Greg Payne

Interview conducted by Mark Jones, PhD June 4, 1997







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Mr. Payne received a Bachelor of Arts in Biology from the University of California San Diego and then immediately went on to work more than 25 years with Hybritech, Inc. in various departments, including research and development, and regulatory affairs. He concurrently served at BCI and Beckman Coulter in management positions. Subsequently, Mr. Payne served in a management position with Gen Probe and then as Director of Regulatory Affairs at Becton Dickinson.



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JONES: You mean they were bringing corporate partners that might not have made

2 good business sense?

PAYNE: Well, they were deals that, you know, we were doing too many different

4 things, we were doing all the therapeutics, we were doing all infectious diseases, so

5 many things. We weren't as focused as we should have been. And I think a lot of

6 those things were necessary to bring in operating revenues, and also to position the

⁷ stock, but after Lilly bought us a lot of those things ended up being canceled.

8 **JONES:** So, your perception was that this was a preparation for the sale.

9 **PAYNE:** I think some of it was, some of the agreements we entered into. My

10 perception. I started in research in 1980, in June of 1980, just working in the lab.

JONES: Well, let me ask you about your background. What, for instance, was your education?

13 **PAYNE:** I had just received a bachelor's degree in biology from UCSD, and I was out

looking for a job. And one of my professors said, 'I know some people who are

15 starting up this little biotech company.' I think he ended up knowing Walt Desmond.

16 Have you interviewed Walt yet?

17 **JONES:** No. He's here?

18 **PAYNE:** Yeah, I can put you in contact. So, I went and interviewed, and I remember

¹⁹ interviewing in a three-piece suit, and if you've talk to Gary, you know he's really

20 informal, he doesn't like to wear ties, doesn't like to wear a suit. But they hired me

anyway, in spite of the fact that I wore a suit. I started working for Richard

22 Bartholomew. So, I worked in research for a year, maybe a year and a half, and then

there was a big push to get all these diagnostic products out on the market. You 23 know, our first kit was for measuring IgE, and it was the first monoclonal antibody kit 24 25 approved, cleared by the Food and Drug Administration. It wasn't really a big seller, but nevertheless, non-controversial, I think, a milestone. But we had a big push to do 26 a bunch of pregnancy tests in various formats, and ANP for neural tubes defects and 27 stuff, so I moved into the development side and worked for Dennis Muriyama, who I 28 believe is still at Gen-Probe. I worked for Dennis, and others for a while, and I worked 29 for Gunars. I moved into the ICON, well actually before that, when we were still 30 doing these visual bead assays, and I worked for Gunars for a number of years, and 31 Rick Anderson. And that takes us to what '88, '89. I worked on instrument support. 32 We've never really been an instrument company, which is one of the things that hurt 33 us, because that's what our customers really wanted. We made great assays, but they 34 also wanted automation, and we couldn't provide any. But we did have some 35 instruments. One was a manual spectrophotometer called the PHOTON. We had an 36 ICON reader, which read one of our ICONs, and we had an instrument we called the 37 PROTON [?], which we still have, actually. It's a batch analyzer, it's rather antiquated, 38 but it's still selling. Anyway, I worked kind of support functions for that for a couple 39 of years, and then went back and worked on assay development on BONEMARKER, 40 which is the trademark name, it's an osteo, and then I came over here to the 41 regulatory affairs department in 1992. I've been here ever since, and now I'm in charge 42 of the department. 43

JONES: And as you made these different changes along the way, did you have a
choice of where to go, who to work with, or did you basically get assigned to different
projects, or did you indicate...?

PAYNE: I don't know. You'd like to feel that you had more control over your destiny, 47 but sometimes a lot of it was just timing. I remember, I was scheduled to work with 48 Gunars on the ICON initially, the first one spot, but unfortunately, I had just finished 49 working on AFP, the test for AFP with Dennis Muriyama, and I had to go back and 50 deal with some manufacturing problems, so somebody else got assigned to work with 51 Gunars on the ICON. Now I subsequently came in and worked on the ICON products 52 in various forms, the various versions of ICON, for many years, but you know, I would 53 have liked to have worked directly on ICON and not got stuck on the other thing, so 54 there were times when...I think I was always well thought of by the people I worked 55 with, you know, with management, and Adams, and different people recognized that, 56 so I think I got, because of that, I got some of the nicer projects to work on. I made a 57



couple of choices. Probably to go back into assay development and also to come over
to regulatory. The choice I remember from going from R&D to development, it wasn't
a choice, it was a corporate priority.

61 **JONES:** Was this before Lilly?

