For **Mark Ahn**, Ph.D., leadership is less about the power of one individual and more about the creation of heroic teams. Using a mix of literature, history, and traditional business skills, Dr. Ahn has found ways to unlock the imagination of his colleagues and employees at Hana Biosciences to build a company with a vision for bringing treatments to patients with cancer.



CLASSICISM AND HISTORY

rarely are considered central planks in corporate leadership. But for Mark J. Ahn, Ph.D., these disciplines are not impenetrable areas of academia but a powerful way to unlock employees' imagination to propel their success and that of the

company.

"Despite the corporate dramas of late, a

central and abiding truth is that business is not about heroic leaders but leadership, and I believe that leadership is fundamentally a group exercise," says Dr. Ahn, president and CEO of Hana Biosciences Inc. "Whether we are speaking about the accomplishments of the ancient Greeks or breakthroughs in today's gene therapy companies, cultures and organizations can produce extraord in ary results when they empower teams capable of heroic behavior."

Dr. Ahn has injected this team spirit into Hana Biosciences, bringing together a group of people who strive to work together for the benefit of the company as well as for each member of the team. The building of that team was a central tenet of Hana's formation.

"Rather than building our team vertically,

which most companies do — in other words, building a research group and then adding functions from there — we built our team horizontally," Dr. Ahn says. "We started sideways with a scalable team and then built out so we could aggregate our assets quickly. We have great people in clinical, research, regulatory, finance, and business development."

Hana Biosciences is a South San Francisco, Calif.-based biopharmaceutical company that acquires, develops, and commercializes products that address unmet medical needs in cancer. The company started out as Hudson Health Sciences in 2002 and merged with a shell company, EMLR Inc., to become a public entity in July 2004. The combined company then changed its name to Hana Biosciences.

The company's name is fitting in a number of ways. Hana means health in Hawaiian, and Hana is an area on the island of Maui.

"Hana is the twisting 56-mile road in Maui, which I often use as a metaphor for what it feels like to be part of a start-up company," Dr. Ahn says.

Though the path of a start up may be full

of twists and turns, Dr. Ahn and his team have big ambitions for the nascent company.

"This might sound like we're reaching, but we aspire to be the Cisco of biotechnology," he says. "The idea is tight focus, scalability, and aggregation of assets that come together to multiply value."

A Worldwide **Perspective**

After growing up in the idyllic surroundings of Hawaii, Dr. Ahn went on to have a truly international career. He completed his

Hana Biosciences' **Development Strategy**

HANA BIOSCIENCES IS FOCUSED ON ACQUIRING, DEVELOPING, AND COMMERCIALIZING INNOVATIVE PRODUCTS FOR THE TREATMENT OF IMPORTANT UNMET MEDICAL NEEDS IN ONCOLOGY.

The company has acquired three oncology products in development: PT-523; IPdR; and Ondansetron Lingual Spray.

PT-523 IS A NOVEL NONCLASSICAL ANTIFOLATE that is a water-soluble, nonpolyglutamatable analogue of aminopterin. PT-523 exhibits 10-fold higher affinity to its target enzyme DHFR than MTX (methotrexate) and uses the membrane-bound transporter (RFC) 10-fold more efficiently than MTX. In addition it has been shown to be 10- to 100fold more potent than MTX in preclinical studies. The results of these studies suggest that PT-523 has the potential to significantly enhance the treatment of patients with cancer and autoimmune diseases. Hana is conducting a Phase I study of PT-523 in solid tumors; a Phase I/II study in non-small cell lung cancer was recently initiated. Phase II trials in acute lymphocytic leukemia, cervical, endometrial, and ovarian cancers are forthcoming.

