Karen Klause

Interview conducted by

Mark Jones, PhD

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Ms. Karen A. Klause is a Strategic Advisor to the life science industry. Ms. Klause served as Managing Director of Europe Middle East & Africa at Response Biomedical Corporation. She served as President of AuntMinnie.com at Lumisys, Inc. since August 1999. From 1995 to 1999, Ms. Klause served as President and Chief Executive Officer of Digirad Corporation, a developer of solid-state detector technology for use in medical and non-medical applications. Ms. Klause served as Chief Operating Officer and Executive Vice President for CMP’s Medical Education division of CME, LLC., which was re-located to New Jersey in 2008. She held several key management positions from 1984 to 1995 of Hybritech Incorporated, a subsidiary of Eli Lilly and Company, including Vice President of Strategic Planning and Vice President of Sales and Marketing for the InVivo Imaging and Therapeutics division of Hybritech Inc. She has over 30 years of experience in the healthcare field. She began her career at Technicare Corporation (which was acquired by Johnson & Johnson), where she held a variety of senior positions. She has been Director of Adamis Pharmaceuticals Corp. since January 13, 2011. She serves as a Director of Ridge Diagnostics Inc.

Source: Bloomberg Businessweek
KLAUSE: Cole had an opportunity to join a business that he’s still with today. It was kind of one of those fluky things. It’s one of the major consulting firms in health care. He does everything from market research through diligence for mergers and acquisitions, and all this kind of stuff. They had an East Coast office, and he was able to set up the West Coast office, which he has ultimately, I guess bought into, whatever -- it’s his business now. So that’s the reason he left. He did that. But what happened was, David Hale said to me, ‘you know, when this merger goes through with Lilly, I’m not really sure if we’re going to have the need for a full-time VP of business development. You know, Hybritech, similar to many of the biotech companies today, and really they were on the initiators of this, not that -- it wasn’t new, the concept of doing deals with companies, but basically, you know, we were trying to find ways to support our R&D, which was very, very expensive, and we had a ton of ideas, and you know, Ted and David and I just realized I left Time out -- he was one of the people I interviewed with. There were just a lot of things that we wanted to do, so one of the ways to foster and support R&D would be to do collaborative relationships with companies, where as a trade-off, you might license them rights to the product that you ultimately developed, or whatever. But that was the role of business development, primarily, a lot of things that Cole did -- he did a tremendous number of deals for the company. So, David said to me, ‘you know, now that we’re going to be acquired by Lilly, I don’t if there’s really going to be a need, so I can’t really justify just hiring another VP to replace Cole. So why don’t you take that on, temporarily, and we’ll just kind of wait and see what
happens, and so, we were acquired in March of ’86, and for the first few months, it was just kind of doing the things that were on-going in business development, I was still managing all of the in vivo business unit from a strategic point of view. R&D did not report into me. Dennis Carlo didn’t report to me. He reported to David Hale. I did. We worked side by side, really running the whole in vivo division and kind of planning it and getting ready for it. So, then what happened was, David, well Ted and Tim ended up leaving -- I think it was August of ’86, to start their own company, Biovest -- but business development really actually took off. Hybritech had a number of very significant patents, the Tandem patent and the Icon patent, and we had had initiated some litigation against Abbott, and we were very successful, and we prevailed in, relative to the merits of the patent. And based on that, we were able to subsequently license the Tandem patent. And so, I took on a much larger role for the whole company, in business development, for both in vitro diagnostics and in vivo, licensing out technology and licensing in products. So, over the next four years, I actually did a number of major deals for Hybritech, licensing some big products that they are still selling today, that generate a significant amount of revenue for the company. We licensed from other companies, brought in some products from Centocor, licensed out the Tandem license and generated a tremendous amount of revenue. So, I was kind of doing that in parallel, so I kind of had two buckets. In August,

**JONES:** This is after the buyout, and so, how did this really change the operation?

**KLAUSE:** It didn’t in terms of me, no. What it did change is, we didn’t go out and aggressively seek partners to get money from them, to invest in us. We didn’t go out and do any of that. We did it differently now, because we didn’t have this need, well, plus Hybritech had now moved into developing a lot more products, and getting them out and generating significant amounts of revenue. So, it was different. In addition to that, there were two things that kind of happened simultaneously, well not simultaneously, but...In 1984, two years before Lilly, did a very large partnership, Hybritech Clinical Partners, and raised a significant amount of money to fund