PAYNE: Yeah, in '81, '82, I went over to development, and there really wasn't much 62 choice. We just had to do it, we had to get these products out. I know Richard didn't 63 want to let me go, but he didn't have any choice. But it worked out well, I have no 64 complaints. You know, having moved to the different formats, isotopic kits, 65 enzymatic kits, and ICON kits, moving into some instrumentation support, happened 66 at the time a lot of people left, including Rick Anderson and Gunars who went to 67 Biosite. I was there, I was available, I knew something about the instruments. I was 68 the one who ended up designated to work with another company that was 69 manufacturing them for us. So, that one was just kind of being at that place at that 70 time. Like I said, Hybritech never really has had much in the way of instruments. 71 There was a period of time in the '90s, the early '90s, late '80s, early '90s, when the 72 company wasn't really committed to new instruments, and I think maybe they knew -73 - an instrument takes a lot to develop, a lot of time, a lot of money -- and maybe they 74 knew Lilly wouldn't support it, but they also had this philosophy like, 'Oh, we don't 75 need an instrument. We can sell premium priced assays.' So, in the mid-'90s, an 76 opportunity came up with the development team, and I decided to move back to 77 development, and I worked there for another year and a half, two years or so, and 78 then another opportunity came up and again I was contacted and decided to take the 79 job in regulatory. But over the years, people would contact me about jobs, and I 80 would always consider them, and determine, you know, whether it was something I 81 wanted to do or not. I had numerous offers to move to manufacturing, but I didn't 82 want to. I wanted to get to the research scientist level in assay development, that had 83 been a goal. I had numerous opportunities to move. They just weren't right. 84

JONES: When you first arrived, fresh out of UCSD, the company was still very small how many employees were there then?

- 87 **PAYNE:** I would say that there probably were about thirty.
- 88 **JONES:** So you had a badge that said #30-something?



PAYNE: No, I was number fifty. I still have my old badge. Yeah, I was number fifty. A
wave of us got hired at that same time, Oonagh Bruni, Jill Hall, Bob Wang came in at
that time.

JONES: You were a young guy then, what was your impression of the company, thisnew start- up?

PAYNE: Well, I was pretty impressed with the technology, and the fact that we were 94 one of the leading companies in the exploitation of monoclonal antibodies. It was a 95 technique that had come about in the mid-70s, and I had always planned, actually, on 96 working for a company....You know, you go to school, you're a science major, and you 97 like science and all, but you really don't know what you're going to do when you get 98 out, and sure you know, you do some work in the lab as you go through school, but 99 you're really not sure that's what you want to do. I had planned on working for a 100 couple of years, and then going back to school, but I just got caught up in everything 101 here at Hybritech, and there were always a lot of opportunities. And one of the things 102 that's nice about working in industry as opposed to academics is there wasn't the 103 same stigma attached if you didn't have a PhD. In academics, you're not going to go 104 anywhere without a PhD. But in industry, if you worked hard, and have proven 105 abilities, you get to the same level. I have to admit that once you get to the same PhD 106 level, your upward mobility from there slows down, and you become a little limited, 107 eventually. But at least there's quite a bit of opportunity for people in industry 108 without a PhD to you know, be in charge of a group, or... 109

JONES: Is that something that you recognized immediately when you arrived, or

- were you even thinking in those terms?
- 112 **PAYNE:** No, when I started in 1980, I was just glad to have a job. I'd been in school for
- a while, I was twenty-three? I guess I just wanted to have a job, I wanted to see what
- everything was like. I guess I started realizing that more in probably '82, '83.
- JONES: And when you came in, did everybody coming in at that time get a little piece of the company?
- 117 **PAYNE:** Yeah, to some extent. Jim Killian here's too, I worked in the lab with him
- when I started. He actually left and went back to school and got his PhD, and was
- working at Scripps, and then came back here. Now he's working in operations. You
- might want to talk to him, too. I'll make a note of that. Getting back to your question,



- 121 did everybody get a piece of the pie, yeah everybody did. Obviously, some got quite a
- bit larger pies than others did. I think you had to work here a year before you got
- anything. They handed them out every January or something.
- 124 **JONES:** Did that mean anything to you at the time? Did you perceive any value it?

125 **PAYNE:** Yeah, yeah, because it was clear...I got hired in pretty inexpensively, and I didn't complain, because, like I said, it was a job, but you know, a year or two later 126 and you see people getting hired in at the same level for a lot more money, and you 127 go, things aren't right. But yet, I had that stock. So, if I looked at it, if I took that stock 128 129 and I amortized it out over the years that I've been here, it just brought my salary up to a reasonable level. When I was hired, I settled for the low wages, because if you 130 don't have experience, you have to get it somehow. So, yeah, it was nice. Was the first 131 stock option, eighteen cents? I think the first one I got was eighteen cents, and it got 132 split five for one. So, I think I got stock options ranging anywhere from eighteen cents 133 to twenty dollars. 134

JONES: And when you came in, what was the atmosphere like? What was it likegoing to work every day?

