

# IMPERFECT SCIENCE

# By Eric Tegler

Tom Watkins is no scientist. Though he leads Rockville-based Human Genome Sciences Inc. (HGS) — one of a handful of pharmaceutical firms that have done something really noteworthy in the past 18 months — he'll be the first to tell you that molecules are not his forte. Bringing capital and technology to bear on intractable healthcare problems, that he enjoys. Managing each of the three is an imperfect science and their intersection in the pharmaceuticals industry is imperfect at best. But that's what's so fascinating.

It's a thought that must have sustained Watkins during one of HGS' all-employee meetings in March of last year. The publicly traded 800-person company he led was bleeding capital and laying off staff. From a market capitalization of \$5 billion and a price of \$241 per share in 2000, its stock was hovering at about \$0.55. HGS had encountered a "perfect storm" in Watkins' view. Its leading product, a treatment for the chronic inflammatory disease Lupus, which attacks the skin, blood vessels and internal organs, had under-performed in late-stage clinical trials the previous year.

In March of 2009, its second major product for the treatment of hepatitis C posted mixed results in its own clinical trials. Wall Street had all but left HGS for dead, and the company's employees were wondering how many more desks would be empty by the end of the month.

And yet, HGS' CEO remained confident and determined to meet openly with his entire staff.

"We had to cut the employee base by about 7 percent," Watkins remembers. "It was a painful day. Two days later, we had one of these all-employee meetings. A lot of people said to me, 'What are you doing? Why are you having a meeting when the stock's at an all-time low and we've lost good colleagues?' I said this is exactly the time to do it. The entire three-hour meeting was basically me answering questions. Communicating openly when times are good is really easy. But you have to be open when times are tough."

Slowly at first, but then urgently, HGS employees began to ask, were they going to make it? Was the company going to change direction? Fortunately, Watkins had seen early data from the final clinical trial of the company's Lupus drug and it was good. HGS partner, pharma giant Novartis, had seen the data too and was impressed.

"I said to them, we've got two other clinical studies coming and those results might be terrific, we don't know. If they're not, we'll change direction, but if you've been here this long, why would you leave when we're only a few months from what could be history?"

Whether that history would be a glowing one, nobody could say for sure. The pharma business always has been an imperfect science.

## good genes

HGS got is start in 1992 as the brainchild of Dr. William Haseltine. A renowned Harvard professor and scientist, Haseltine was one of the most important figures in the mapping of the human genome. In 1992 he joined J. Craig Venter, another seminal figure in genomics, pairing his for-profit venture, Human Genome Sciences, with Venter's not-for-profit Institute for Genomic Research.

Dr. Haseltine envisioned HGS as a discoverer of genes that would lead to the development of pharmaceutical drugs for the treatment of a wide variety of health problems. A colorful character, Haseltine (and the promise of the genomics research HGS was to undertake) was able to attract a sizeable tranche of private venture capital followed by a \$125 million investment from pharmaceutical major, SmithKline Beecham, in 1993. During the same period, HGS went public, attracting further capital from institutional investors including T. Rowe Price.

Thus well capitalized, HGS went about the business of research. Led by a scientist and largely populated by scientists, many formerly with National Institutes of Health, the firm had a collegial, academic feel to it. HGS employees believed in the research they were doing and the path it potentially opened to effective commercial drugs, Susan Bateson says. Bateson who joined the company in 1997, is HGS' senior vice president of human resources. The relaxed, communicative nature of HGS hit her as soon as she walked in the door.

"I remember when I walked in for my interview for the head of HR position, the place exuded a caring for its people," she says.

As genomics research progressed and the enthusiastic investing climate of the late 1990s blossomed, HGS attracted yet more capital and more favor on Wall Street. Though it was still far from showing any concrete developments from its genomics targeting, the company's timing was indeed fortunate.

Tom Watkins was peripherally aware of the company and the whole genomics movement. After graduating from William & Mary and working in Washington, DC, as an accountant, he went to the University of Chicago in the late 1970s, earning an MBA. His next move was to McKinsey & Co. where he found himself working with a variety of healthcare clients. His connections led to Chicago-based Abbott Laboratories. He joined Abbott in 1985 and spent the next two decades there, first in its diagnostics business and later in its pharmaceutical operations. Along the way, he spent four years in Japan as an executive with one of Abbott's Asian affiliates. A great experience for both him and his family, Watkins says while there, he learned that there are more approaches to problem solving than those he grew up with.

"As Americans we don't appreciate not having the dominant way of thinking about a particular problem," he says. "When you go to China or Japan, it's different."

Watkins returned to the U.S. in 1998 and took over a joint venture that Abbott had with its Japanese partner, Takeda Pharmaceutical. As president of TAP Pharmaceutical Products,

he helped double TAP sales to \$4 billion but also saw the firm plead guilty to a fraud charge related to the marketing of its prostate cancer drug. The activities that led to the plea happened before Watkins' tenure and were one of the challenges he overcame as TAP president. Such compliance issues, he acknowledges, are typical in the oft-Byzantine regulatory world of pharmaceuticals.

