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# Pharmaceutical Executive

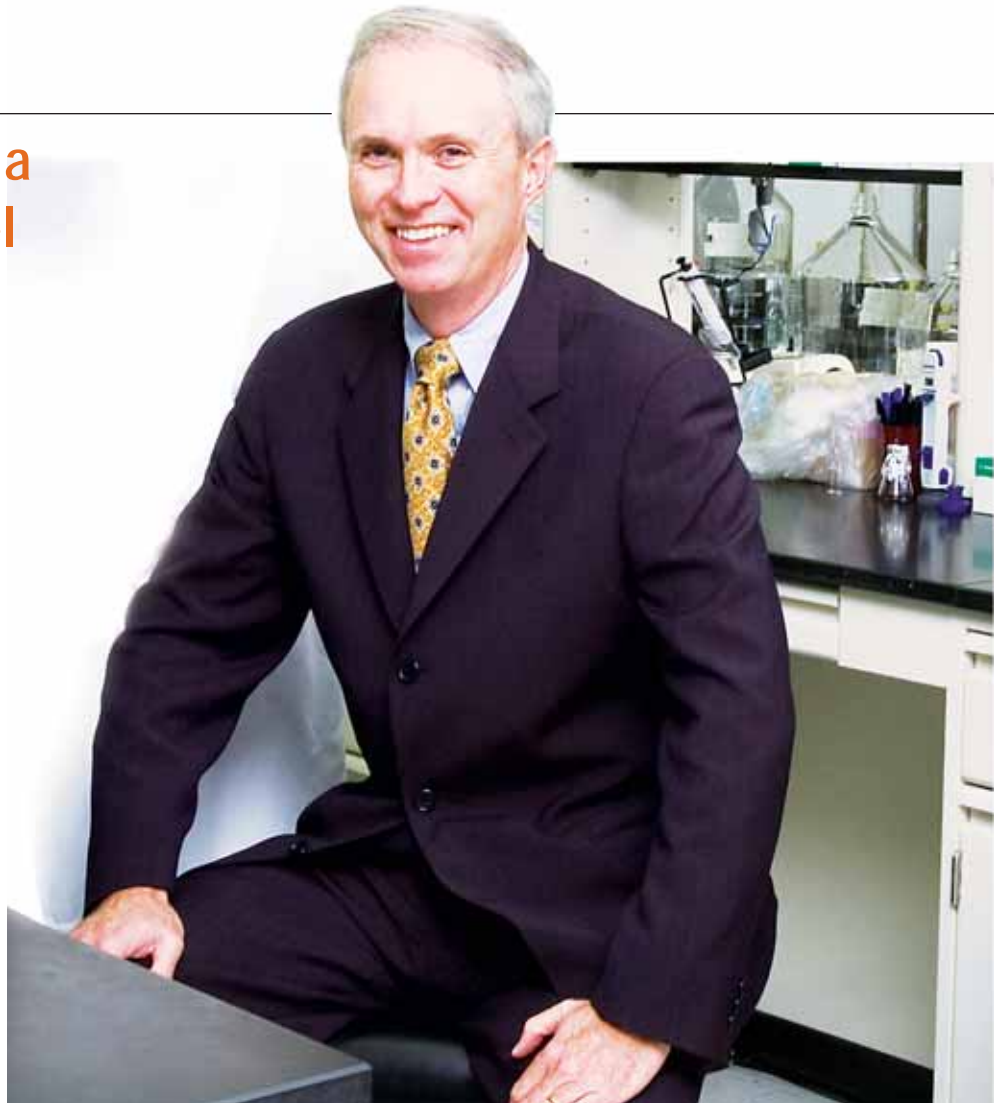
## Chief OF Staph

**Nabi Biopharmaceuticals  
is betting on a new vaccine  
for a major killer**

Nabi Biopharmaceuticals CEO Tom McLain

**“We can create a business model that is not burdened by history—not burdened by old treatment patterns, reimbursement schemes, or regulatory approaches.”**