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primarily the R&D for the in vivo side of the business. Well, Tim Wollaeger was president of that partnership, of both that and Hybrigenetics. When he left in August of ‘86, after the Lilly merger, David Hale asked me, 'Why don't you take,' because this kinds of fits in with the in vivo, 'why don't you take over as president of both of the partnerships. So now I kind of had three buckets -- I was president of the two limited partnerships, had kind of the business direction for the in vivo business unit, and then did all of business development worldwide -- corporate wide, for both in vitro diagnostics and in vivo -- for the company. So, I kind of had a lot on my plate. Busy. But it all tied together and it was really good. So, you question of, how did it change? Not really, to the extent that we had an opportunity for more interaction on the in vivo side with Lilly's R&D group -- Dennis Carlo and his scientists had a lot of interaction with the Lilly scientists because drug development was a lot closer to development of in vivo diagnostics than the in vitro diagnostics group David Kabakoff was running at the time. So, we had a lot of interaction with Lilly, talked through a lot of licensing opportunities, so from my perspective, we never had any negative issues with Lilly. Lilly was actually a lot of fun on the in vivo side, contrary to perhaps some opinions that Lilly really stifled creativity, yea, I would say that they probably, and you'll probably get a better answer from David Kabakoff or something, they were probably not as supportive of all of the creative ideas that the in vitro diagnostics groups wanted to do, because they didn't totally understand that. But on the in vivo side, they were completely supportive, and that's where I had most of my interaction, so I had a very positive interaction with Lilly, and all of the in vivo stuff. And then what happened in about 1990, we were getting a lot closer, or we thought we were a lot closer, to marketing a first in vivo product. We actually submitted our PLA in 1989, our first in vivo product, to the FDA. So, it kind of shifted my focus at that time, and I kind of dropped -- I had business development for both in vitro diagnostics and in vivo -- I dropped the in vitro diagnostics portion of business development responsibilities. So, now everything I focused on was in vivo. So, my position of kind of vice-
president of the in vivo business unit, was responsible for business development, licensing activities, and then setting up the whole sales and marketing, and really kind of getting ready to launch a product, ultimately. And then I still was responsible for the partnerships. Kind of bucketed that a little closer together. And I kind of did that really up until October of ‘93, when Lilly made the decision to, ultimately they made a decision to sell nine companies, they didn’t announce that initially, although that was part of the plan, and in preparation for that, they closed the in vivo division. It was three years now, almost four, ‘89, ‘90, ‘91, ‘92, four and half years, and we didn’t have approval yet on the product. We were in final approval. We were working on the labeling claims; I was actually hiring some sales reps, I had a national sales manager on board, I had a regional manager I had hired for sales, plus I had a whole marketing department. We had a full ad campaign. So, we were gearing up to launch the product. We had also done an exclusive deal with the largest radio- pharmaceutical, radiopharmacy supplier in the company, so we were ready to launch the product. We were getting very close. Lilly, however, in preparation for getting ready to put Hybritech up for sale, along with the other eight companies in the NDD division, felt that they really couldn’t sell, put Hybritech up for sale, if it had a division, the in vivo division, that didn’t have a product yet. We had 172 people in the division generating, you know, a lot of expense, and there is no guarantee. We all believed the product would have been approved, but you can’t, it’s not like you were spending $500,000 a year in expenses, it’s a lot of people, it’s a big expense, and they just felt that it would be probably a liability in terms of trying to sell the company, so they said, ‘We want to close down the in vivo division.’ So, we kind of plans to do that, and then it was in January of ‘94, three months later, when they made the announcement to sell all nine companies, so that is what happened. So, my role, at that point, was basically to wind up all the licensing all the licensing activities, close down the business, you know, kind of clean up all kinds of stuff, see who was going to end up buying Hybritech, and seeing what was going to be possible. And it was really
sad, because this product, I feel the worst for the patients -- they're the ones who are at a loss. This was absolutely a phenomenal product.