IPDR IS A NOVEL ORAL PRODRUG OF

IUDR being developed as a radiation therapy sensitizer for the treatment of brain cancers. IPdR is converted to IUdR by a hepatic aldehyde oxidase. Intravenously administered, IUdR has demonstrated efficacy and survival advantage in a Phase II trial, but has unacceptable gastrointestinal and myelotoxicities. Because of the low concentration of aldehyde oxidase in the small intestine and bone marrow, IPdR treatment may avoid previously observed toxicities with intravenous IUdR. Preclinical studies have demonstrated that oral IPdR possesses a superior effica cy and toxicity profile versus IUdR. A Phase I trial in solid tumors will be conducted at Case Western Reserve University and a Phase I/II trial in glioblastoma multiforme will begin later this year.

ONDANSETRON LINGUAL SPRAY (LS) IS A NOVEL DELIVERY SYSTEM that uses the vast and highly absorptive surfaces of the oral mucosa to deliver ondansetron directly into the bloodstream, thus achieving therapeutic levels in a shorter period of time than conventional oral dosage forms. Ondansetron is a selective blocking agent of the seratonin 5-HT3 receptor and is accepted as the standard of care to prevent chemotherapy-induced nausea and vomiting. Ondansetron LS may provide a more rapid delivery of ondansetron as compared with current oral forms by avoiding the first-pass effect since drug delivery via the oral mucosa avoids degradation in the gastrointestinal tract and metabolism by liver enzymes. Hana licensed the exclusive rights to develop and commercialize Ondansetron LS in the United States and Canada from NovaDel Pharma. Initial studies are ongoing to determine pharmacokinetics of Ondansetron LS versus the oral pill formulation.

Ondansetron LS is Hana's product nearest to market, and Mark Ahn, Ph.D., president and CEO, says the focus is on adjuvant breast cancer as the launch target indication.

"Breast cancer patients are younger, and they value maintaining their active lives," Dr. Ahn says. "They routinely receive chemotherapy regimens that induce nausea and vomiting. We think Ondansetron LS can make an impact on the quality of life for these patients in terms of a convenient oral spray and enhanced efficacy as measured by time to onset of action to relieve nausea and vomiting."

A component of the company's strategy is to acquire global rights to additional product candidates and form alliances in oncology, while continuing to develop and commercialize new products and line extensions.With that in mind, the company has reached out to the academic community.

"Academia is more likely to develop breakthroughs be cause they have more scientists, resources, and patience," Dr. Ahn says. "Academia is built for target validation and lead optimization but it's not built for translational development. That's where our partnership approach comes in to create value by advancing cancer care." undergraduate degree in history in Hawaii, and then he furthered his studies in England and Australia.

At Amgen, he was responsible for a subsidiary that develops and promotes biotechnology-based pharmaceutical products throughout the Greater China region, including China, Taiwan, and Hong Kong.

At Bristol-Myers Squibb, he oversaw budgeting, strategic planning, business development, and communications for Japan and China. And he was project leader for Bristol-Myers Squibb's Secure the Future program, a \$100 million commitment to provide care and support for women and children with HIV/AIDS in sub-Saharan Africa.

That role took him to Africa on many occasions, where he researched ways to work with people and governments to help those living with the disease. Today, Dr. Ahn continues his strong involvement in HIV/AIDS programs through his ties to the medical school at The University of South Africa. (For more information, see box below.)

His world view and focus on values have undoubtedly had a significant bearing on his business drive as well as the path he has helped establish for Hana.

"Breaking ground, overcoming fears, con-

tinuously innovating, and building enduring teams that are value-based has been a stepwise process for me made possible by the phenomenal constellation of mentors who I've had along the way and whom I'm indebted to," Dr. Ahn says.

To help define that path and engender excitement and enthusiasm in his team, Dr. Ahn has sought to embrace all aspects of human greatness in how he manages, including the use of poetry.

"We live in a technology filled, wired world of change and temporal security," he says. "Ironically these conditions are precisely those that demand a need for competitiveness, which is only possible when team members can bring their full and focused commitment and imagination to their work. At its best, poetry is about capturing the essence of being fully human and facing our deepest fears, which in turn allow us to bring out our best selves."