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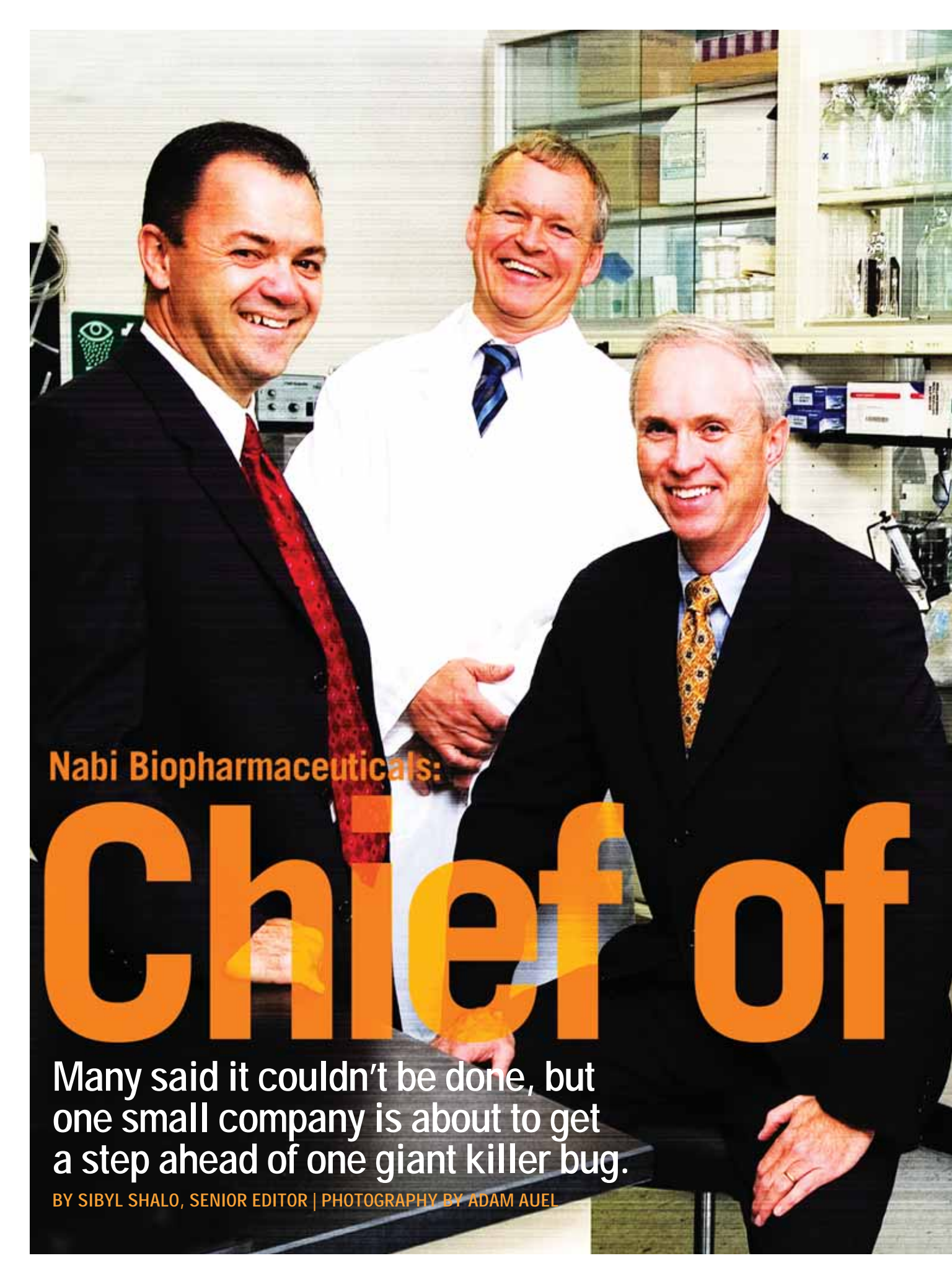
ADAM AUDEL

## Cover Story

# Chief of Staph

*Sibyl Shalo*  
Senior Editor

Nabi Biopharmaceuticals is not after the next blockbuster cure—it wants to eliminate the need for one altogether.