PAYNE: In the beginning anyway, you know, you had the TGs on Friday, and I 137 assume that eventually that kind of atmosphere sort of evaporated as the company 138 started to get bigger. Well, it was always an exciting company to work for. It was 139 always exciting in those days, primarily because you were always learning new things. 140 You always kind of felt like you were doing things that not many other people in the 141 142 country, or the world, were doing, which was nice. We used to have the TGs on Fridays, every Friday, and it was actually a good time for all the people in the lab, for 143 everybody to mingle. You know, in a big company, you'd never talk to the president 144 or CEO. But there were times when you were in conversations with Ted, or you know, 145 there were times when we'd be in the cafeteria and they'd have food, and beer and 146 147 wine and stuff, and Tom Adams would come up and ask me a question. He'd be talking to somebody else and come over and ask me a question. So you would 148 interact with everybody in the company, and that really made it nice because you 149 really got to know people 150

151 **JONES:** Did that change as the years went by?



- 152 **PAYNE:** Well, I think it's going to change no matter what as you get to be a bigger
- 153 company. Obviously, it makes it more difficult. It started to change a little bit when
- 154 we...We first started out in the La Jolla Cancer Research Foundation buildings.
- 155 **JONES:** When you arrived, they were still in the trailers?
- 156 **PAYNE:** Yeah, we were in the trailers. And then, shortly thereafter, we got a building down at Torreyanna, but that was just right down the street. In probably '81 or so, I 157 can't remember, '81, '82, Hybritech purchased, or leased a building over here on 158 Carroll Canyon Road, just down the street, for manufacturing, and it started to be a 159 160 little bit more disjointed then, because now you had people over there, you know, 161 twenty minutes apart. So the TGs kind of took on a little bit different atmosphere, because there would be some over there, and they'd come over here sometimes. But 162 they were still a lot of fun, and I think they continued to be quite a bit of fun, 163 actually, even after Lilly took us over. I think it was about a year or so after Lilly took 164 us over that....Well, actually, even before Lilly took us over, I think people began to 165 realize that it was a little bit of a liability, providing alcohol to employees. And that's 166 when the drunk driving stuff, the laws came into effect. So, whereas before they 167 would just keep handing out the beer, and people would take beer home after, if it 168 was left over, or sit there all night, or sit there for a couple of hours. They started 169 pulling it in at a certain time, to the point where, when Lilly took us over, it 170 continued for a while, and then I think everybody could kind of see, you know, it's a 171 big liability for a corporation. So what they did was they cut the alcohol out, which 172 immediately cut down the popularity of the TGs. But they continued for a while after 173 that, on a weekly basis. And then they started going every couple of weeks, and we 174 still have them, sometimes, but the nature of TGs has changed. 175
- JONES: How hard were you working in the early days? How many hours would youput in?
- 178 **PAYNE:** Yeah, people definitely put in some long hours. I think it depended on the
- person to some extent. Those with families...Everybody put in a lot of hours. It
- seemed like Gary was always there. Some weekends.
- 181 JONES: And odd hours working in the lab?
- 182 **PAYNE:** Right, yeah. Sometimes people would go in on a holiday to finish something
- up, or late at night. I remember Howard Caudler, who I also worked with in the lab,



- 184 he always had something he had to come in later, in the middle of the night for, it
- 185 seemed like, or off hours. And Jim Killian was in there a lot. He might be able to help
- 186 you with that.
- JONES: But there was a sense that people were really committed to the company?Was there a spirit of teamwork?
- 189 **PAYNE:** Yeah, I think there was a lot of camaraderie, and a lot of excitement about
- what we were doing. And Ted Greene was also pretty good about pumping upmorale.
- 192 **JONES:** Did he gather everybody at times, to speak?
- 193 **PAYNE:** There was a lot of stuff at TGs as I recall. There were some all-employee
- meetings where they would present milestones. Actually, those all-employee
- meetings probably got larger and larger and more frequent as time went by, because
- 196 when you're a small company, everybody pretty much knows what's going on, you're
- all there at one place, but then once the company got split up in a couple different
- locations, people may not have any reason to go over to the manufacturing facility,
- 199 which was over here at Miramar, or they wouldn't have had any reason to go over
- 200 there, so you really needed to start having big company meetings. There were a lot of
- 201 tours through the labs. There were a lot of investors who came in, a lot of visitors.
- JONES: And who would generally lead the visitors through?
- PAYNE: Ted had his secretary doing that, or David Hale would bring them through. I
 think actually, my dad at the time was a stockbroker, for Shearson/American Express,
 and Shearson was doing an underwriting of Hybritech Clinical Partners or something,
- so he actually came through one time on a tour. Karen Klause, too.
- JONES: And Hybritech Clinical Partners was a private placement with a lot of high net individuals -- a lot of those people came and visited?
- 209 **PAYNE:** Yeah, I think so. I mean, we didn't always get introduced to everybody.
- Again, like I said, I was mostly in the lab.
- JONES: And when you were working in the lab, did you have a lot of autonomy, in
- terms of, you know, you have a project to do, in terms of how to do it?