When Dr. Ahn and his team got together to write the culture statement for Hana, they were determined to establish a company with a very firm set of beliefs and one built around values.

"Our culture statement was inspired from a line from Keats, which is, 'I'm certain of nothing but the holiness of the heart's affection and the truth of the imagination," Dr. Ahn says. "That line speaks to four areas of our culture. Firstly, we enhance the lives of patients through bold and continuous innova-



Drawing Strength from Angels of Hope

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, MARK J. AHN, PH.D., PRESIDENT AND CEO OF HANA BIOSCIENCES, TALKS ABOUT THE PEOPLE AND PRACTICES THAT INSPIRE HIM, HOW HE SEEKS TO GUIDE OTHERS, AND THE CHALLENGES HE FACES AS A LEADER OF AN ONCOLOGY-FOCUSED COMPANY.

YOU'VE BEEN INVOLVED IN HIV/AIDS PROGRAMS IN AFRICA, WHAT IMPACT HAS THIS HAD ON YOU PERSONALLY AND IN SOME OF THE PROFESSIONAL DECISIONS YOU HAVE MADE, AND WHAT DO YOU BELIEVE PHARMA'S ROLE, AND THE ROLE OF OTHER AMBASSADORS IS OR SHOULD BE IN THIS AREA?

HIV/AIDS is a global pandemic, afflicting more than 40 million people. But 95% of those living with HIV are in the developing world. So the impact is disproportional, and in many instances on those most vulnerable. From a professional perspective, I believe the biopharmaceutical industry needs to be a leader and part of the solution in stemming the pandemic, which also takes political courage.

I've witnessed increasing mobilization from people and institutions of goodwill, but at the same time a lot of frustration at the cultural complexities of making a difference in an environment that, in many cases, is faced with grinding poverty and vulnerable people. The response is often clouded by these frustrations.

I've had the opportunity to meet individuals who, despite all the odds stacked against them, despite being in areas where ignorance prevails, where there's a lack of medical supplies, provide hope, not only for their communities, but I think for us all from a very human standpoint. They capture the very best of what it is to be human. I draw great strength and energy from them, and it makes our everyday problems pale by comparison.

WHAT IS IT ABOUT THE PHARMA/BIOTECH INDUSTRY THAT MOST INSPIRES YOU, AND HOW DO YOU HOPE TO INSPIRE OTHERS?

Healthcare in general and cancer specifically are major concerns of people and their families everywhere. These are pressing social issues and important commercial opportunities. We tion; secondly, we develop extraordinary team members who can realize their full potential and their talent and imagination; thirdly, we c reate high performance teams committed to the unlimited success of one another as well as our suppliers and partners and shareholders; and fourthly, we seek goodness and grace in others with the highest standards of integrity. We use this as a way to communicate with prospective as well as current employees, and we also set this up as our performance review criteria."

A culture built around goodwill is one Dr. Ahn believes will thrive.

"We need to explore how we recognize the inherent goodness in others, and I think great literature is timeless precisely because it describes the principles about our existence," he says.

Though culture is clearly a high priority for Dr. Ahn, he is equally aware of the vagaries of the capital markets and therefore the importance of knowing how to operate within the financial world.

Both his academic background — Dr. Ahn has a Ph.D. in business administration — and his extensive work experience in finance, strategic planning, sales and marketing, and general management have been a boon to him in developing and communicating Hana's business model, and in creating sustainable approaches to growth and value in the biopharmaceutical industry.

"While the industries of our economy vary widely, we're all in a continuous competition for capital, which by comparison makes the political cycle look like a lunar eclipse," he says.

"This constant referendum in the capital markets makes the value of being able to raise, allocate, and manage capital critical for a company's success and sustainability. I learned this lesson in real time in finance positions and was also fortunate enough to have profit-and-loss responsibility early in my career at Amgen, which gave me an appreciation for maintaining a tight focus and making tough choices."