As Watkins was navigating TAP through profitable and troubled waters, William Haseltine was looking for a successor at HGS, one who could take the company from R&D to the pharmaceutical market.

# the management guy

"The genomics world had gone through a period of very high expectation," Tom Watkins explains. "By the time I got here [early 2005], the realities of the time and expense of developing drugs had set in. I think the promise of the company and the opportunities we had were still there. The stock was reflecting concerns and the company was very much at a crossroads. We'd gone through some belt-tightening, as many companies had. We downsized very significantly right before my arrival and were still in the process of shedding buildings and capacity to become a more focused company. That was difficult."

Human Genome Sciences had been going through a progressively more difficult patch since the tech boom went bust in 2000. The promise of genomics-based drug development seemed to have faltered. As a 2004 *New York Times* article put it, "While drug companies have been inundated with genes, they must still figure out what the genes do and still must develop chemicals to influence the effects of those genes."

HGS was in the midst of doing just that, though on a narrowed scale. In March of 2004, the company announced it was dropping the development of nearly half of the drugs in its pipeline and about 200 jobs. Despite having put more drugs discovered using the human genome database into clinical trials than any other company, HGS had few results to excite the market. Simultaneously, its founder CEO, William Haseltine, announced his retirement.

Haseltine said his move was necessary as the company shifted from gene research to drug development. At that point, Haseltine concluded, HGS needed an experienced pharmaceutical executive to take it to market. Tom Watkins was the man.

"I will not come close to filling [Haseltine's] shoes technically," Watkins told the *New York Times* in late 2004. Nearly six years later, he reiterates the sentiment sitting at the table in HGS' conference room.

"My background and Bill Haseltine's background couldn't be more different," Watkins says. "He's a leading scientist. I'm a management guy. I thought this was just a terrific opportunity."

A terrific opportunity, Watkins explains, because it gave him the chance to accelerate and complete the transformation of HGS as a commercial enterprise. Contrary to the perception





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# **HUMAN GENOME SCIENCES**

Human Genome Sciences, Inc., (HGS) is founded by Dr. William Haseltine in a joint venture with J. Craig

HGS attracts a \$125 million investment from pharmaceutical major, SmithKline Beecham

HGS goes public and raises an additional \$34 million

HGS achieves a market capitalization of \$5 billion and a price of \$241 per share

Tom Watkins joins HGS

Watkins leads the company into partnership with Novartis on HGS' hepatitis C drug, Zalbin



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that Haseltine's genomics-based drug development thrust had run aground, he had actually put the company on the right path, its current CEO maintains.

"Bill laid a terrific base for this company," he says. "We would not be where we are today without his vision and leadership, establishing the product base and setting the direction. His investments in manufacturing, process development and product development were crucial."

He also raised a lot of capital. "Bill made sure the company was well capitalized at a time when the opportunity to raise it was pretty robust. He recognized that wherever you go, you're going to need capital."

Indeed, though its stock price had fallen to around \$11, HGS had a bit over \$1 billion in cash. It was an important cushion, though there was a sense of urgency, Watkins reveals.

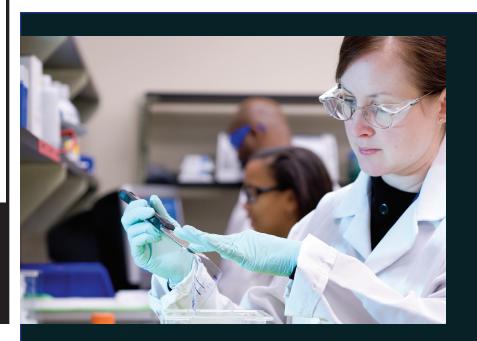
"It may not have been a loud fire drill, but the alarm was going off," he says. "There was a billion dollars, but the rate at which we were burning that cash was frighteningly high."

HGS was burning in excess of \$200 million a year and its most mature products were still in early Phase II clinical trials. Drug development is, at best, a drawn-out evolution - the average three-stage clinical trials process requiring 10 years or more. When he came aboard, HGS was about halfway through development of its Lupus drug, called Benlysta. Getting Benlysta through clinical trials and to a potential \$2.9 billion market while surviving in the meantime was Watkins' prime directive.

His marketing and sales background was just what HGS needed, but Watkins admits it was an "enormous shift" for the company. Susan Bateson agrees. "I think of Tom having come in and precipitated a frame shift," she says. "We had already done a lot of the work. What he brought with him was a disciplined approach to realizing the capability that we had."

