

Karen Klause

Interview conducted by

Mark Jones, PhD

November 25, 1996

SAN DIEGO TECHNOLOGY ARCHIVE



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Karen Klause



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.

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1 **KLAUSE:** Cole had an opportunity to join a business that he's still with today. It was
2 kind of one of those flukey things. It's one of the major consulting firms in health
3 care. He does everything from market research through diligence for mergers and
4 acquisitions, and all this kind of stuff. They had an East Coast office, and he was able
5 to set up the West Coast office, which he has ultimately, I guess bought into,
6 whatever -- it's his business now. So that's the reason he left. He did that. But what
7 happened was, David Hale said to me, 'you know, when this merger goes through
8 with Lilly, I'm not really sure if we're going to have the need for a full-time VP of
9 business development. You know, Hybritech, similar to many of the biotech
10 companies today, and really they were on the initiators of this, not that -- it wasn't
11 new, the concept of doing deals with companies, but basically, you know, we were
12 trying to find ways to support our R&D, which was very, very expensive, and we had a
13 ton of ideas, and you know, Ted and David and I just realized I left Time out -- he was
14 one of the people I interviewed with. There were just a lot of things that we wanted to
15 do, so one of the ways to foster and support R&D would be to do collaborative
16 relationships with companies, where as a trade-off, you might license them rights to
17 the product that you ultimately developed, or whatever. But that was the role of
18 business development, primarily, a lot of things that Cole did -- he did a tremendous
19 number of deals for the company. So, David said to me, 'you know, now that we're
20 going to be acquired by Lilly, I don't if there's really going to be a need, so I can't
21 really justify just hiring another VP to replace Cole. So why don't you take that on,
22 temporarily, and we'll just kind of wait and see what happens, and so, we were
23 acquired in March of '86, and for the first few months, it was just kind of doing the
24 things that were on-going in business development, I was still managing all of the in
25 vivo business unit from a strategic point of view. R&D did not report into me. Dennis
26 Carlo didn't report to me. He reported to David Hale, like 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 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 kind 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

62 interaction with the Lilly scientists because drug development was a lot closer to
63 development of in vivo diagnostics than the in vitro diagnostics group David
64 Kabakoff was running at the time. So, we had a lot of interaction with Lilly, talked
65 through a lot of licensing opportunities, so from my perspective, we never had any
66 negative issues with Lilly. Lilly was actually a lot of fun on the in vivo side, contrary to
67 perhaps some opinions that Lilly really stifled creativity, yea, I would say that they
68 probably, and you'll probably get a better answer from David Kabakoff or something,
69 they were probably not as supportive of all of the creative ideas that the in vitro
70 diagnostics groups wanted to do, because they didn't totally understand that. But on
71 the in vivo side, they were completely supportive, and that's where I had most of my
72 interaction, so I had a very positive interaction with Lilly, and all of the in vivo stuff.
73 And then what happened in about 1990, we were getting a lot closer, or we thought
74 we were a lot closer, to marketing a first in vivo product. We actually submitted our
75 PLA in 1989, our first in vivo product, to the FDA. So, it kind of shifted my focus at
76 that time, and I kind of dropped -- I had business development for both in vitro
77 diagnostics and in vivo -- I dropped the in vitro diagnostics portion of business
78 development responsibilities. So, now everything I focused on was in vivo. So, my
79 position of kind of vice-president of the in vivo business unit, was responsible for
80 business development, licensing activities, and then setting up the whole sales and
81 marketing, and really kind of getting ready to launch a product, ultimately. And then
82 I still was responsible for the partnerships. Kind of bucketed that a little closer
83 together. And I kind of did that really up until October of '93, when Lilly made the
84 decision to, ultimately they made a decision to sell nine companies - they didn't
85 announce that initially - although that was part of the plan, and in preparation for
86 that, they closed the in vivo division. It was three years now, almost four, '89, '90, '91,
87 '92, four and half years, and we didn't have approval yet on the product. We were in
88 final approval. We were working on the labeling claims; I was actually hiring some
89 sales reps, I had a national sales manager on board, I had a regional manager I had
90 hired for sales, plus I had a whole marketing department. We had a full ad campaign.
91 So, we were gearing up to launch the product. We had also done an exclusive deal
92 with the largest radio- pharmaceutical, radiopharmacy supplier in the company, so
93 we were ready to launch the product. We were getting very close. Lilly, however, in
94 preparation for getting ready to put Hybritech up for sale, along with the other eight
95 companies in the NDD division, felt that they really couldn't sell, put Hybritech up
96 for sale, if it had a division, the in vivo division, that didn't have a product yet. We
97 had 172 people in the division generating, you know, a lot of expense, and there is no