Appreciating the volatile nature of funding, Dr. Ahn has sought multiple ways to keep the company's finances fluid. Hana completed two financing rounds in its first year, which raised \$14.7 million, and the company raised \$12 million in grants. Furthermore, the company acquired a product in later stage development — Ondansetron Lingual Spray, which Dr. Ahn says is set for a late 2006 or early 2007 launch — to enhance Hana's revenue stream.

Creating a **Cooperative**

For Dr. Ahn, the formation of Hana cemented a desire to create a new, more inclusive business model. At the outset, Hana comprised three people: Dr. Ahn, Fred Vitale, who is VP of business development, and Dr. Ahn's assistant, Eva Cabico, who came with him from Genentech.

"When we looked at the predominant business models out there, we believed there was an important gap that was not being addressed," he says.

Essentially there are two chief models in the biopharmaceutical industry, Dr. Ahn explains. The first is a small company that is backed by venture capitalists and that conducts its research and development from a single technology platform.

"Its strength lies in the fact that it allows focus and iterations from a specific platform," Dr. Ahn notes. "But, this model is high risk because of the lack of diversification and because of long development periods."

The second major model is specialty pharma, which is based on redirecting sales of smaller products acquired from bigger companies, which Dr. Ahn says allows those companies to accelerate speed to market, but is lower on the innovation front.

live in the most exciting period of biological insights and discovery known to man, and we've only begun to realize the many ways in which biology will lead to changes in how long we live and the quality of our lives. Front and center is certainly cancer care, which is an important, unmet medical need.

WHAT IS YOUR MANAGEMENT STY LE, AND HOW DO YOU SEEK TO INFLUENCE AND ENCOURAGE YOUR EXECUTIVES?

My management style is to be customerled, which in Hana's case means making significant advances for cancer patient care. As a company, I believe it is imperative to have a key competency focus: a company can only be great doing a few things. And then a company needs tight organizational alignment to reinforce all actions and resource allocations. My objective is to identify high potential people and their individual strengths, then focus on how their gifts can drive innovation and team speed and sustainable results. Hana is the anti "mini-me" approach company. The idea is everyone has individual gifts, and the goal is to identify them and put people in places where they thrive. The management dogma of the West has been focused on remediating people, on trying to fix their weaknesses. I say focus on their strengths exclusively and work around their weaknesses. Celebrating people's strengths may seem a more fatalistic approach to management, but it's one I've thoroughly come to believe in.

AS YOU PREPARE HANA BIOSCIENCES FOR FUTURE GROWTH,

WHAT IS YOUR MOST PRESSING CONCERN?

It is important that we enhance the level of patient participation in clinical trials. The fact that the five-year survival rate of patients with cancer is 62%, which is great because this percentage has increased over the years, but the fact that it's only 62% means we have a long way to go. The only way we can definitively answer questions and have evidencebased medicine is to have increased part icipation in clinical trials. It's the only way innovation will move forward. But fewer than 5% of all oncology patients in the United States participate in clinical trials and that's impeding our progress. That's one of the reasons we're going abroad to help fill the clinical-trial roster.

"This model is opportunistic with lower margins, and I question its sustainability," he says. "This model requires that companies can find opportunities that other companies don't recognize on a serial basis, and I don't believe an industry can flourish around the idea of being strategically opportunistic."

With this in mind, Dr. Ahn and his colleagues set out to establish a company that could best be described as collaborative. The company's business approach has been threefold: the first has been to build a technologically agnostic set of platforms, which frees Hana from being locked into a single technology and gives the company greater flexibility should one technology fail; the second has been to remain focused on one disease area — oncology; and the third has been to create a true and ongoing partnership with academia, one in which academics have a stake in the company.