**JONES:** What's happened to all the R&D that went into that? Has anybody picked this up?

**KLAUSE:** No, the problem is the FDA’s rules on -- anything you put inside a patient, whether it's a drug or an injection, or whatever -- the clinical trials that are done, the material that's used has to be manufactured in a GNP approved FDA facility, and that material that you manufacture in this building is what you use in the clinical trial, that's what you get approved, so what you ultimately manufacture has to be made in that. So there wasn't anybody that could sell this to that would -- they couldn't just move it to their factory -- this is the problem, they'd have to completely redo the approval that took us five years, and we weren't totally approved. They would have to redo all of the clinical trials, four years worth of clinical trials. The FDA just wouldn't accept...You couldn't build another factory and make it identical and have them approve it. They would say, 'the material that you put in those patients in 1987, '88, and '89, is not manufactured in the same bottles, the same widgets. That's the problem with an in vivo operation. There were a lot of people who were very interested in licensing the product, but you have to remember what was happening. 1993 was the first year Clinton was in, and health care reform was the hottest agenda. You go back and you look at the stock market -- every major pharmaceutical company's stock had just essentially lost half its value, maybe not half, I'm rounding -- Lilly did -- Lilly went from like eighty dollars down to forty-seven dollars a share. Merck did, Johnson did, because everybody was really worried about what was going to happen to health care reform with Hilary at the wheel. So, people didn't have money to say...yea, the big pharmaceutical companies have a ton of money, I'm not saying that, but the point is, they all have a zillion products on their plate. So why would they but a product from a company, where they then have to buy the manufacturing facility and have a one of a kind facility sitting in San Diego that doesn't fit in with the rest of their business? It was just a very hard sell. You know,
there were a ton of companies that were interested but...So, this is why it was very sad. There were so many patients who could benefit from this product, and that's the crime in mind, and I was so frustrated. That's the only thing I was frustrated with Lilly about. I felt that they could have found a way to keep that alive until the company was sold, and if we maybe would have had approval by then. They didn't have to cut that off at that point. And then, especially when you see that it took Hybritech almost two years to be sold, sorry, a year and a half. We would have had approval. But there's no guarantee, but especially because it took Hybritech so long to be sold. This product could have been approved and on the market and that would have changed it. I guess that I just feel that that was the wrong decision to close the in vivo division because we were so close. That's the only thing that I don't think that Lilly fairly took a look at the in vivo division. They just made a decision, a business decision, but you have to look at what was happening at Lilly at the same time. Management was changing. That was the exact time they moved Von Bryson out, who'd only been in there for like two years, and they brought in a brand new CEO, Tobias, who...I'm not criticizing him at all, but the point is, there was a lot of stuff, Lilly was under a lot of pressure because of health care reform as all the other pharmaceutical companies were. They made a strategic decision that I don't think was based on, really, what was going on at Hybritech, it was just a big picture thing for a six billion dollar company located in Indianapolis. But Hybritech bore the brunt of it. And that's a shame because patients -- I've said this now three times -- the patients are the ones who lost out. So what happened was, over the next few months then, a lot of opportunities -- I was still there, and I wasn't going anywhere -- but this opportunity [Digirad] came along. The thing that's so exciting about is, I actually met the founders of this company the summer of '93. They had some really neat technology that was defense-based technology. But again, once Clinton was elected, in the beginning of '93, he had a real focus on downsizing the Department of Defense. This company which was very, very small, and its name was Aurora Technologies at the time -- it was
not Digirad, we changed the name -- was making products for the defense industry. Now, we make unique detectors, and these detectors had applications in the defense industry. Well, with General Dynamics, a lot of layoffs at General Dynamics, and the downsizing, it was very difficult for them to think about what kinds of contracts they might be able to get. So, the Department of Defense had some incentives. You could apply for a grant. If you would convert your defense technology into other applications, they’d pay for your R&D. So, this company figured, ‘you know, there are medical imaging applications we could do.’ Somebody contacted somebody -- you know, it was kind of a networking thing, and somebody ended up contacting me, and this was the summer of ‘93, so this was before the Lilly announcement to shut down.

**JONES:** Why did they contact you?

**KLAUSE:** Well, it’s networking. Do you know anybody who has a nuclear medicine background, who knows about this, and yea, how about this person, and it’s a small community in San Diego. Somebody ended up suggesting, yea, call Karen Klause, you know, she’s got this background, she knows all about that. They called me and they said, ‘you know there’s this company that has this idea for a gamma camera, it sounds really interesting but the founders really don’t have a background in the medical side at all, they’re in the defense side. Maybe you could go over and meet them and see if there’s anything...and, well, because I could literally see them from my office at Hybritech, I came over and met them. I was so impressed with their technology. But at the time, my purpose, my objective was for Hybritech, because we were working on a monoclonal antibody for breast cancer. One of the things for breast cancers is you had to find very, very small tumors, very small -- the current gamma cameras, the smallest they could find was a centimeter -- so you’re looking at a half-inch. Well, cancer's a lot smaller than that. I was so impressed with technology here. I said, ‘You can resolve things smaller because you’ve got such high resolution that, if you guys -- Aurora -- build a camera, it will make my product at Hybritech look better. So, we actually wrote a grant with Aurora and submitted it to the
Department of Defense to try to get some funding for this specialized breast cancer camera.

Well, then in October of ’93 when Lilly said, we’re closing the division, I had to call up the president here and withdraw our application: “we can’t participate with you guys, you can still go ahead with your camera, but you’ll have to get additional funding because Lilly’s closing us.”

