

# → Converging on a SOLUTION ←

MOVING FROM DIAGNOSTICS TO PHARMACEUTICALS, FROM EUROPE TO THE UNITED STATES, AND ULTIMATELY FROM BIG PHARMA TO A SMALL STARTUP COMPANY IS NOT FOR EVERYBODY. BUT CHRISTINE BUNT HAS THE CONFIDENCE, KNOWLEDGE, AND BUSINESS ACUMEN TO TAKE ON ANY CHALLENGE, AND SHE REVELS IN EACH OPPORTUNITY.

In the harsh economic climate that has prevailed in the past couple of years, it's hard to imagine any successful pharmaceutical leader willingly wanting to enter the unpredictable world of startups. But that's just the course Christine Bunt, the German-born chief operating officer of Taris Biomedical, has chosen.

To some it might appear that the opportunity to lead the specialty pharmaceutical company, which is focused on local minimally invasive drug-device convergence products, was divine intervention.

After a successful career with two of the industry's most respected pharmaceutical companies, several familial relocations, and an appreciation and understanding of the necessity to converge drugs and devices to address unmet needs, Ms. Bunt was in the right place at the right time to take the helm of Taris, whose name stands for targeted intravesical system.

The company is focusing its initial development efforts on bladder diseases, which are difficult to treat with systemic therapies and affect 50 million people in the United States alone.

For Ms. Bunt, what separates Taris from the pack is both the technology and the groundwork done by the company's founders to ensure their solutions address unmet medical needs. To that end, the company has worked with thought leaders and invited the input of urologists with regard to where to focus its research efforts.

The market and the company's physician-friendly approach, as well as a much-in-demand and feasible technology solution have enabled Taris to attract investors at a time when money has all but dried up.

But without a strong business visionary who can succinctly explain those benefits, who has the ability to develop key contacts, and

who can explore all options incisively, the funding would not have been forthcoming. The scientists — Massachusetts Institute of Technology's Michael Cima, Ph.D., and Robert Langer, Ph.D. — behind the Taris technology made a wise strategic decision to team up with Ms. Bunt as co-founder and chief operating officer.

Having worked many years at Hoffmann-La Roche and then Merck, Ms. Bunt understands the importance of having a good business plan, building contacts, and delivering a clear message about the company's products and goals. This combined experience, along with time spent as VP of marketing and commercial development at CombinatoRx, a biotech company that is pioneering the new field of synergistic combination pharmaceuticals, have given her the confidence to pursue financial opportunities for Taris.

There's a refreshing frankness to Ms. Bunt that, along with her quirky sense of humor, make her easy to get along with, while commanding respect.

Ms. Bunt has thus far been able to negotiate \$15 million in Series A funding from three venture capital firms: Flagship Ventures, Flybridge Capital Partners, and Polaris Venture Partners. (Series A is the first round of stock offered during the seed or early-stage round by a portfolio company to the venture capitalist.)

In fact, Ms. Bunt talked to five VCs and all five wanted to invest. The company, however, only had three investor spots, so it held an auction. It's an outcome that flies in the face of expectations in the startup world today.

"We raised our Series A financing during a dark



→ We've given careful thought to building this company and have a well thought-out development plan. We have a clear understanding of the path leading to our first NDA. On top of this, we have a strong, experienced, and good team. All of these elements provide strength and clarity in tough financial times.



time,” Ms. Bunt concedes. “Highly respected leaders in the biotech industry advised me against raising money in this environment, and one well-known individual in the biotech field said a best-case scenario would be seed funding of around \$300,000 to \$500,000 after a year.”

Not easily daunted, however, Ms. Bunt maintains funding always comes back to fundamentals.

“The idea of Taris is unique, and there is a high unmet medical need for bladder disease treatments,” she says. “We’ve given careful thought to building this company and have a well thought-out development plan, choosing first to address interstitial cystitis, which is a large market with millions of patients and no real effective therapy. Our interactions with regulatory authorities so far have been good and we have a clear understanding of the path leading to an NDA. On top of this, we have a strong, experienced, and good team. All of these elements provide strength and clarity in tough financial times.”

Due to her experience at Merck and with Vioxx, Ms. Bunt has deep insights into the machinations of the FDA.

“Safety is a key concern for the FDA, and it’s very important to understand early on any potential concerns regarding a program’s safety,” she says. “This has been a key learning from my experience with Vioxx, which I’ve been able to apply to my role at Taris.”

## DIVERSITY AT PLAY

From a technology standpoint, Taris is the brainchild of renowned MIT scientists Dr. Cima and Dr. Langer. But as a business, it owes its reputation to the dynamic and outward-looking approach of Ms. Bunt.

Having moved to the Boston area, where Taris is based, in 2005, she has become well-

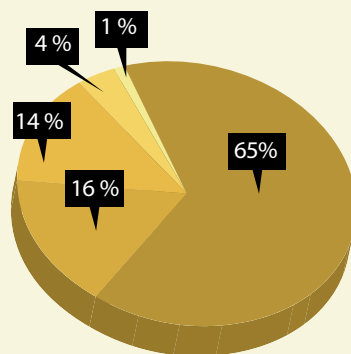
### TARIS’ THERAPEUTIC AREAS

Taris is focusing its development efforts in disease areas with high unmet need in which current therapies or systemic treatments have failed. Bladder diseases, which are difficult to treat with systemic therapies, affect 50 million people in the United States alone. These diseases include:

#### THERAPEUTIC AREAS/PATIENT DISTRIBUTION

- Overactive Bladder (33 million)
- Interstitial Cystitis (IC)/Painful Bladder Syndrome (PBS) (8 million)
- Urinary Tract Infection (UTI) (7 million)
- Chronic Prostatitis/Chronic Pelvic Pain Syndrome (CP/CPPS) (2 million)
- Bladder Cancer (0.5 million)

Total: About 50 million



Source: Taris Biomedical; internal market research, American Urology Association, NCI, ob/gyn literature, IMS Health.