- PAYNE: Yeah, that kind of always depended on a number of factors. One, it
- depended on the project, and two, it depended on how competent you were,
- obviously. I had a lot less autonomy when I started. Several years later, I was probably
- the person in the lab, and I had a lot of reporting, not necessarily reporting directly to
- me for reviews, but reporting to me on a daily work basis, including a bunch of part-
- time people. So, the amount of autonomy I had increased over time, as my skills
- 219 increased.
- JONES: What kind of management styles did the various people who were in charge of these various projects have?
- PAYNE: That always varied, because initially, there were a lot of PhDs that were
 brought in to run a lot of this stuff.
- JONES: From academic settings?
- PAYNE: Sure, and just because you have a PhD doesn't mean you have good 225 management skills, and if fact, a lot of times, you don't. So there were some, you 226 know...and the Human Resources Department was small and in its infancy, too. So, 227 there wasn't very much help. And as I moved up the ranks, you know, the interesting 228 thing is that you work in the lab and you're good at what you do, and you're good at 229 working at the bench, so the promote you to work as a supervisor, and you're out. It's 230 kind of an interesting dichotomy there. And after a while, they started bringing in 231 some management classes, and helping, but you were pretty much on your own. And 232 so the crop of people, the young people that worked their way up from inside the lab 233 234 to supervisorial responsibilities came by it sort of naturally, or they picked up whatever they could on the way. And maybe they even ended up being selected 235 because they showed some management skills. So, after a while, you got a group of 236 people that had better managing skills. You know, just because you had a PhD didn't 237 mean you were any good at managing people. You were probably very good at 238 239 science.
- JONES: When you got to the point that you were supervising people, had you
- developed a certain philosophy based on your experience of how to do it?
- PAYNE: Sure.
- JONES: And what was your approach?



244 **PAYNE:** Well...

JONES: It wasn't something that you consciously thought about?

PAYNE: No, it wasn't. That's not to say that the scientists that we had at the very 246 beginning weren't good supervisors, or weren't good managers. It was just that 247 248 perhaps a lot of them didn't have any training in it, they didn't have any reinforcement, so it was just like sink or swim, and here you have to do it, and some 249 of them did better than others, and some of them probably never wanted to do that, 250 you know, I think, you need to accommodate all different types. It takes a lot of 251 different types of people to make a successful company. No one person, no matter 252 how intelligent they are can bring a product to market. It takes all these people. So, 253 you had to have the right people maybe working in the research phase, and the right 254 people then to work more on development, to interface more with operations people. 255 You know, it took all different types. I think Gary, for instance, he, over time, ended 256 up getting more and more management responsibility, and then actually, he kind of 257 shed that, because he didn't want that. It kept him out of the science. And there were 258 some that were that way. And to me, it made more sense, to, you know, if somebody's 259 passion was really to be involved with science day-to-day, why make them a manager 260 if they don't want to be? But then, you have to account for how are you going to 261 manage these people? 262

JONES: Well, when the company starts to grow and you have these different things going on in different parts of the company, you have to coordinate different activities, did that just sort of emerge organically, too? Did it just sort of happen?

PAYNE: Well, in the early days, it was very much a research and development driven 266 company. Research and development had a lot of power, and we would essentially do 267 all of the submission work, and all of the testing and everything in R&D, on R&D lots. 268 And we would, and I'm not saying it derogatorily, but we would shove it over the wall 269 to manufacturing, and they would sink or swim. You know, it was a small company, 270 and a lot of the necessary processes weren't in place. We just didn't know. And we 271 ended up in situations where we manufactured product that really didn't meet the 272 same performance specs and claims as the ones that were developed in research. So, 273 we had to work that out. I think it was a big challenge for us, in transitioning from a 274 research organization to actually making product. For a while, some of the 275 management in operations found they could hire anybody. I really shouldn't name 276