A move to become more product focused and to intensify drug development had indeed begun (Haseltine had hired Genentech veteran, David Stump, as head of clinical development) but the "commercialization" of HGS had to accelerate.

"I came in and asked business and return-on-investment questions from the beginning, which I'm sure were asked before my time," Watkins allows, "but they became the first ques-



HGS makes the decision to concentrate on two large programs - Benlysta and Zalbin

### March 2009

HGS' hepatitis C drug posts mixed results in its clinical trials; stock hovers at \$0.55

### July 2009

HGS releases its Phase III trial results for Benlysta. Results show that Benlysta improved important symptoms of Lupus without worsening others, the first drug to do so in nearly six decades

### November 2009

A final late-stage trial in November 2009 confirms the Benlysta results

### December 2009

HGS ends the year with \$1.2 billion in cash and investments. Its first product sales of Raxibacumab, an anthrax drug, help it post its first-ever modest (\$1.6 million) profit

tions rather than the 10th."

Watkins remembers in his earliest days asking how HGS was going to make money from pipeline drug X or Y and that the answers were less clear in some areas than they are today. Undaunted, he describes the process as "the healthy evolution of promising companies."

### commercialization

Key to enabling that healthy evolution was raising more cash. Financing was significantly harder to arrange by 2005, so Watkins began looking at HGS' assets.

"One of the things we had done internally was build and pay for our manufacturing facility," HGS vice president of communications Jerry Parrott explains. "Tom led the company to sell the buildings to turn them into cash and then lease back the facilities. We still had the control and flexibility that we wanted, but it was a different way of thinking about what we needed to own."

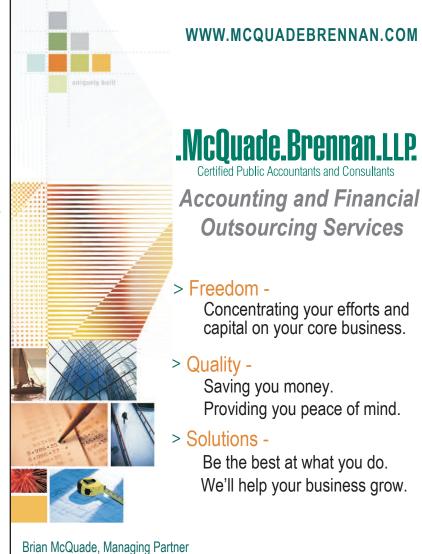
"Tied up cash in bricks and mortar for a company where we were didn't make a lot of sense," Watkins agrees. In his first 12 months, he complimented what he calls "financial engineering" (selling the land and buildings generated about \$380 million with no financing) with a necking-down of ongoing drug development programs to preserve and redirect the

"All of them had promise, but instead we said, 'We're going to pick a couple with the most potential." They'd pick those that had promising clinical data, a foreseeable pathway to market, and market potential.

"Sometimes companies get enamored with the science of a program and the market potential is less well defined," Watkins observes. "We were a bit in that situation. It's a tricky

Watkins further strove for balance by spinning off some of HGS' assets into a separate company. He also pushed development of an anthrax antidote the company had discovered

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called Raxibacumab. Though its market potential was relatively modest, it offered an opportunity to sell to the U.S. government and get cash quickly. Watkins also saw the value in partnership.

"I came to this position recognizing that we were going to need several partnerships and that we'd have to figure out the organizational skill to make them work. That's tougher for a small company to do in its early stages. I think we've done a pretty good job."

Partnerships could help HGS speed development, aid with the design of clinical trials and help defray their cost. In 2005, Watkins led his firm into partnership with Novartis on HGS' hepatitis C drug, Zalbin. "It's very much a 50-50 sort of relationship, which are hard to make work because nobody has the deciding vote," Watkins acknowledges.

He's confident that HGS will make both its Glaxo/Benlysta and Novartis/Zalbin partnerships mutually beneficial and stresses the rarity of a small player like HGS being considered an equal.

"Usually when a large company partners with a small biotech company, the scenario is, 'Boy this is a great discovery you've made. We will take it and we will run it from here. We will run the clinical studies,'" Watkins says. "Often that makes sense because the smaller company doesn't have the expertise to run large-scale clinical studies. In both of our cases, [GSK and Novartis] found the capabilities we had to run those trials to be advanced enough that they said, 'You know this product, you run the trials.' They both trusted relatively little HGS."

Among the other product-focused changes Watkins initiated was his first executive hire, Barry Labinger. Labinger is HGS' chief commercial officer, charged with building a marketing and sales organization that will compliment the company's R&D foundation. Head of 3M's pharma business before coming to HGS, Labinger admits he didn't know much about HGS, though he had previously worked at Abbott and knew of Tom Watkins. Missing an opportunity to spearhead commercial development at Immunex (a successful early bio-pharma company acquired by Amgen on the strength of its arthritis medication, Enbrel) spurred him to join HGS.