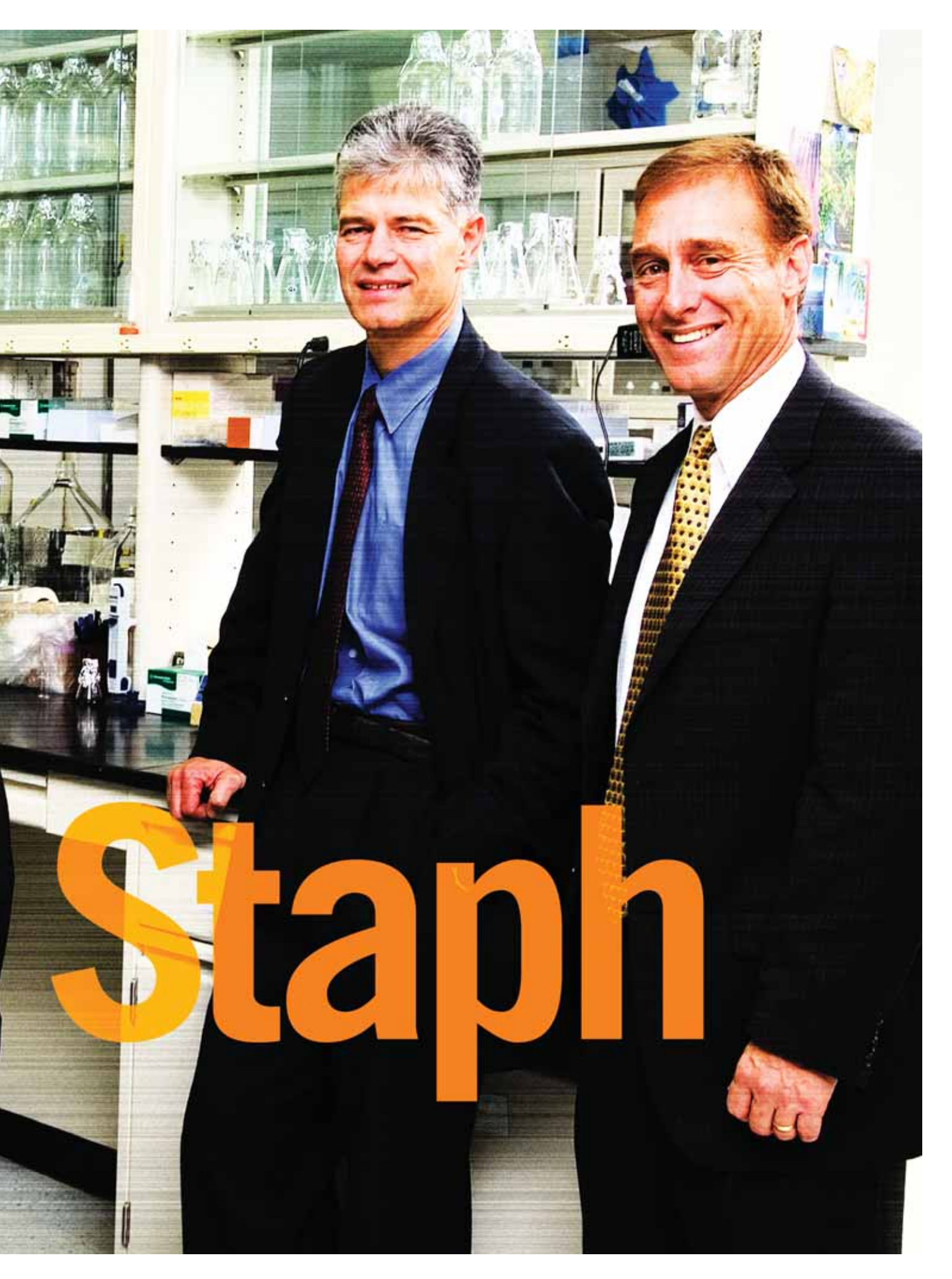


Nabi Biopharmaceuticals:

# Chief of

Many said it couldn't be done, but one small company is about to get a step ahead of one giant killer bug.

BY SIBYL SHALO, SENIOR EDITOR | PHOTOGRAPHY BY ADAM AUER



Staph

**S**ome would argue that surgeons achieved one of medicine's top breakthroughs when they first thought of washing their hands *before* operating. That was an important first step in protecting patients from the bacteria and viruses that have evolved into some of humanity's most deadly enemies. In keeping with the idea that prevention is the best way to deal with infection, vaccines have eviscerated the power of organisms causing polio, measles, and tetanus.

Government endorsed and subsidized immunization programs have done a remarkable job of keeping most children—in developed nations, anyway—free of the diseases that once took or destroyed millions of lives. Other, more recently adopted vaccination programs, for groups at high risk for viruses causing the flu and meningitis, have become the norm in many places around the world.

And still, despite their successes, many of the world's most widely used vaccines don't bring in big bucks for their corporate marketers. So it isn't surprising that the industry perceives vaccine manufacturing as a relatively low-margin business. Consider some sales figures: In 2003, the \$3.8 billion in combined US/European sales of all marketed vaccines was about the same as sales for Johnson & Johnson's Procrit (epoetin alpha), which neared \$4 billion that year. (See "One Among Hundreds," page 7.)

The typical vaccine is hardly a good candidate for traditional pharmaceutical blockbuster status. But that couldn't matter less to the 727 employees of Nabi Biopharmaceuticals. Nabi is a small but growing, vertically integrated company that has long caught the eye of analysts. In 1998, for instance, it was honored as Frost & Sullivan's Market Engineering Entrepreneurial Company of the Year, for "working harder, faster, and more efficiently than its more established competitors and making solid inroads in the market despite its smaller size."

In many ways, Nabi resembles many other biopharmaceutical companies in that its business hinges on its scientific acumen in one area—immunology. Publicly traded on the NASDAQ, it has, thus far, focused on just two professional specialty markets—hematology/oncology and more recently, nephrology. It has three products on the market:

- » Nabi-HB® [Hepatitis B Immune Globulin (Human)] antibody treatment
- » PhosLo® (calcium acetate), a treatment for elevated blood phosphate levels associated with kidney failure

» Aloprim™ (allopurinol sodium), an inhibitor of uric acid production for chemotherapy patients.

The company has a handful of new agents in the pipeline—some in late-phase research or awaiting approval—and is exploring additional uses for its current commercial product line. (See "Nabi's Pipeline," page 8.) Revenue hit \$180 million in 2004, and Nabi's executives are constantly on the road selling the company to investors.