names, but anyway, this management philosophy in operations was we could hire 277 anybody, and it was just expanding so fast, it was hire anybody. And it didn't matter if 278 279 you had a science background or not. So, we'd be working in development to write these manufacturing documents, but you know, you have to have a little bit of 280 knowledge of basic science, of basic techniques, before you can use this. So, one of 281 the things that I still remember coming up as a big problem was, we would say in our 282 documents, 'dialyze the antibody,' which meant put the antibody solution which we 283 284 had precipitated via high salt concentrations. You would put it in a bag, a semipermeable membrane, and all the low molecular weight salts would dialyze out, go 285 out through that membrane, and essentially what you'd end up doing over time, over 286 multiple changes of this buffer, you would end up lowering the salt concentration. 287 Well, I think anybody that knew any science at all would know that when you did 288 that, you had to put a magnetic stir bar at the bottom, and that you had to have good 289 mixing in order to get efficient dialysis. Well, all of a sudden, we're working on these 290 documents, and they'd say, 'Well, it didn't say stirring so we didn't stir.' Well, you 291 know, what happened to your common sense? What happened to your basic 292 knowledge? All of a sudden then, these documents, because of this philosophy in 293 294 operations that anybody could come in, had to be really specific. We had to say 'with stirring,' and so on. I don't know, I always thought it was kind of funny, and I guess I 295 was a little resentful of the fact, because you can't just pull in anybody off the street to 296 make the products. So, there were some things that we had to go through. I think 297 that there were a lot of things that the development people had to go through in 298 learning about what it takes to make products under Good Manufacturing Practices, 299 you had to document things very well, you had to have somebody verify it, you had to 300 follow established procedure. It was a little tough for some of the people in 301 development. 302

JONES: Well, Hybritech is doing very new stuff at this time, the early '80s, what were Good Manufacturing Practices? Did the FDA have this stuff all worked out?

PAYNE: Oh yeah, they were well-defined. It's in the 21 CFR 820.

JONES: Yeah, but I mean for the specific application or interpretation for whatHybritech was doing.

- **PAYNE:** No, they're broad guidelines, but they do tell you that you have to have
- documented procedures, that the procedures, when somebody does it, they have to



- 310 be signed, any corrections -- they don't go into a lot of detail, but you have to design
- 311 your system and to meet that, because the GMPs cover, not only in vitro diagnostics,
- they cover a lot of other medical devices, so you have to make them apply. But it was
- tough getting some of those systems in place, you know, early on.

JONES: Well, do you think a lot of that was because it was so novel, because nobody had ever done anything like this before?

- **PAYNE:** No, because there were companies that were out there that were making 316 product at the time. I guess I'm just pulling one out for example, Miles Labs, Calstat, 317 all these other ones doing it. I mean, we were a young company. The oldest people at 318 319 the company were probably forty, and that was really unusual. And the people at the company were very educated, but a lot of them, maybe they hadn't been around in 320 the industry long enough to know a lot of these things. As time went by, we hired 321 more and more people in from the outside that had some of this experience, and they 322 had to develop the systems and put them in place. You know, there were growing 323
- 324 pains.

JONES: I talked to Ron Taylor, and he told me that first manufacturing facility was somewhere around here?

- PAYNE: Right down the street, 7120 Carroll Canyon Rd. We don't have that building
 anymore. The building's there, but we don't use it anymore.
- JONES: Well, I've heard stories about 30,000 mice a month going in and out of this
- building -- that sounds like kind of an unusual operation. Were people really doing
- 331 that elsewhere, immunizing animals in those numbers?
- PAYNE: Well, the typical way immunodiagnostics had been made previous to that
 had been with polyclonal serum. The amount of serum that you could bleed from a
 rabbit is a lot more than the amount of serum you would get from a mouse, or even
 ascites. I think there were some companies doing it. Maybe not on the same scale.
 We were definitely in front of the pack. But there were other small companies like
 Monoclonal Antibodies, Inc., that were working hard.
- **JONES:** What was the perception of the competition at this time? There was
- 339 Monoclonal Antibodies, Genetic Systems?



