

CRO providing in-house studies using Humanized Immune System Mice for Pharmaceutical Companies doing Preclinical Testing on Drugs and Therapies



Dr. Gerold Feuer
Founder and
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CEOCFO: Dr. Feuer, what is the idea behind HuMurine Technologies?

Dr. Feuer: We have commercialized and standardized a humanized mouse platform that I developed as a professor when I was in academia. What we found is that there are many commercial applications for this platform that large pharmaceutical, as well as small biotechs, are interested in utilizing for preclinical testing and for performing multiple scientific types of studies, particularly for preclinical testing of drugs and therapies.

CEOCFO: How do you humanize a mouse?

Dr. Feuer: We use a special strain of mouse, that lacks an immune system, and we inject human stem cells into these mice. What these mice develop is essentially a human immune system. They start out like the 'bubble boy' of mice. They have no immune system. Then when we inject them with human stem cells the mice become engrafted with a sustainable human immune system.

CEOCFO: Is humanization of mice a brand new concept? What is the history and some of the intricacies in how it works inside the mouse?

Dr. Feuer: It is a model that was developed in the late 1980s, early 1990s. I started working in this field around 1991 when I was a post-doctoral fellow at UCLA. Over the decades we have refined and perfected the humanization of these mice. Concurrently, better and better immune deficient mouse have been bred and developed which now allows for more effective engraftment of human stem cells. Therefore, it is a combination of both the technology and the science. However, the essential platform was started in the early 1990s.

CEOCFO: Wouldn't it always be better to use a humanized mouse for a trial?

Dr. Feuer: That has always been my argument. We are at a stage now where the human immune system, while not perfect in the mouse, it is substantially broad and robust enough that many preclinical evaluations can be performed in this mouse as opposed to say, a primate model or in other animal models. Moreover, because the humanized mouse has actual human immune cells you are getting a more accurate representation and read out in preclinical studies, which will be more reflective of what happens in human patients.

CEOCFO: Are more researchers or drug developers and testers aware? Is cost a factor?

Dr. Feuer: They are not as aware as I think they should be, primarily because it has been a model used primarily by academic researchers. That has been one of the goals of our company, to spread awareness and utility of this model for commercial applications. Granted that there are limitations in the human immune system that develops in the humanized mouse, but it is much more cost effective, particularly when compared to primate models such as monkeys or rhesus macaques. As well as being cost-effective, it has the added benefit of being a model that is more closely representative of the human immune system.

CEOCFO: Are you conducting these studies. Are you shipping or supplying mice to other researchers? What is the full role of HuMurine?

Dr. Feuer: We actually license the mouse from Taconic Biosciences. In our license we are allowed to breed and humanize the NOG mice, and to perform contract services for commercial and pharmaceutical companies. We actually do not ship out humanized mice. In my experience that is preferable because there are certain standards of care that have to be implemented when you are working with humanized mice. That is because the mice are very susceptible to being infected with opportunistic infections and dying. HuMurine has an extensive knowledge base of caring for these mice we

have very exact standards in place that allow these mice to thrive and to retain the human immune system. Once you start shipping the mice to other individuals and other labs the assumption is that they know how to take care of these animals. However, that is usually a faulty assumption. The mice can get contaminated and/or potentially lose the engrafted immune system, and this then compromises the studies and the data generated. Therefore, we actually prefer to run studies in house for quality assurances. That is what HuMURINE specializes in.

CEO CFO: *Your site shows, “From initial inquiry to project implementation in three easy steps.” Would you walk us through an engagement?*

Dr. Feuer: Generally, a client will approach us and we will have a conference call to get an understanding of the project. That conference will generally involve one or two PhD scientists. We will then sketch out what we call a ‘scope of work’ detailing what experiments the client actually wants to have performed, what kind of information that client wants to ascertain, delineating details of the study. Once the scope of work is agreed to and finalized then we humanize the mice for the project. That will take anywhere from ten to twelve weeks before those mice are actually ready to go. Once the study is performed we then produce a project report and basically provide follow up support to those project reports where we actually help interpret the data with the client. We discuss future studies and give our input as to the quality of the results or our interpretation of the study results. HuMURINE prides itself on providing a very high level of scientific expertise and support services.