**A small company with an ambitious goal—to prevent infections instead of treating them after the fact—is about to start a revolution.**

But that's where the similarities end. Nabi differs from its biotech peers in three valuable ways: It has no debt, it runs a two-way contract manufacturing operation, and sales of its currently marketed products are enough to fund year-over-year increases in R&D spending—a 10 percent increase from 2004 to 2005 alone.

And it has an exceptionally ambitious goal: to curb the threat of global antibiotic resistance. These days, it looks like Nabi could be the first

company to market a vaccine, StaphVAX® (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine), that could prevent infections of the deadly and pervasive *Staphylococcus aureus* (staph) bacterium.

Mark Schoenbaum, MD, a biotechnology analyst for Bear Stearns has classified Nabi as an "outperform" stock, based on his prediction that "StaphVAX will succeed in its ongoing Phase III trial." In a recent report, he writes, "If successful, StaphVAX will eventually dwarf Nabi's current base [business]." The report estimates that income from the product will start at approximately \$70 million in 2006 and grow about 3 percent every year, to more than \$250 million by 2010. (Full disclosure: The author of this article has had a small investment in Nabi Biopharmaceuticals since 2001.)

That will bring it as close to blockbuster status as any vaccine is likely to get—that is, unless Nabi gains approval to market another product in its pipeline. NicVAX™ (Nicotine Conjugate Vaccine), currently in late Phase II studies, is a smoking-cessation product. Critics say it's a long shot, but it could theoretically have one of the largest patient populations in the history of biotech if the Centers for Disease Control's estimates are right—



Pictured previous page: 1. Mark L. Smith, senior vice president of finance, treasurer, and CFO. 2. Henrik S. Rasmussen, MD, PhD, senior vice president, clinical, medical, and regulatory affairs. 3. Thomas H. McLain, chairman, CEO, and president. 4. H. LeRoux Jooste, senior vice president, global sales and marketing. 5. Mark Soufleris, vice president, investor and public relations.



NABI CHAIRMAN, CEO, AND PRESIDENT

## Thomas H. McLain

**A** CPA by training, McLain served in roles of increasing responsibility at Nabi for four years before taking the reins in November 2002 from retiring CEO David Gury. Within a year, McLain was named the 2003 "Best Technology Company CEO" by the South Florida Business Journal. Words of wisdom: "Leadership isn't about 'I need to know this,' and 'we need to do that.' It's about building a rapport with the people who work with you and asking questions and learning from the answers."

it says about 70 percent of 47 million US smokers have tried to quit.

### Deliberate Decisions

Sitting at a conference room table in a non-descript building a stone's throw away from FDA headquarters in Rockville, Maryland, CEO Tom McLain is flushed with the typical enthusiasm of a small biotech company executive. He and his team have just returned from a BIO investor conference on the West Coast and have agreed to an interview at the company's R&D facility before continuing on to their headquarters in Boca Raton, Florida. McLain is joined by Henrik Rasmussen, MD, PhD, senior vice president of clinical, medical, and regulatory affairs; H. LeRoux Jooste, senior vice president of

meeting them. So the 1998 to 2001 period was spent refocusing the business model.

"It was out of that refocusing that one of our fundamental principles was put in place—that our efforts in research and clinical trials to develop new products were to be funded from cash flow from operations. It is a commonsense business model not ordinarily followed in biotech, but by 2000 the biopharmaceutical products business was self-sustaining."

McLain went on to lead a team responsible for divesting Nabi of most of its 56 plasma collection centers in 2001. "Because the biopharmaceutical business supported itself, we could take that strategic action," he explains. The transaction, which brought in \$153 million, allowed Nabi to pay its debt obligations and make a fresh beginning. "We really began to

global sales and marketing; Mark Smith, senior vice president of finance, treasurer, and CFO; and Mark Soufleris, vice president of investor and public relations. They take turns describing their vision for the company and its products.

"I came to Nabi in 1998 as the company's senior vice president of corporate services," says McLain. "I was the CFO and headed up HR, IT, and legal as well. Finances were tough. Nabi had some very large debt obligations and cash flow from the business was not

## One Among Hundreds

**N**abi's vaccine work is in a part of the industry that some have characterized as "slow" or "dead." But that's a myth, according to Janice Reichert, PhD, a senior research fellow and biotech expert at the Tufts Center for the Study of Drug Development. According to her analysis, the perception lingers because 65 percent of all the vaccine development work is being done by 12 percent of companies. Her research shows 1,200 vaccines in the Tufts Center for the Study of Drug Development database. Of those, 550 are in clinical development (Phase I, II, III, or already filed), including some research sponsored by the NIH. Of those 550, 75 percent (about 420) are being developed by US and foreign multinational companies—70 percent for preventive vaccines and 30 percent for therapeutic purposes. In Big Pharma, the undisputed billion dollar-plus players are Chiron, GSK, Merck, the Sanofi-Pasteur division of Sanofi-Aventis, and Wyeth. But Reichert says there are about 90 smaller players, companies such as Therion Biologics, Immune Response, Corixa, and others, including Nabi Biopharmaceuticals.