- 340 **PAYNE:** I don't know. This is just from my perspective. I remember, and again, why I
- think of the competition is because when you were preparing your submissions, and
- again, they were mostly 510k submissions, you had to show that yours was
- 343 substantially equivalent to another product that was on the market, or that had been
- cleared. And I remember going against clinical assays from Calstat. But I remember
- doing a lot of testing, CEA testing against Abbott. Abbott was a big competitor of
- ours. And Monoclonal Antibodies was also a competitor of ours, on HCG and HL
- 347 testing fronts, and a more rapid test.
- JONES: Was it in the air, did everybody have a general idea about what they were doing? Did you talk about it?
- 350 **PAYNE:** Oh yeah, yeah. That's true. Abbott's always been a big competitor. They're a
- formidable competitor. I remember they came out with a QUANTUM, and again, we
- really didn't have very much in the way of instruments, so we made a module that
- could fit into the QUANTUM, I think, to be able to use the wavebreaks that we used
- on our chemistries. And then Abbott came in, they went through all their
- instruments and cut the connection, so we couldn't do that anymore. Abbott was
- always a pretty fierce competitor, in fact, there were several people that were hired
- from Abbott, and Abbott had lawsuits against us.
- 358 **JONES:** Because of non-compete clauses?
- 359 **PAYNE:** Yeah, they said that those people were stealing their secrets away. Yeah,
- there were several people, and we ended up with some people from Abbott who kind
- of came in a roundabout way, too. So, we were always keenly aware that Abbott was a
- 362 major competitor.
- **JONES:** Well, the first big suit, Hybritech sued Abbott for infringement?
- **PAYNE:** Well, Respess would be a better one to talk to. There were lots of suits.
- 365 Abbott sued us a couple times over hiring people. I'm trying to think of these people's
- names, and I can't. And we sued Abbott once, I think, for bundling, bundling a bunch
- ³⁶⁷ of tests or something, and I don't know what happened with that. And, when did we
- 368 get the TANDEM patent? In the mid-80s, there were some suits with the TANDEM
- 369 patent. I think Gary would be a better person to talk to about that, because I know he
- was deposed a lot, which is a very fun process. And then we also had the ICON
- patent, which we sued them on, as well. And I did get deposed on that one.



JONES: But that seems like it would be pretty clear cut -- this was Gunars Valkirs'
invention, right?

PAYNE: Well, there were a couple of people that were actually on the patent. I think

- it was Gunars and Cole Owen.
- 376 **JONES:** Was he on the patent? Did he contribute?

PAYNE: I don't know. He was in there. I'd have to say that primarily, it was Gunars', 377 but there were a couple of other people listed on the patent. No, that was a tough 378 one, I think. Abbott came out right after ICON, Abbott came out with their own 379 TESTPACK [?] that they had invented. I think what they really had done was reverse 380 engineered the ICON, because if you look at Abbott, if you look at TESTPACK and 381 ICON, they were very similar. I got deposed for that ICON patent, but I don't know 382 how it finally resulted. But to this day, I think, Abbott is still a pretty fierce 383 competitor. For instance, we really developed the market for PSA testing. We got 384 approval, I think, in '85 or '86 for the first PSA format. The PSA market was really 385 kind of slow. There were really a lot of people who did a lot of work to build that 386 market. Dale Sevier was very involved with that, and we were very fortunate, in that, 387 in the early '90s, we went and got, the original approval was for monitoring people 388 who were already diagnosed with prostate cancer, and in the mid '90s, we decided to 389 go for approval for use in detection of those people that might have prostate cancer, 390 in conjunction with the digital rectal exam. And we received clearance in the early 391 '90s, and to date, we're the only company that has approval for that. But yet, eighty 392 percent of the market now is probably owned by Abbott because they have 393 instrumentation, and everybody is using their assay off-label, because they don't have 394 approval for this. So, FDA regulates us, but they don't regulate the clinical labs, so 395 once it goes in the clinical labs, the clinical labs can do whatever they want. So, in 396 essence, Abbott just kind of stole the market, because again, most of the market is for 397 detection, not monitoring of those people who already have diagnosed prostate 398 cancer. Most of Abbott's sales are coming in off-label. 399

- 400 **JONES:** Well, has this always been kind of a David and Goliath thing, Hybritech vs.
- 401 Abbott? Has that been the perception around here?
- 402 **PAYNE:** Yeah, and I think, from my perspective, I think Abbott's been a pretty
- 403 formidable, and a pretty reasonable, company. I think the thing that gives Abbott, the
- rough, bad name is the sales reps. I think their sales reps are pretty...they're real



- aggressive. They're known for that, you know, for maybe operating a little bit out ofthe standards of the other people in the industry.
- 407 **JONES:** But Hybritech's been able to survive...
- 408 **PAYNE:** In spite of everything?
- 409 **JONES:** Well, you know, the mismatch of resources

PAYNE: Yeah, absolutely. Actually, I think it's pretty amazing that we've done as well 410 as we have. The other thing that happened is, Lilly bought us in '86, and there were 411 these ten-year CPUs, contingency payment units, so they couldn't sell us for ten 412 years, and what happened is, you could see that, in the mid-80s, my perception was 413 that Hybritech was purchased for the therapeutic side, not for the diagnostics side, 414 and we used to always hear that, 'Yeah, therapeutics is always going to be the big 415 thing.' So, those of us working on the diagnostics side are going, 'Yeah, look at all this 416 money we're bringing in.' And we eventually ended up being profitable, just on the 417 diagnostics side of it. And the therapeutics side suffered from a number of issues, the 418 market was changing fast, the FDA was being more sophisticated. Timing is 419 everything. If you didn't design your process and your product correctly up front, and 420 you made all these changes, and now you want to get approval for it, it was really 421 tough. And also around the late '80s, Lilly started to get disenchanted with Hybritech. 422

423 **JONES:** Because the therapeutics hadn't evolved?