From Moliere to Molecules

DR. MARK AHN — RESUME

2003 — PRESENT. President and CEO, Hana Biosciences Inc., South San Francisco, Calif.
2001 — 2003. VP, Hematology, Sales and Marketing, Genentech Inc., South San Francisco, Calif.
1997 — 2001. Senior Director, Immunology Sales, Bristol-Myers Squibb Co., Princeton, N.J.;
Senior Director, Operations & Planning, International; Director, Operations & Planning, Japan & China

1991 — **1997.** General Manager, Amgen Greater China Ltd. (Hong Kong, China), Amgen Inc.; Associate Director, Business Development, Asia Pacific (Thousand Oaks, Calif.; Hong Kong); Assistant Treasurer, International (Thousand Oaks, Calif.)

1987 — **1991.** Project Finance Manager, FMC Corp., Philadelphia; Foreign Exchange Manager, Chicago; Foreign Exchange Specialist, Chicago

1984 — 1990. First Lieutenant, Infant ry Branch, U.S. Army-Regular and Reserve, Ft. Bragg, N.C.

EDUCATION:

2000. Ph.D. in Business Administration, University of South Australia, Adelaide, Australia1986. Rotary International Graduate Fellowship in Economics, University of Essex, Essex, England

1985. MBA with emphasis in Finance, Chaminade University, Honolulu

1984. BA in History, Magna Cum Laude, Chaminade University Honolulu

TEACHING EXPERIENCE:

2002 — PRESENT. University of Notre Dame de Namur, adjunct faculty

- 2000 2002. College of New Jersey, adjunct faculty
- 1999 2001. National School of Public Health, MEDUNSA, adjunct faculty
- 1998 2002. Be rkel ey College, adjunct faculty

BOARDS AND FELLOWSHIPS:

2002 — PRESENT. University of Notre Dame de Namur, School of Business Trustee

- 2001 PRESENT. As pen Institute, Henry Crown Fellow
- 2001 2002. Global Health Organization, Board Member
- 2000 2004. National School of Public Health, MEDUNSA, Board of Trustees
- 1997 2000. New York Pharma Forum, Board Member
- 1994 1998. US-China Business Council, Board Member

"Rather than haggle over up-front milestone payments for intellectual property, we offered scientists equity in the company, with the promise of a greater slice of that equity if their drug succeeded," Dr. Ahn says. "The reality is that in oncology a lot of prospects don't succeed. But in our model, if a scientist's drug fails, he or she still gets a position in other products by way of having equity in the company."

On the other hand, the scientists whose drugs do succeed will obtain a larger slice of equity, he explains.

"So, we've developed a cooperative model, and as we expand our portfolio, the research cooperative grows and we all benefit as a result of coming together," Dr. Ahn says.

In selecting its product targets, Dr. Ahn looked for areas that other companies were missing.

"Big biopharmaceutical companies predominantly do licensing either in early-stage science to accelerate the company's own discovery efforts or after proof of principle," he says. "But the middle area — going from an optimized lead to a clinical product — is fertile ground for those willing to do the work."

Dr. Ahn adds that it was important not to lock the company into a single platform.

"I call this the 'no mouth-to-mouth resuscitation policy," he says. "Companies with only one technology have an overwhelming propensity to keep looking for a use for it even if it should be discontinued. And this model scares me."

Keeping an **Open Mind**

In his management, Dr. Ahn promotes a universal and open approach, one that seeks what is best for the company as a collective and one that searches for practical and constructive solutions to the challenges facing the industry.

"In the pall mall complexity and pace of the corporate environment it is easy to get pulled into the firefight of the day," he says. "History teaches us that things will go wrong and how we respond to those problems is often the difference between survival, success, or disillusion."

To ensure Hana doesn't get bogged down in the quagmire of complacency, Dr. Ahn keeps a keen focus on what he refers to as first principles.

"First principles are about making sure

that all of the resources and focus are on the big priorities," he says. "In defining our culture, for example, we wanted to make it clear that while we wanted great people with individual functional skills, it was equally as important that they be committed to other people's success. This does not overlook, for example, the fact that someone might be performing well functionally, but may not be fitting in culturally."