With 75 companies working in the area, the notion that few companies are interested in vaccines makes little sense. But the myth lives on.

"What sticks in people's minds is the idea that

a particular vaccine, such as the flu vaccine, comes from a single manufacturer," says Reichert. "And obviously, that's a problem when you start having shortages. [People think] 'Oh, if there's a shortage of vaccines, then there must be an issue associated with the entire industry interest in this product type'."

Dr. Franz-Robert Klingan, a manager and vaccine expert with Bain & Company, agrees that the industry is alive and well and that population growth and the need to address vaccine-preventable diseases will keep it that way for the foreseeable future. He points to emerging research in the area of human papilloma-virus (HPV) and its connection to cervical cancer as a particularly attractive opportunity—and there's pretty fierce competition.

Merck is the leader in this area, with a prophylactic HPV vaccine in Phase III clinical trials. In a recent report, Business Insights predicts a 2006 launch and global sales of \$492 million by 2010—just ahead of GSK's Cervarix, which is also in Phase III trials. Business Insights projects a 2007 launch for Cervarix and global sales of \$345 million by 2010.

"Broadly, the market is difficult in terms of entry barriers and maintaining the necessary steadiness," he says, "but fundamentally attractive with a lot of growth coming out in the next couple of years."

Klingan describes the obstacles inherent in the vaccines field, which are generally characteristic

of biologics. "It's a market that has high entry barriers because it requires a very specific knowledge that cannot just be copied," he says. "It has to be individually developed because those are probably the most complex biologics you could imagine. And you cannot just copycat the process like you would do with small molecules, or just develop a very clean process to produce a biologic as you would do with monoclonal antibodies."

That's why, he explains, the typical Big Pharma-biotech or Big Pharma-small pharma licensing deal isn't really a possibility in vaccines if one of the partners lacks relevant capabilities. The business model is completely different. On the sales side, in particular, there's really no similarity to pharma's prescription sales model—reps sell product directly to doctors who vaccinate patients in their offices. On the manufacturing side, vaccines need a lot of TLC and have higher regulatory hurdles to clear.

"Very few people can maintain a 'cold chain' to the requirements demanded by FDA," says Klingan. "You need to have excellent biological capabilities, because vaccines are not clearly defined chemical entities. They're defined by the manufacturing process, immunogenicity tests, and unlike small molecules or other biologics there's lot-by-lot testing and release by the authorities."

### Who says the vaccines biz is dead? There's a lot going on and Nabi's right in the thick of it.

redefine clearly what we were about and what our future was," says McLain. "We built the business model, and we have adhered to it ever since."

The remaining nine centers collect plasma and use it to produce purified antibody products—the foundation of the Nabi-HB hepatitis B virus antibody business, which brought in about \$40 million in 2004. While not a core business, antibody production generates revenue from sales to companies including Bayer, AmerisourceBergen, and Cardinal Health. It also produces the antibodies for Nabi's investigational Civacir™ [Hepatitis C Immune Globulin (Human)], which the company hopes will help keep liver transplant patients virus-free after surgery.

In 2003, Nabi acquired Braintree Labs' PhosLo, a treatment for elevated blood phosphate levels in patients with end-stage renal disease (ESRD)—which is approved for Medicaid reimbursement. The acquisition launched the nephrology franchise on which the company's entire future hinges.

The franchise, although niche, promises to be lucrative. Not only do there is an aging population and increase in the prevalence of diabetes portend growth in the population of kidney disease patients, but since 1973 all patients with chronic kidney failure requiring dialysis, no matter what their age, have automatically been covered by Medicare. In addition, PhosLo's key role in treating a common condition among kidney failure patients boosted the visibility of Nabi's sales force with nephrologists

worldwide—and will almost certainly get them through the door when the company brings to market its first-of-its-kind pipeline star, StaphVAX, and its Phase II, orphan-designate adjuvant staph antibody treatment Altastaph™ [*Staphylococcus aureus* Immune Globulin Intravenous (Human)].

"StaphVAX will remake us as a company," says McLain. "And because that is the transforming event and has not happened yet, we are in a unique position to define ourselves and how we will do business. There are best practices in other pharmaceutical and biotech companies that we

hope to draw on, but what is unique about us is we can create a business model that is not burdened by history, that is not burdened by old treatment patterns, old reimbursement schemes, old regulatory approaches.

"We are building a company that is focused on where the pharmaceutical industry is headed. So with an understanding of that, what we are doing is building a new business

model, what we hope will become a new model for the biopharmaceutical investor and something that will make us unique in our space. But I also think it would put us in a position for unparalleled success, because we will be the company designed with the future in mind."