PAYNE: Yeah. The promise wasn't there. And I think it was political at Lilly as well. 424 And I think that people did as best they could at the time, but again, there maybe 425 wasn't the same amount of up-front planning that was required. And since a 426 therapeutic product takes so long to get through an agency, there's bound to be 427 process changes and different things that happen, and that really compounds it, 428 when you get to the end and say, 'Boy, yeah, but this is what we submitted, so this is 429 what we were originally going to do.' It makes it more difficult, where diagnostics had 430 a quicker approval time. We were getting 510k approvals, you know, in under a 431 month a lot of times. And so, it was easier to react to market situations than for the 432 433 people on the therapeutics side. So, Lilly kind of got disenchanted with it, and in the early '90s you could see Lilly decided to divest itself of its non-drug companies. And 434 Lilly, I think a lot of it was benign neglect with Lilly. They just didn't know what to do 435 with us and how to manage us. And of course, they weren't willing to pour the money 436



- in to give what we really needed, which was an instrument to sell assays. So, the
- therapeutic side went out in '93 or so, '94? They closed down therapeutics. They
- hadn't at that time made the announcement that they were going to divest all their
- other non-pharmaceutical companies, but you could see the writing on the wall, and
- then the following year, they decided to divest all their non-pharmaceutical, and
- Lilly got into a little bit of trouble from a compliance point of view. FDA, at that point
- in time, you know, they were quite a bit friendlier in the early '80s, and then they
- started being really compliance oriented in the '90s, and they decided to make an
- example of a couple of lead companies, to scare everybody. So, they really went after
- Lilly. They did an inspection back at Lilly, and Lilly got a big warning letter. They
- came in and nailed physio-control, they nailed us, they nailed IVAC.
- 448 **JONES:** What were the particular problems they identified here?
- 449 **PAYNE:** Well, we had invalidated our software, that's what they got us for. I can't
- remember what they got everybody else for, but they were just basically coming to try
- to get everybody to shape up in the industry, and they made a big example of a
- 452 couple of companies. And I think every single one of the Lilly subsidiaries had an
- 453 inspection, a GMP inspection, and got a warning letter of some sort.
- 454 **JONES:** Did this cost a lot of money then to comply?
- 455 **PAYNE:** Yeah. I think it did cost a lot. Now, did we need to? In some areas, yeah, we
- probably did, but the government can come in and inspect and always find
- 457 something wrong. But anyway, they really targeted Lilly.
- 458 **JONES:** And that just made them even more eager to...?

PAYNE: Maybe. Maybe. So, they divested all of their non-pharmaceutical companies, 459 with the exception of a couple, one, IVAC, which was not doing real good and got a 460 warning letter, and Pacific Biotech, which is another rapid diagnostic company right 461 down the street that Lilly bought, and it wasn't doing good, and Hybritech. And the 462 problem was that Hybritech was the last, because of those CPUs, they couldn't sell us, 463 right till the end. So, there was a period, it seems like three or more years, where 464 465 nobody wanted to make a decision around here because they were always afraid, 'Oh, it might screw up the purchase.' These companies would be coming in to look to 466 purchase Hybritech, but who wants to purchase a company like, 'Well here, I'll buy 467 the company,' but you can't take it over for three years. So we were really in a crappy 468



- position. And we were the last company to go, in a last minute deal to Beckman. We 469 were originally going to be sold to, Beckman was originally interested in us, but they 470 471 were trying to bundle Hybritech and PBI, and Beckman didn't want to take over PBI. They felt they were too much of a liability. They didn't want them. So, they said, 472 'Forget it.' And then, you know, various other people like EG&G came through, and 473 other people, and then right at the end, there was a guy named Scheuler from Abbott, 474 an ex-Abbott person. He was going to come in and run the company and sell off a lot 475 of the assets, basically just strip it, and right at the last minute, Lilly said, 'Nope. We 476 don't want to sell it to him,' and they just gave it, sold it inexpensively to Beckman. 477
- 478 And that was '95, '96.

JONES: Well, going back to the time when Lilly was buying the company, did youknow about it?