"For me it was like Immunex at an earlier stage than when I was there," Labinger says. "One of the few regrets I had about my Immunex experience was that I got there right after their big product was launched, so a lot of the table had been set. The partnership deal had been done five years earlier, a lot of the portfolio decisions had been made, trial design issues had been resolved. And I believe, as Tom did, that the ideal time to bring in a senior commercial voice is to do it early."

Leading the marketing effort isn't just about hiring sales reps. Despite the fact that Benlysta had yet to prove itself in clinical trials, Labinger and his team busied themselves researching potential markets, communicating with investors and giving their own input to the design of clinical trials.

"It's so that when we get the data, it's not only data that will get regulatory approval but also give us what we need in order to promote," Labinger says. "If you don't think about that early on, it's too late to do it later. We're not going to go out and do another expensive trial."

Timing the physical expansion of HGS' marketing arm is crucial, Labinger adds. "That's been a careful thought process for Tom and I over the last few years. What work do we do? You don't want everything backed up until the last minute. On the other hand, while the product is still at high risk, you may not need the people. We're getting close to the point where we'll be full speed ahead to get everything done as quickly as we can."

As he made strategic and tactical decisions for the company's future, Tom Watkins committed to ensuring that the culture that had driven it would be maintained. Early and midphase clinical trials of Benlysta yielded mixed results during 2005 through 2009 and more people left the company. By the middle of 2006, Watkins said it became clear HGS would bank on two large programs - Benlysta and Zalbin. Though HGS' stock continued to slide, employee turnover remained remarkably low.

"This was in an environment," Watkins relates, "in which neighboring companies like MedImmune, which was founded only a couple years before we were, was flourishing as an independent company and was bought out by Astra Zeneca at a sizeable premium. I give our employees a tremendous amount of credit for sticking with the program."

They stayed, Susan Bateson says, because of the responsibility and autonomy they'd been given at HGS, because they understood the vagaries of the pharma business and because they understood and bought into the direction in which Watkins was taking the company.

"From the day he walked in, Tom has been a very good communicator," Bateson says. "He likes talking with employees and he comes across authentically. He's real. You can feel that and we get that feedback from employees all the time."

Communication is put into action monthly in management committee coffees wherein Tom and another senior executive invite employees to join them and ask whatever questions come to mind. Candor is highly encouraged.

"People here really have the expectation that a spade's going to be called a spade," Jerry Parrott adds. "If the data is bad, it's acknowledged. There's a sense of being treated with

That candor and the collegiality and passion that HGS researchers have must be upheld by the company's new marketing arm, Watkins, Labinger and Bateson agree. Soon enough, it looks like they'll have something quite beneficial to sell.

# out of the depths

On an evening late last July, HGS released its Phase III trial results for Benlysta. Analysts at nine research firms had predicted its failure. They were wrong. Benlysta improved important symptoms of Lupus without worsening others, the first drug to do so in nearly six decades. The results were "results you don't see in a lifetime in this industry," Parrott explains. "We had people literally weep when they saw the data."

A press release, timed to coincide with the start of London trading day for UK-based

"Most things fail. I'm reminded of Michael Jordan who said, 'I've missed 37,000 foul shots and that's why I've succeeded.'"

Glaxo, came out at midnight in the U.S.

"I think almost every employee was awake at midnight to click onto the internet and they saw that the stock was positive," Watkins says. Ending the previous Friday at \$3.30 a share, HGS stock opened at \$9 on Monday and closed at \$12.50. Two months later it stood at \$22.

"Later that week, we had another all-employee meeting. You can imagine that meeting was a little different than the one we had in March," HGS' CEO enthuses. A final late-stage trial in November 2009 confirmed the results.

"I don't think the situation we faced was different than many companies face," Watkins says. "The striking nature of last year was that we hit what some would have said was the depths and four months later we were way up."

Tom Watkins and his team wasted no time taking advantage. In August and December 2009, the company issued successful public offerings of HGS common stock. "What did we do right after we got the results in July and November?" Watkins asks. "We went right to the capital markets. You cannot wait."

HGS ended the year with \$1.2 billion in cash and investments. Its first product sales of Raxibacumab helped it post its first-ever modest (\$1.6 million) profit. While 2009 was transformational, in 2010, HGS will have to execute, Watkins affirms – standing up its marketing and sales organization, adding manufacturing capacity, filing its biologics licensing application for Benlysta with the FDA, continuing late-stage trials of Zalbin and further building its drug pipeline will tax the company.

"I tell people, only half in jest," Tom Watkins smiles, "it was a simpler company to manage this time last year."

Though on a solid footing, HGS will face minor reversals. It's the pharma business, Watkins explains. "The nature of drug development is that most things fail. I'm reminded of Michael Jordan who said, 'I've missed 37,000 foul shots and that's why I've succeeded." CEO



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