The combination of exceptional strategic planning and cash in hand not only sets Nabi apart in the eyes of the financial community, but also instills the company's leaders with a sense of security and momentum that will enable them to grow even more as a fully integrated R&D, manufacturing, and commer-

### Nabi funds its R&D with its own cash flow, an uncommon commonsense business model.

## NABI's Pipeline

RESEARCH	PRECLINICAL	PHASE I-II	PHASE II	PHASE III	LICENSE APPLICATION	MARKETED	PHASE IV
<b>HYPERPHOSPHATEMIA [ESRD]</b>							
PhosLo [US]							
PhosLo [EU]					CTD		
<b>HEPATITIS B</b>							
Nabi-HB [US]							
<b>HEPATITIS B INTRAVENOUS [LIVER TRANSPLANT]</b>							
Nabi-HB Intravenous [US]					BLA		
HEBIG [EU]							
<b>HYPERURICEMIA</b>							
Aloprim						MAA	
<b>S. AUREUS INFECTIONS</b>							
StaphVAX [EU/ESRD]					MAA		
StaphVAX [US/ESRD]							
StaphVAX [US/Orthopedic & Cardiovascular]							
StaphVAX [UK/Orthopedic]							
<b>SMOKING CESSATION</b>							
NicVAX [US]							
<b>S. AUREUS INFECTIONS</b>							
Altastaph [US/Nenoates]			COMPLETED				
Altastaph [US/Adults]		COMPLETED					
<b>HEPATITIS C LIVER TRANSPLANT</b>							
Civacir							
<b>S. AUREUS</b>							
StaphVAX Type 336							
<b>STAPHYLOCOCCUS EPIDERMIDIS, ENTEROCOCCAL INFECTIONS</b>							
S. epidermidis vaccine							
EnteroVAX							

Strategic acquisitions of both technology platforms and actual products have yielded an active and attractively staggered pipeline for Nabi Biopharmaceuticals. With several products awaiting approval from both US and European regulators, the company is poised to capture the lion's share of the market for end-stage kidney failure treatments. That is due, in part, to its solid relationship with the nephrology community and its portfolio of currently marketed and investigational products for the continuum of patients' anti-infective and maintenance needs.

cial operation. And they're already well on their way—with the opening of a brand new European headquarters in Bray, Ireland announced in May, Nabi will be able to hit the ground running with StaphVAX. (See “Lure of the Emerald Isle.”) The company has already filed for EMEA approval for StaphVAX use in ESRD patients, and analysts expect that to come through later this year. In the United States, Phase III clinical trials have been capturing the attention of not only the financial community, but the medical community as well; a BLA filing is expected by the end of 2005.

### Resistance Assistance

Fred E. Husserl, MD, FACP, director of clinical services, nephrology, at the Ochsner Clinic Foundation in New Orleans can testify to the particular importance of a staph vaccine for the approximately 180,000 patients on dialysis nationwide today. And while that seems like a relatively small market, the need is so overwhelming it seems incredible that a vaccine hasn't been developed already.

Although healthcare professionals and patients have learned to take precautions with gloves, masks, antiseptics, and other obvious measures, infection prevention is still a lost cause for most ESRD patients. That's where the threat of antimicrobial resistance comes in, especially the threat of methicillin-resistant staph aureus (MRSA), which has the CDC, FDA, WHO, and just about every other public health agency in world in a justifiable state of emergency.

A resistant infection can keep otherwise healthy or recovering people in the hospital for days or even weeks after they are scheduled for discharge. The costs associated with that extended stay were the subject of a presentation at the annual meeting of the International Society for Pharmacoeconomics and Outcomes Research. Larry Liu, MD, PhD, director of US outcomes research for Pfizer and lead investigator of a study

## Lure of the Emerald Isle

**N**abi CEO Tom McLain had a lot to say about the company's new European headquarters and how it ended up in Ireland.

“We opened our European headquarters—for commercial, distribution, clinical, regulatory—in Ireland to take advantage of the amazing transformation that's happened there in the past 20 years. It's really at a point where for all the business reasons, it makes sense.

Ireland is the fastest growing economy in Europe in terms of the educated workforce between ages 25 and 40—it beats every other country in Europe today. In terms of thought capital, it's off the charts. The investment has been in scientific education so it really is an amazing place in which to have access to the people resources that we need. In addition they're building a business environment that is very friendly for biotech. We're

located in a biotech-only park south of Dublin, in a town called Bray. And the business environment in Ireland is ready access to the European Union and certainly it's created a business friendly environment—businesses that locate there get advantages they don't in other European countries.

The new headquarters are open and right now the European clinical regulatory group is based there. As we hire the heads of our commercial business during 2005 for Europe, they will also be located there. Next year we will add the people who will staff our distribution functions. People are coming primarily from other biotech companies and we're trying to draw from Europe. It's clearly an advantage when they've had, in addition to experience working for European companies, the experience working for a US-based company. Certainly over time, we expect to move people from the US to assignments in Europe and people from Europe to assignments here as a way of developing them and gaining depth within the organization. But right now, recruiting efforts are focused on EU nationals.”

examining the economic burden of MRSA on the healthcare system, concluded that patients with MRSA stay an extra 10 days in the hospital, including time spent in the ICU, costing hospitals between \$3.2 and \$4.2 billion every year. And although that study was ostensibly done to support the use of Pfizer's antibiotic Zyvox (linezolid), it illustrates how serious—and costly—the resistance problem has become.