98 guarantee. We all believed the product would have been approved, but you can't, it's
99 not like you were spending \$500,000 a year in expenses, it's a lot of people, it's a big
100 expense, and they just felt that it would be probably a liability in terms of trying to
101 sell the company, so they said, 'We want to close down the in vivo division.' So, we
102 kind of plans to do that, and then it was in January of '94, three months later, when
103 they made the announcement to sell all nine companies, so that is what happened.
104 So, my role, at that point, was basically to wind up all the licensing all the licensing
105 activities, close down the business, you know, kind of clean up all kinds of stuff, see
106 who was going to end up buying Hybritech, and seeing what was going to be possible.
107 And it was really sad, because this product, I feel the worst for the patients -- they're
108 the ones who are at a loss. This was absolutely a phenomenal product.

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

111 **KLAUSE:** No, the problem is the FDA's rules on -- anything you put inside a patient,
112 whether it's a drug or an injection, or whatever -- the clinical trials that are done, the
113 material that's used has to be manufactured in a GMP approved FDA facility, and that
114 material that you manufacture in this building is what you use in the clinical trial,
115 that's what you get approved, so what you ultimately manufacture has to be made in
116 that. So there wasn't anybody that could sell this to that would -- they couldn't just
117 move it to their factory -- this is the problem, they'd have to completely redo the
118 approval that took us five years, and we weren't totally approved. They would have to
119 redo all of the clinical trials, four years' worth of clinical trials. The FDA just wouldn't
120 accept...You couldn't build another factory and make it identical and have them
121 approve it. They would say, 'the material that you put in those patients in 1987, '88,
122 and '89, is not manufactured in the same bottles, the same widgets. That's the
123 problem with an in vivo operation. There were a lot of people who were very
124 interested in licensing the product, but you have to remember what was happening.
125 1993 was the first year Clinton was in, and health care reform was the hottest agenda.
126 You go back and you look at the stock market -- every major pharmaceutical
127 company's stock had just essentially lost half its value, maybe not half, I'm rounding -
128 - Lilly did -- Lilly went from like eighty dollars down to forty-seven dollars a share.
129 Merck did, Johnson did, because everybody was really worried about what was going
130 to happen to health care reform with Hilary at the wheel. So, people didn't have
131 money to say...yea, the big pharmaceutical companies have a ton of money, I'm not
132 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

169 some incentives. You could apply for a grant. If you would convert your defense
170 technology into other applications, they'd pay for your R&D. So, this company
171 figured, 'you know, there are medical imaging applications we could do.' Somebody
172 contacted somebody -- you know, it was kind of a networking thing, and somebody
173 ended up contacting me, and this was the summer of '93, so this was before the Lilly
174 announcement to shut down.

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

176 **KLAUSE:** Well, it's networking. Do you know anybody who has a nuclear medicine
177 background, who knows about this, and yea, how about this person, and it's a small
178 community in San Diego. Somebody ended up suggesting, yea, call Karen Klause, you
179 know, she's got this background, she knows all about that. They called me and they
180 said, 'you know there's this company that has this idea for a gamma camera, it sounds
181 really interesting but the founders really don't have a background in the medical side
182 at all, they're in the defense side. Maybe you could go over and meet them and see if
183 there's anything...and, well, because I could literally see them from my office at
184 Hybritech, I came over and met them. I was so impressed with their technology. But
185 at the time, my purpose, my objective was for Hybritech, because we were working
186 on a monoclonal antibody for breast cancer. One of the things for breast cancers is
187 you had to find very, very small tumors, very small -- the current gamma cameras, the
188 smallest they could find was a centimeter -- so you're looking at a half-inch. Well,
189 cancer's a lot smaller than that. I was so impressed with technology here. I said, 'You
190 can resolve things smaller because you've got such high resolution that, if you guys --
191 Aurora -- build a camera, it will make my product at Hybritech look better. So, we
192 actually wrote a grant with Aurora and submitted it to the Department of Defense to
193 try to get some funding for this specialized breast cancer camera. Well, then in
194 October of '93 when Lilly said, we're closing the division, I had to call up the
195 president here and withdraw our application: "we can't participate with you guys, you
196 can still go ahead with your camera, but you'll have to get additional funding because
197 Lilly's closing us." So, I met with these guys, and then, January of '94, Lilly makes the
198 announcement to close it down, for a few months, I was really busy, you know, we
199 were re-deploying employees, laying them off, giving them severance packages, kind
200 of focusing on this. I was winding up deals, terminating licenses, agreements, and
201 kind of cleaning everything up. And it was May of '94, Tim Wollaeger, who now had
202 another company, Kingsbury, ended up meeting one of the people here, accidentally,
203 on a plane. To make a long story short, he was so impressed with the technology, he