Keeping Hana's overall mission in mind, first principles also mean ensuring that the company stays focused on oncology.

"When we do our business development audit, we often are presented with the opportunity to focus on different products," he says. "While it might be tempting to be opportunistic, if we get away from our focus, then we may damage the company or limit its valuation upside along the way."

In addition, teaching, which Dr. Ahn continues to do as an adjunct faculty member at the University of Notre Dame de Namur, keeps him open to novel ways to approach problems.

"Having a group of MBA students

do a case study provides fresh, pioneering, nonlinear thinking that challenges long-held dogmas about how things should work," he says. "As one consultant said, 'sacred cows make the best hamburgers."

Adaptability and imaginative approaches to seemingly huge problems are vital for the future of the biotechnology and pharmaceutical industries, Dr. Ahn contends. But the industry has been reluctant to tackle change.

"If one looks at the phenomenally productive and profitable pharma industry, we're clearly at a fork in the road," he says. "On the one side we have more biological insights and discoveries at a basic science level than we've ever had before. On the other side, the consolidation of big pharma has not led, by and large, to increasing the pace and intensity or the productivity of innovation."

In fact, while shrinking pipelines and other problems took their toll on big pharmaceutical companies last year, the biotechnology industry largely remained strong. The AMEX biotech index posted a gain of 11% while the AMEX pharmaceutical index fell 6%. Biotech's gain is well above the Dow Jones'



We need to explore how we recognize the inherent goodness in others, **and I think great literature is timeless precisely because it describes the principles about our existence.**

3.1% gain, the S&P 500's 9% increase, and the Nasdaq Composite's 9% rise.

Innovation challenges are not the only issues the industry is facing.

"Patient access to medication is a key issue," Dr. Ahn says. "The industry needs to go from a defensive posture to being an active member in the debate on expanding access in the United States and globally to medication. It's not just about pricing."

By way of example, Dr. Ahn points out that in the United States the price of food is not set, yet those in need are assured access to food.

"As a society, as expressed through our legislative bodies, we need to make a decision as to what to do about minimal levels of healthcare as opposed to backing into higher numbers of uninsured populations, which is exactly what we're doing now; we're making a decision by not making a decision," he says. "This is hurting the industry's image."

Dr. Ahn believes that by acting in concert with the government, in the long run this will improve the industry's image and expand its base of business.

"Blindly relying on the argument that

high prices are needed because of increasing research development costs is disingenuous, and we risk alienating ourselves precisely when we have so much to contribute to the political and social debate," he says. "The biotech industry should be leading the debate on these hard choices to ensure access to medicines in the developed and the developing world."

In finding solutions for these difficult problems, the industry could look to other creative deals that have been struck between the biopharma industry and government legislators, Dr. Ahn notes. In particular, he points to the Orphan Drug legislation, which encourages biopharmaceutical companies to develop treatments for patient populations with fewer than 200,000.

"A tremendous wave of innovation arose from that legislation," he says. "For example, Genzyme is entirely built on developing orphan drugs. The company has achieved sales of about \$2 billion on a number of very small drugs."

Ultimately, the therapeutic solutions must come from the industry itself, not from government.

"History shows that the government is not good at choosing winners and losers; innovation is best conducted in the private sector, and, therefore, the industry needs to seize the initiative," Dr. Ahn says.

Besides innovation and access, a third issue the industry faces is governance, and again Dr. Ahn encourages his industry colleagues to rise to the challenge.

"Instead of complaining about the high cost of compliance, my steadfast belief is that an appropriate balance will emerge," he says. "At Hana, we started working on governance when we only had a few people because we knew we wanted to build a sustainable, scalable, and public company. So instead of trying to fight it, I think we should be embracing governance. We should be working with legislators to make sure that procedural implementation is appropriate for the size and scale of businesses. This is going to be an ongoing debate but one I think ultimately will strengthen business in general."

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.