“Hospital infections are caused by a number of bacteria, but the most common bug in the skin is *Staph aureus*, which is the meanest one of them,” Husserl says. “It sometimes accounts for up to 50 percent of the bacteria that we see in cultures. And it varies from area to area in the country and different programs. If patients are in nursing homes, there is a much higher incidence. It is becoming more and more of a problem.”

Husserl explains that ESRD patients are especially susceptible to staph infections because of the way the dialysis machines are connected to their bodies. Hemodialysis patient have three options for access:

- » an external catheter, which has the highest risk of infection and is used short-term
- » an internal access which can either be made of a synthetic material such as Gore-Tex, or
- » a surgical procedure called an arteriovenous (AV) fistula, in which an artery is connected to a vein. »

What all these options have in common is that they require needle sticks—an average of six times a week. Even patients on peritoneal dialysis, in which a catheter directs fluid into the abdomen, have a high infection rate.

“It is probably the second most common cause of death of

NABI SVP, FINANCE, TREASURER, AND CFO

### Mark L. Smith

**L**ike the man at the top, Smith is a CPA by training and spent eight years at Price Waterhouse in Sydney, Australia and San Jose, California. Before Nabi, Smith worked for various healthcare companies, including Genzyme Genetics, a subsidiary of the Genzyme Corporation. Words of wisdom: “It's good to make a better decision slowly than a bad decision very quickly. But unless you act, you have not done something strategic. You have only thought about being strategic.”





NABI SVP, GLOBAL SALES AND MARKETING

## H. LeRoux Jooste

**H**e spent 20 years at companies such as Cephalon, Aton, Eli Lilly, and Wyeth, where he led the marketing team that launched Enbrel (etanercept) with Immunex. At Lilly, he directed the launch of Prozac (fluoxetine) in South Africa—the first country in the world to launch the drug. Words of wisdom: “What’s our vision? It’s that ultimately, there is recognition that prevention is better than cure and that we will get there over time. If we try to achieve that tomorrow, we’ll fail. We need to make some sacrifices and do what’s realistic in the short-term.”

our patients on dialysis,” says Husserl. “The most common cause of death is some kind of a cardiovascular event, but of the cardiovascular deaths, a large number are also due to infection. About 30 percent have to do with gangrene of an extremity.”

### Pay Now, or Pay Later

The potential for StaphVAX to reduce or even eliminate resistant infections in hospitals makes a strong case for it to be adopted and paid for by any healthcare organization. Just ask Husserl, who as a clinical investigator ran a blinded study with 18 patients on his service. Would the product make economic sense at his clinic? “Absolutely,” he says. “An admission to the hospital for an infected graft probably is going to cost Medicare, which pays for the admission, \$15,000 to \$20,000. That’s \$20,000 you could avoid with a \$300 or \$400 injection.”

StaphVAX will fall under the new Medicare Part D rules, explains Phil Patrick, president of PharmaStrat, a managed markets and reimbursement market research and strategy consulting firm. Reimbursement models will be changing in the months ahead, but he expects reimbursement of StaphVAX to follow the same pattern as the erythropoietin (EPO) market, where reimbursement policies and procedures vary by the setting in which the drug is delivered.

“EPO products such as Epogen and Procrit are commonly used for ESRD and dialysis patients,” Patrick says. “Under the

infections—a revolution, really, from treatment to prevention. He says for ID specialists, it’s a no-brainer from both a clinical and economic perspective.

“How many vaccines can you give [for the cost of] one admission?” he asks. “You can vaccinate half a state. I would think that Medicare would jump on this if they just do the numbers, looking at the tremendous savings they can realize.”

Whatever reimbursement structure prevails, Nabi will still have to convince hospitals to use the product if it takes more than one injection—booster shots—to confer long-term protection. Anatole Besarab, MD, director of clinical research for the division of nephrology and hypertension at Henry Ford Hospital in Detroit and spokesperson for the National Kidney Foundation, says that an effective vaccine would be useful but wonders how it will be used in the clinical setting.

“I do not look at a staph vaccine, at least in hemodialysis patients, as something you would necessarily use the way you would a hepatitis B antibody,” he says. “With hepatitis B, the risk is always present. With staph, once you get past the initial phase of the first year or so, particularly if we can get AV fistulas in, then there is probably going to be less dependence. My feeling is that the utility would, in part, depend on whether we could start it three or four months before someone needs dialysis to have the immunity onboard in case we need to use a catheter.”

## Dialysis Risk Continuum

Between StaphVAX’s active- and Altastaph’s passive-immunization capabilities, Nabi is working to develop complementary products that offer patients protection across the continuum of infection risk.