PAYNE: No. It was really a well-kept secret. That's interesting that you should ask, 481 because it was really a well-kept secret. And maybe I was just too junior in the lab, 482 you know, I didn't know what was going on, but I remember that when the 483 announcement was made, I don't remember the day, but it was early morning, and 484 my dad called me up in the lab. My dad was a stockbroker, and he said, 'Hybritech's 485 stock has stopped trading. What's going on?' And I said, 'I don't know.' And right at 486 that time, they had a very impromptu meeting called in the lobby with Kabakoff. And 487 I remember going out there and Kabakoff announcing that Lilly had purchased us. 488 And everybody was pretty excited about it. Everybody thought it was a great deal. 489 Because there had been times, I think, when the company had been just really 490 struggling to keep afloat, and we all knew that. You know, when there's not that 491 much revenue. 492

493 **JONES:** So you recognized this as a financial windfall?

PAYNE: Yeah, I think everybody was really excited about it. But then with a new 494 495 company, there always comes change. Things changed here, and change can be good, and some people work better in an entrepreneurial environment and some people 496 work better in a bigger environment, and you know, you saw David Hale leave, and 497 some other people leave, and Lilly sent some people up. Lilly, for a couple years, it 498 seemed, used Hybritech as a training ground, sending out some of their young execs 499 and saying, you know, 'Here, have at it. Play around.' So, there was a wave of people 500 that kind of left right after Lilly bought us. I think that's probably to be expected. 501



JONES: Well, when people did start to leave, and especially the senior people whoare connected to the capital, and...

504 **PAYNE:** Well, they got their money out, so they were happy they were gone.

JONES: Well, yeah, but they started all these other companies and there started to be a real industry here. Before, it was just Hybritech, basically.

- 507 **PAYNE:** There was a little resentment in some respects, sometimes, like, you know,
- 508 OK, here's all these people, they made their millions and now we're stuck, and there
- was a feeling sometimes, I think, that certain things were done just to sell the
- 510 company, and they knew they'd never have to live these deals through, so after Lilly
- 511 bought us, it fell to the rest of us to deal with these things.
- 512 **JONES:** Well, this industry started to grow here, were there more opportunities? Did
- 513 you ever think, 'Well, gee, if this doesn't work out with Lilly, you know, I can go some 514 other place?'
- 515 **PAYNE:** Sure. Oh, absolutely. And I interviewed. I've interviewed at a number of places here. But I always found enough...I really like the people here. Hybritech's 516 always been real special, you know? I always had enough room for advancement and 517 growth, moving around, that instead of moving companies, I just moved 518 departments. So, I didn't leave. But there was like Synbiotics, there were a lot of 519 people that went there, a veterinary company, veterinary diagnostics. There were 520 some people that went to Quidel. Quidel is almost as old as Hybritech, but it's really 521 never done much. You know, it kind of went along, and maybe even in the last year, 522 it's kind of gotten better, but so although you could see there were a lot of these 523 companies out there being started, they weren't doing much. They weren't really 524 doing very well. And so you go, 'Hmm, Hybritech's doing pretty good. Why should I 525 go?' I mean there were years when we were getting ten percent bonuses, eight 526 percent bonuses. So, why should you move? And there were a lot of companies that 527 just never did very well. Telios bit it. Synbiotics never really did much. Quidel, again, 528 has never really done very much. There's not too many that are doing well. Do you 529 530 think Biosite's doing well?
- 531 **JONES:** They appear to be.



PAYNE: Biosite's doing well. Dura Pharmaceuticals. And I think you could almost 532 look at the thing....you know, there's probably certain problems that companies go 533 534 through at each stage, and you could probably say in this industry that OK, here's a company, they've got this many people, they've got sales of this much, here's their 535 problems. And you know, those companies all have those problems. And a lot of 536 people left thinking, 'Oh, I'll fix all this stuff,' only to realize that they've got the same 537 problems wherever they go. The early '90s was particularly bad for biotech here in 538 San Diego. Funding dried up and there were a couple of problems. Telios had 539 something in trial and it didn't pan out and that just crashed everything. A lot of the 540 companies here, it seems like there's more drug or biological companies here than 541 diagnostics. The diagnostics are more even-keeled in some respects because their 542 cycle times are shorter, their approval times are shorter, revenue streams can begin 543 coming in a little quicker, whereas, see biotech companies, or pharmaceuticals, like, 544 maybe let's say Gensia, where David Hale went, you know, it was just going great 545 guns, and then all of a sudden, the FDA said, 'Man, we don't like your thing, your 546 product.' They didn't have anything else. And it takes so long in the pipeline, and 547 they've invested so much that they burn up all this money. 548

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.

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