“We have decided as a small biotech to focus on performing very high quality scientific studies. By that virtue we are not the cheapest CRO in business, but we pride ourselves on the exceptional quality level of data generation and scientific analysis for every one of our customers.”- Dr. Gerold Feuer

CEO CFO: *Are there particular types of projects, diseases, stages or is it somewhat across the board, depending on what a client might want?*

Dr. Feuer: It really is very client specific. That was a learning curve for me as an academic going into private industry. That is because I thought that client’s interests were predominantly in one area. However, what we found is that they really range across many areas, from gene therapy to immunology, hematopoiesis and anti-HIV studies. Now, in the last few years the big push has been in immuno-oncology. Most of our efforts now are now focused on using the humanized mice to really study the efficacy of these novel anti-cancer agents; these new immuno oncology agents that target specific cancers and activate the human immune system to eliminate those cancers.

CEO CFO: *Can you breed the mice? Is there a point in time where they will just be bred or does each mouse need to be created?*

Dr. Feuer: You cannot breed these mice to generate a whole litter of humanized mice. The human immune system must be engrafted in each animal individually. We inject two-day old pups with the human stem cells. Then that animal will have a stable human immune system engrafted for over a year. But yes, each humanized mouse has to be generated individually. You cannot breed humanized mice to create more humanized mice.

CEO CFO: *Is there a difference in behavior? If someone did not know and was looking at two groups of mice could they tell? Would they know from activities or reactions?*

Dr. Feuer: We wish that were the case, because that would make our lives easier. We see no difference at all between mice that are engrafted with a human immune system versus mice that are not engrafted. Therefore, we have to screen each and every individual animal that we humanize to ascertain and confirm that indeed the mouse is humanized and does produce human immune cells. There is no way to ascertain just by their behavior. There is no difference in their behavior. A white mouse is a white mouse.

CEO CFO: *Would you tell us about the recent grant from the National Cancer Institute?*

Dr. Feuer: This grant is essentially a one-year grant to fund the proof of concept that we can implant primary human tumors, what are called PDX tumors, into humanized mice and then develop a platform where we can test these immunotherapies to see if these agents will perform identically as they have been shown to perform in humans. Namely, they activate the human immune system to combat and fight the tumor that is implanted in these mice. Therefore, the National Cancer Institute funded this study to essentially determine whether this humanized mouse platform will be useful and accurate in preclinical studies in immuno oncology.

CEO CFO: *What is the strategy for the upcoming year?*

Dr. Feuer: So far we have three or four projects that are lined up for the upcoming year. We also have the National Cancer Institute grant project initiating in May. Additionally, a number of clients have also expressed interest in joining the

NCI study to look at their own individual immunotherapies. Over the last few months we have actually become very, very busy in performing commercial projects as well as outlining and preparing for the project that is funded by the NIH.

CEOCFO: *Is it easy to get people to work at HuMurine? Are people in your industry excited by the humanized mice?*

Dr. Feuer: From my perspective, we generally attract clients that are very interested and surprised by our capabilities and what we can do using humanized mice. So generally there is a 'learning curve' for clients that we engage. Also, HuMurine does not have a lot of competition in this field, and we pride ourselves on producing humanized mice of very high quality. Much of our quality and high level out-put of science that we produce at Humurine is essentially based upon my background and expertise that was developed during my decades of research in academia. I know there is also a lot of interest in people that would like to work for HuMurine. We just hired one project scientist this month. I think that also goes along with the fact that we work very closely in alliance with the UC Davis Medical Center in Sacramento. Therefore, there is quite a bit of scientific overflow from the academic sector that benefits HuMurine in terms of the high quality of scientists and people that we attract to work here.

CEOCFO: *Are you seeking funding or partnerships as you continue to grow and commercialize?*

Dr. Feuer: We, as any small company, are always looking for strategic partnerships and/or funding. I have bootstrapped HuMurine, basically with 'friends and family' money. We transitioned fairly quickly into a revenue sustaining business model. That being said, our recent expansion of workload now has taken us to a different level, requiring us to hire additional scientists and expand our laboratory operations. Much like any other company we are always looking for strategic partners to increase and expand our operation.

CEOCFO: *Why should people pay attention to HuMurine Technologies from all aspects; both the scientific and the business?*

Dr. Feuer: HuMurine Technologies provides a very unique niche model platform that has been shown to important and cost-effective in many, many preclinical applications. Moreover, we are a U.S.-based company that specializes in preclinical animal studies utilizing humanized mice, and our background in academic studies serves as the foundation of the company. We have decided as a small biotech to focus on performing very high quality scientific studies. By that virtue we are not the cheapest CRO in business, but we pride ourselves on the exceptional quality level of data generation and scientific analysis for every one of our customers. Almost all of our clients are also repeat customers, which attest to their satisfaction with HuMurine services.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine



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