### FUTURE RISK

#### Prevention

Elective patients who have 7–10 days before they are admitted to the hospital can get a dose of StaphVAX, which will offer protective levels of antibodies.

### IMMEDIATE RISK

#### Prophylaxis

Emergency patients who don’t know they’re going into the hospital—and can’t wait the 7–10 days for StaphVAX to work—get Altastaph, which offers immediate antibody protection.

### ALREADY INFECTED

#### Treatment

Clinical trial results announced in January 2005 suggest that even patients who already have an infection can benefit from a combination of antibiotics and Altastaph. Data show positive impact on time to resolution of infection and time to discharge.

### RECURRENCE RISK

#### Prevention

Hospitalized patients who get complicated staph infections, like MRSA, are treated with antibiotics and discharged. But research shows a 30 percent recurrence rate 18 months after discharge. StaphVAX offers long-term prevention of post-discharge relapse.

McLain addresses this challenge in a description of the results of StaphVAX's first Phase III trials in immune-compromised dialysis patients. These patients maintained protective levels of antibodies for 40 weeks, he says, "but clearly they're at long-term risk, because as their dialysis access line stays open, the bacteria have ready access to their bloodstream. They need booster doses to restore antibody levels."

In fact, in the ongoing Phase III study, patients are being followed for eight months after their first dose of vaccine to ensure efficacy. At the eight-month point, they will get a booster shot to see, within the following four months, how it restores protective levels. But while that research continues, Nabi has already figured out another way to protect patients who, even if they are

re-infected, can get immediate treatment. Currently in Phase II trials and designated as an orphan drug by FDA, its passive immunity-conferring Altastaph antibody product, is designed to serve the needs of renal failure patients throughout the typical progression of their disease and treatment. (See "Dialysis Risk Continuum," page 10.)

### Progress and Potential

Like any well-conceived lifecycle management plan, Nabi's R&D program is filled with studies examining new indications for currently marketed and experimental products. The company launched a UK-based trial studying StaphVAX in orthopedic and cardiothoracic surgical patients and a head-to-head study that pits PhosLo against Genzyme's Renegel, its main competitor, in pre-dialysis patients. This year, McLain says Nabi will take on new research on *Staph epidermidis* infections, another bacteria prevalent on the skin of hospitalized patients including neonates and diabetics, and then, enterococcal infections.

As positive as the analysts and physicians are about the potential of Nabi's nephrology franchise, they are relatively skeptical about Nabi's nicotine vaccine, NicVAX. NicVAX, a conjugate nicotine vaccine, blocks nicotine from crossing the blood-brain barrier, which removes the pleasurable sensation



NABI SVP, CLINICAL, MEDICAL, AND REGULATORY AFFAIRS

## Henrik S. Rasmussen, MD, PhD

After earning a medical degree and doctorate in cardiology at the University of Copenhagen in Denmark, Rasmussen went on to work for 15 years (and counting) in clinical research and regulatory leadership positions at companies including GenVec, British Biotech, and Pfizer. Words of wisdom: "It may be more important to develop a rapport with site coordinators than physicians to be competitive in patient recruitment."

that smokers experience. Nabi's theory is that by eliminating that feeling, people who want to quit get vaccinated and are "immune" to the effects of nicotine for about a year. At that point, a broader smoking cessation program would help them kick their habit for good.

The product potentially serves an enormous market, but that, critics say, is the problem. "Given the financial resources and capabilities of Nabi," says Bear Sterns' Schoenbaum, "we do not see this program moving forward until the company signs a partnership with a large pharmaceutical company which could sponsor additional clinical trials and which has the infrastructure to market to a large number of primary care physicians."

That opinion isn't surprising to McLain, who admits that the search for viable partnerships is still in an active phase. He says, "We are in a fortunate position with NicVAX in that with the expectation that we'll have con-

tinued funding from the National Institute on Drug Abuse (NIDA), it allows us to wait for the right business relationship rather than having to accept any business relationship. That's a nice part of what we've built by working with NIDA."

### Why Look for Cures?

Despite vaccines' excellent track record, most Big Pharma companies that pursued other avenues of attack find themselves in the difficult position of commercializing antibiotics that have been made virtually impotent by the constant mutation and evolution of the hardest of the planet's inhabitants. Even the CDC, in its recently released "Public Action Plan to Combat Antimicrobial Resistance," emphasizes the urgent need for better education in dealing with the

misuse of antibiotics. And while that worrisome to Nabi's leaders and workforce, it's not their main concern. To illustrate their focus, Jooste asks a simple question: "Why bother looking for a cure when you can prevent it in the first place?" As obvious as that sounds, Nabi's on to something big. Like a Jackson Pollock painting, people look at it and think, "I could have done that." But, they didn't—Nabi did. ☉

**Maybe Big Pharma should learn from Nabi's approach—give up the search for a cure and find ways to prevent infections instead.**



**NABI**  
BIOPHARMACEUTICALS

**Nabi Biopharmaceuticals**

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