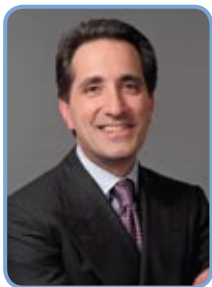


Interview with James A. Bianco, President & CEO, Cell Therapeutics Inc.



Established in 1991, James A. Bianco, M.D. is the principal founder of Cell Therapeutics, Inc. (CTI). He has been the company's President and Chief Executive Officer since 1992. As the chief architect of the company's portfolio, Dr. Bianco's strategy led to the acquisition of CTI's PG drug delivery technology, Trisenox®, Novuspharma's pixantrone,

worldwide license and co-development agreement for development and commercialization of Xyotax™ with Novartis, and the acquisitions of Systems Medicine and worldwide rights to brostallicin. Dr. Bianco has brought CTI back into the commercial arena with the acquisition of Zevalin®, the first FDA-approved radioimmunotherapeutic agent for the treatment of non-Hodgkins lymphoma. Following is an excerpt from an interview OBR conducted with him regarding CTI's goals and strategic plans.

OBR: *CTI finalized the acquisition of Zevalin (ibritumomab tiuxetan), the first radioimmunotherapy ever approved for NHL, from Biogen Idec in December 2007. Can you give us some background—why Zevalin?*

JB: I always felt that the drug would become a very effective way to treat relapsed lymphoma and that it would have significant clinical benefit for patients. Thought leaders in the lymphoma community also shared that opinion, but the drug just never got the resources, focus, and attention it deserved. At Biogen, it just never took off. In 2007, we were looking at the landscape of lymphoma products and noticed that Zevalin had great clinical data. We saw that from the time of its FDA approval in 2002 from the initial study of lymphoma patients who had failed first-line therapy with rituximab and chemotherapy and had relapsed that the complete response rate of patients taking Zevalin versus Rituxan was almost twice as high.

OBR: *What factors were involved in why the drug never got off the ground?*

JB: Biogen bought Idec in 2005 and they took a lot of sales support away. The company became so big it wasn't conducive to building a successful franchise for Zevalin. There were also some politics going on because Idec had co-developed and co-marketed Rituxan with Genentech. Then Idec launches a potentially competing product with Zevalin with a separate sales force, while Genentech had its own sales force for Rituxan and everybody's reporting into the same management structure. You couldn't possibly have a non-conflicted position—it was kind of schizophrenic.

OBR: *So you thought Zevalin had a lot of potential and did market research. What did you find out?*

JB: We began to understand that the data visibility intended for oncologists—meaning the clinical trial results—and having oncologists understand Zevalin's utility as a radioimmunotherapy and where it should fit in as a treatment wasn't there. We also learned that 75% of Zevalin's use was in the hospital outpatient setting, with very little use in so-called integrated delivery networks or free-standing cancer clinics. The care path really discouraged oncologists from using Zevalin because they had to send their patients to an outside facility to get the drug. If I were an oncologist, I too would look for a different way to treat my patients. So in spite of the fact that Zevalin showed superiority as a single agent when compared with Rituxan, physicians chose Rituxan instead of referring the patient to a nuclear medicine physician or radiation oncologist who would then treat the patient.

OBR: *What happened to open up the marketplace and position Zevalin for more visibility and higher usage by the oncology community?*

JB: Two important things happened: 1) rituximab went from average wholesale pricing to average sales pricing and end users turned away from the drug due to its sizable economics, and 2) most of the integrated delivery networks started using PET scanners to follow their lymphoma patients. About the same time Biogen instituted a new program, the Zevalin Community Access Program, Z-CAP for short, which was quite ingenious and made the radiopharmaceutical more accessible to those networks.



OBR: *How does Z-CAP work and why does it benefit the oncologist and patient?*

JB: With Z-CAP the total treatment regimen, and the economics for using the drug, are consolidated. The program basically educates a clinic. If a clinic has a patient eligible for the radiopharmaceutical they no longer have to send that patient to a tertiary center for their infusion. A nurse practitioner can administer the drug right in the clinic and there are no biohazard issues. The PET scan however, because of the radioactive gamma component, still needs to be given in a facility with the appropriate licensure and staff.

OBR: *What are your expectations now in terms of market potential for Zevalin?*

JB: With our sales and marketing strategy we expect to grow Zevalin's sales over the \$15 million figure reported in 2007. We're encouraged that U.S. sales in 2007 were steady, compared with 2006 levels, especially considering the lack of any substantial sales, marketing, or medical information effort by Biogen on behalf of the product in '07. The market for Zevalin will also expand as more sites become operational for Z-CAP. Forty-nine sites were up and running in 4Q '07 and we've identified 50 more that we're working on.

OBR: *How would you sum up your goals then for Zevalin?*

JB: Breaking down the barriers to treatment, clinical data and proper education will actually make this an important therapeutic for lymphoma patients that needs to be recognized by physicians—that's our objective.

OBR: *We've talked about the commercial plans for Zevalin. What about clinical development?*

JB: We're currently accruing patients for a post-marketing commitment study, a front-line study to show Zevalin's true clinical benefit (which Biogen promised to the FDA), and we'd like to get data from the European investigators who conducted the Follicular Immunotherapy Trial [FIT] for which data was presented at the last ASH Meeting, for possible registration with the FDA.

OBR: *Can you explain the business strategy that you've built around Zevalin?*

JB: We see Zevalin as the engine to the train in terms of building both a lymphoma business and a commercial business. We have two other products near the end of their development cycles in 2008. We just finished up Phase 3 trials of Xyotax (paclitaxel poliglumex) for first-line treatment of performance status 2 (PS2) patients with non-small cell lung cancer (NSCLC), and submitted the drug for approval in Europe. We're also finishing up a Gynecologic Oncology Group (GOG) Phase 3 trial of Xyotax in front-line ovarian cancer this year and we're finishing up trials of pixantrone (BBR 2778), an anthracycline for several types of NHL, in '08. We don't feel we need to do a lot of parallel studies on Xyotax and pixantrone so we've saved money and cut 35% from our operating expenses in the beginning of the year. We've made our investments in Xyotax and pixantrone and are confident that they'll be approved alongside Zevalin.

We saw the Systems Medicine, Inc. (SMi) acquisition, which took place in 2Q '07, as a strategic part of the company's future direction in terms of genomic-driven trials. So the second part of our strategy is that we now have a genomics unit and an integrated capability to do preclinical toxicology all the way up to Phase 1 testing, kind of a smart clinical research organization (CRO) capability. Getting brostallicin, a DNA minor groove binding agent, was attractive, but what was really attractive to us was the potential to build integrated network relationships and strategic affiliations with, for example, a Translational Genomics Research Institute (TGen), which the SMi deal brought to the table.

OBR: *What are your plans since you now have a partner in bioinformatics data management?*

JB: Our bioinformatics guys talked to a Seattle-based company with a technology platform using artificial intelligence. Their search engine can shorten the time for our genomic screening from roughly six months to one week. We could greatly accelerate the process of going [cont. on pg 57 >>](#)



through vast ‘terrabites’ of data as it applies to the human genome and identifying more targeted oncology drugs for use in personalized medicine. It would be a spin-off for us, a Newco which CTI would own a part of but funded by another source. An investor group has expressed interest in it. The interesting piece again for us, though, would be the potential for building relationships with institutions like the Mayo Clinic or the Molecular Profiling Institute, which have personalized networks for developing personalized medicine and which the Newco and its bioinformatics data search engine could work with.

OBR: *How would you sum up where the company is right now?*

JB: I’d say we’re done with the funding stage. Now we want to see the results.

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