So, I met with these guys, and then, January of ’94, Lilly makes the announcement to close it down, for a few months, I was really busy, you know, we were re-deploying employees, laying them off, giving them severance packages, kind of focusing on this. I was winding up deals, terminating licenses, agreements, and kind of cleaning everything up. And it was May of ’94, Tim Wollaeger, who now had another company, Kingsbury, ended up meeting one of the people here, accidentally, on a plane. To make a long story short, he was so impressed with the technology, he and they decided to really get into the nuclear medicine business. He decided to invest in the company. He called me not knowing, he had no idea that I had known these guys for one year already, and that I thought it was the greatest thing. He called and said, ‘I just invested in this really neat little company,’ -- he didn’t tell me their name -- he said, ‘they've got this really neat technology for a gamma camera, and I know you've got a background, I'd love you to be involved in it.’ And I said, “It’s not by know.” And I said, “I know them. I've known them for a year, and I think it's the greatest technology.” He said, “Are you serious?” And I said, “Tim, you have no idea what that technology can do. It is phenomenal, I'd love to.” I felt I kind of had an obligation to Hybritech. I really didn’t, but it's me and my personality. I just said, ‘Look, I can’t leave right now. I just feel like I want to wind up some of these projects.’ And he said, 'Well, would you write a business plan for Digirad?” I said, “Sure, I can do that at night and everything.” So, I kind of worked on a business plan, and for the rest of ’94, I stayed at Hybritech. You know, they were just kind of getting going over here, and so then I came over here in ’95 and joined the company. The interesting thing is, I’m still a consultant over at Hybritech. When I left, they basically said, ‘You know, you’ve run these two partnerships now
for nine years, and there isn’t anybody else -- would you be a consultant and still manage the
two limited partnerships?’ So, I’m still a consultant at Hybritech and manage the two limited
partnerships for them, and I do any questions that might come on business development. We
were just a handful of defense-related folks here, so we’re building a business. We have thirty-
four employees, I’ve raised nine million dollars since I’ve been here. We just closed a big round -
- six million. The funny thing is, over the years from ‘86 on, when all the Hybritech VPs left
between ‘86 and probably ‘88, they all kind of individually went off and did something different.
All of them, many of them, over the years would call me with an opportunity: ‘Hey, there’s going
to be this start-up. Why don’t you go over and check it out, and you know, join it.’ There was
nothing that really got me excited, and I said, knowing me personally, I thought that the next
thing I do, whatever it is, it’s going to be for me. It doesn’t matter or it’s running a company, I
don’t know, but it’s going to be something that, I don’t know, it’s just me. And that’s why I never
really left. I stayed longer because there was nothing that really got me, and I loved what I was
doing at Hybritech, there was nothing that got me really, really excited. There were a lot of great
opportunities -- I passed up Pyxis -- Ron Taylor offered me the number two position at Pyxis
back in ‘88 when he left. I said, ‘Ron, it sounds good.’ But it really didn’t sound exciting to me.
We joke about it now, because I could have been retired now with who knows how much
money, but that’s not the point of doing something. But you know, it’s opportunities like that,
that at the time, it just didn’t seem right for me. This really did. If I could have designed the
perfect job for me, this would have been it. It has my background -- nuclear medicine -- I’ve kind
of come full circle, I’m back to instrumentation. I was originally in instrumentation, eleven years
at Hybritech, now back to instrumentation. But it’s still nuclear medicine, I know all the
customers, it’s using my marketing/sales skills, the raising money was exciting. I like selling a
company and getting out there. Creating a whole business -- I like setting something up from
scratch, and it’s really me -- I really believe in the technology. What we have is so impressive.
It's a true paradigm shift. There's been nothing new in forty years, and no one has ever done solid state imaging. We've done it. All of the technology today still uses old-fashioned vacuum tubes, so we've gone from vacuum tubes to transistors. Just like back in the 1940s with radios - vacuum tubes to transistors. Philco to Sony, same thins. So, I feel like we're on the verge of really exploding a new medical technology. You know, I'd like to think that this could happen twice in my career, I was there when CT came on the scene and totally dramatic because we're not introducing a new modality, it's just a new a way of imaging.

END INTERVIEW
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The San Diego Technology Archive (SDTA), an initiative of the UC San Diego Library, documents the history, formation, and evolution of the companies that formed the San Diego region’s high-tech cluster, beginning in 1965. The SDTA captures the vision, strategic thinking, and recollections of key technology and business founders, entrepreneurs, academics, venture capitalists, early employees, and service providers, many of whom figured prominently in the development of San Diego’s dynamic technology cluster. As these individuals articulate and comment on their contributions, innovations, and entrepreneurial trajectories, a rich living history emerges about the extraordinarily synergistic academic and commercial collaborations that distinguish the San Diego technology community.