the leading intellectual property position.

CEOCFO: Is the medical community paying attention?

Mr. Berlin: That is a good question. MicroRNAs have gone from being a

scientific curiosity to something that people say, "You know these are real, we just need to figure out how to use them and how they work. We are still understanding their role." I would say that I have seen a few changes even since I've been here. I started in November of 2009 and I have seen a pretty dramatic change in the receptivity by scientists and clinicians to microRNA-based diagnostics. They understand that microRNAs play a central regulatory role and they can provide a finer resolution or view of what is going on in a particular patient. It is still early days commercially, but we are starting to see some receptivity and we are pretty encouraged about what we are seeing in the marketplace.

CEOCFO: Is reimbursement an issue?

Mr. Berlin: Reimbursement is always an issue in the area of molecular diagnostics. Today, the US represents 90% plus of the worldwide opportunity for high value diagnostics because of reimbursement, and because reimbursement is less well developed for these products outside the US, say in western Europe or Japan, which are noted to be large markets for other types of products like pharmaceuticals. This situation could change down the road, but today that is the case. However, the US system is not exactly well adapted yet for high-priced, high-value, cancer diagnostics. It is undergoing some change and you will see this happen in the next few years. So working through that system, which is imperfect, but still one of the best in the world is always an issue. We are early in commercialization, so we are working through the system to get reimbursement for our tests. We are in discussions with the local Medicare carrier in our territory to get reimbursement for our lead tests for cancer of unknown primary or CUP.

CEOCFO: How does Rosetta Genomics reach potential customers?

Mr. Berlin: We just launched our own

direct selling effort in the U.S. last month, so we are still new at it. We put four sales reps in the field on the eastern seaboard, but prior to that we had a licensee in the United States. We ended that relationship at the end of last year, and raised some capital earlier this year, which helped us to fund this small commercial pilot program. We expect to expand upon it as we see traction in the marketplace. Outside the US, we work through distributors.

CEOCFO: Do you do any investor outreach?

Mr. Berlin: We are a public company, so yes a fair amount of our time is spent talking to investors. We have an investor relations firm and we work through them. We also have an investment bank that we have used for our last three raises and through them we certainly reach investors. I just started to go back out on the road talking to investors and we do a fair amount of investor outreach.

CEOCFO: What is Rosetta Green in Israel?

Mr. Berlin: Rosetta Green started as a division of Rosetta Genomics that focused on applying the microRNA capabilities and technologies that we developed for healthcare indications into a different space, into the green space, mainly Clean Tech. In this case, they are looking at oil producing algae and trying to optimize the production of oil by algae. In addition, they are looking at different agricultural applications, for example trying to develop drought resistant crops. They do both of those efforts and others through manipulation of the microRNA. They have had some initial signals of being able to do that. It is still early days, but our hope is that they will be successful, and that will lead to major collaboration with some big players.

CEOCFO: What is the financial picture like today for Rosetta Genomics today?

Mr. Berlin: We publicly stated that we have enough cash to get us through the end of the year. We are still early in the revenue ramp phase. We expect that the commercial effort that I described earlier, with our four sales reps focused on our cancer of unknown primary tests called miRview® mets and miRview® mets² as well as our recently announced commercial effort in the area of mesothelioma, will help improve our financial situation. We anticipate that these two efforts will help us over the next eighteen months to ramp up our revenues and help us reduce our burn rate. It is hard to predict how quickly and how big that ramp will be at this point, but we will have a better sense of it at the end of the 3rd Quarter, so we are not giving any guidance on revenues at this point.

CEOCFO: In closing, why should potential investors pick Rosetta Genomics out of the crowd and what should people realize about the company that may not come through clearly?

Mr. Berlin: The case for Rosetta Genomics really has to do with location. We are working in one of the hottest areas in healthcare today called MicroRNAs. We are the leading company from both a scientific understanding perspective as well as an intellectual property perspective and we are really just beginning to monetize those capabilities through the different commercial efforts that I described. Therefore, near-term for investors we hope you will see a nice revenue ramp, but longer term we have a number of opportunities on very large indications like heart failure and preeclampsia. We believe microRNAs can be the solution to some of these important unmet needs. Therefore, longer term there is some tremendous upside potential in Rosetta Genomics if we are successful in developing tests for those big unmet needs.



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