204 and they decided to really get into the nuclear medicine business. He decided to
205 invest in the company. He called me not knowing, he had no idea that I had known
206 these guys for one year already, and that I thought it was the greatest thing. He called
207 and said, 'I just invested in this really neat little company,' -- he didn't tell me their
208 name -- he said, 'they've got this really neat technology for a gamma camera, and I
209 know you've got a background, I'd love you to be involved in it.' And I said, "It's not
210 by know." And I said, "I know them. I've known them for a year, and I think it's the
211 greatest technology." He said, "Are you serious?" And I said, "Tim, you have no idea
212 what that technology can do. It is phenomenal, I'd love to." I felt I kind of had an
213 obligation to Hybritech. I really didn't, but it's me and my personality. I just said,
214 'Look, I can't leave right now. I just feel like I want to wind up some of these projects.'
215 And he said, 'Well, would you write a business plan for Digirad?' I said, "Sure, I can
216 do that at night and everything." So, I kind of worked on a business plan, and for the
217 rest of '94, I stayed at Hybritech. You know, they were just kind of getting going over
218 here, and so then I came over here in '95 and joined the company. The interesting
219 thing is, I'm still a consultant over at Hybritech. When I left, they basically said, 'You
220 know, you've run these two partnerships now for nine years, and there isn't anybody
221 else -- would you be a consultant and still manage the two limited partnerships?' So,
222 I'm still a consultant at Hybritech and manage the two limited partnerships for them,
223 and I do any questions that might come on business development. We were just a
224 handful of defense-related folks here, so we're building a business. We have thirty-
225 four employees, I've raised nine million dollars since I've been here. We just closed a
226 big round -- six million. The funny thing is, over the years from '86 on, when all the
227 Hybritech VPs left between '86 and probably '88, they all kind of individually went off
228 and did something different. All of them, many of them, over the years would call me
229 with an opportunity: 'Hey, there's going to be this start-up. Why don't you go over
230 and check it out, and you know, join it.' There was nothing that really got me excited,
231 and I said, knowing me personally, I thought that the next thing I do, whatever it is,
232 it's going to be for me. It doesn't matter or it's running a company, I don't know, but
233 it's going to be something that, I don't know, it's just me. And that's why I never
234 really left. I stayed longer because there was nothing that really got me, and I loved
235 what I was doing at Hybritech, there was nothing that got me really, really excited.
236 There were a lot of great opportunities -- I passed up Pyxis -- Ron Taylor offered me
237 the number two position at Pyxis back in '88 when he left. I said, 'Ron, it sounds
238 good.' But it really didn't sound exciting to me. We joke about it now, because I could
239 have been retired now with who knows how much money, but that's not the point of

240 doing something. But you know, it's opportunities like that, that at the time, it just
241 didn't seem right for me. This really did. If I could have designed the perfect job for
242 me, this would have been it. It has my background -- nuclear medicine -- I've kind of
243 come full circle, I'm back to instrumentation. I was originally in instrumentation,
244 eleven years at Hybritech, now back to instrumentation. But it's still nuclear
245 medicine, I know all the customers, it's using my marketing/sales skills, the raising
246 money was exciting. I like selling a company and getting out there. Creating a whole
247 business -- I like setting something up from scratch, and it's really me -- I really
248 believe in the technology. What we have is so impressive. It's a true paradigm shift.
249 There's been nothing new in forty years, and no one has ever done solid state
250 imaging. We've done it. All of the technology today still uses old-fashioned vacuum
251 tubes, so we've gone from vacuum tubes to transistors. Just like back in the 1940s
252 with radios -- vacuum tubes to transistors. Philco to Sony, same things. So, I feel like
253 we're on the verge of really exploding a new medical technology. You know, I'd like to
254 think that this could happen twice in my career, I was there when CT came on the
255 scene and totally dramatic because we're not introducing a new modality, it's just a
256 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.