**Christine Bunt (seated, center) leads a team of researchers and developers devoted to pioneering the field of drug-device convergence for targeted therapies.**

acquainted with the way small businesses in this biotech hub operate and the way the area’s life-sciences leaders, in business and academia, move in and out of a tightly knit network.

“It’s common to run into the same people time and again, and I’m not convinced that’s a healthy dynamic,” she says. “I believe it’s important to gather different perspectives.”

Ms. Bunt has taken a deeply considered approach to the company’s hiring strategy. For example, Taris has brought on Dennis Giesing, Ph.D., as its chief scientific officer. Dr. Giesing is also CEO and co-founder of CepheidRx LLC, a pharmaceutical consulting company. Before joining Taris, he served as chief scientific officer for Urogen Pharmaceuticals, which specializes in the design and implementation of innovative products for patients with urological ailments. For more than 30 years, Dr. Giesing served in a variety of senior scientific and leadership roles within large pharmaceutical companies with the last appointment being senior VP, lead optimization, at Aventis Pharmaceuticals Inc.

“As a former senior VP for Aventis in the field of pharmacology/toxicology and metabolism, Dr. Giesing brings preclinical insight to his role,” Ms. Bunt says. “He also took several drugs into clinical development and to NDA in the fields of immunology, allergy, and interstitial cystitis, which is our first indication.”

Ms. Bunt looks for people who are experienced, self-motivated, self-confident, and able to hire their own team members.

"My management style is hands-off; we agree to a strategy, and the team members know when they need to touch base with me," she says.

Part and parcel of that style is flexibility. Ms. Bunt is not a 9-to-5er.

"I don't believe a 9-to-5 workday reflects people's lives anymore," she says. "There are a lot of people like myself with small kids who need flexibility. Others have outside-of-work passions and should be given the flexibility to pursue those interests. For example, one of our team members competes in triathlons, so he requires training times, and I respect that."

To Ms. Bunt it makes good business sense because, in her experience, people who have more balanced private lives tend to contribute far more to the workplace.

### HOLISTIC APPROACH

As chief operating officer, Ms. Bunt brings an eye for detail and intrinsic knowledge of many aspects of the life-sciences industry to her role, including diagnostics and pharmaceuticals, and numerous therapeutic areas.

"There are two different sides to diagnostics: the main lab, which is a highly competitive business, and personalized or specialized testing, which is high science and high inno-

There are two different sides to diagnostics: the main lab, which is a highly competitive business, and personalized or specialized testing, which is high science and high innovation, and in fact is close to pharmaceutical development.

vation, and in fact is close to pharmaceutical development," she says. "Working in the diagnostics lab gave me the combat training to deal with competition, while my experience working with polymerase chain reaction (PCR) taught me the importance of working closely with thought leaders."

On the pharmaceuticals side, Ms. Bunt has worked with new molecules, which, she notes are very capital intensive to develop, as well as repurposed drugs, which are the focus of CombinatoRx.

"I don't take competition lightly; I learned early on not to become too attached to a technology, but rather to step back and stay close to the market and the customer," she says. "It is crucial to speak with physicians since they provide insights that can't be gathered elsewhere. Their knowledge could uncover a weakness in the technology, point to a new

player or competitor out there, or even raise new opportunities. Without the insights of these key leaders, it's impossible to innovate and maintain a leadership position."

Managing a startup company is a demanding endeavor, but Ms. Bunt has proven her mettle in handling stressful situations. Having had marketing oversight for Vioxx, before the COX-2 inhibitor was withdrawn, Ms. Bunt has lived life in the fast lane.

"Having worldwide marketing responsibility for a \$3 billion drug is hugely stressful," she says of Vioxx. "A typical day might involve dealing with press inquiries, managing matters in an overseas market, and so on. On top of that, there were the day-to-day aspects of managing a team. This job required multitasking and doing a lot of things that didn't come with the job description."

Ms. Bunt is well-equipped to handle the challenges of product development and managing a startup company.

She is aware of the opportunities that partnerships with larger companies may bring, but her experience on the other side of the fence has taught her not to rush headlong into the pursuit of deals.

"When I was at big pharma, I had many biotech companies present to me far too early," she says. "Before approaching a partnership opportunity, I know that it's critical to be able to answer the questions that will inevitably be raised, such as 'when is the product going to be in the clinic' or 'when will safety and tolerability criteria be established in humans?'"

Already, Taris' technology is gaining attention, and several big companies have begun to seek out the young startup company to discuss applications for its platform.

"These discussions are in the early stages, but there's significant interest in the company," Ms. Bunt says.

As Taris currently does not have a CEO, Ms. Bunt is filling that role in addition to her responsibilities as chief operating officer.

"Beyond the day-to-day management of the business, my chief responsibilities are building the company; in other words hiring and making sure we are adequately capitalized," she says. "We are always in the fundraising mode."

An astute and experienced pharma leader, Ms. Bunt remains watchful for opportunities, which is essential, especially in the current financial climate. ♦

### CHRISTINE BUNT — RESUME

**2008 – PRESENT.** Chief Operating Officer and Co-founder, and Interim CEO, Taris Biomedical Inc.

**2005 – 2008.** VP, Marketing and Commercial Development, CombinatoRx Inc.

**2004 – 2005.** Senior Director, Worldwide Human Health Marketing, Hospital Products Cardiovascular, Merck & Co.

**2000 – 2004.** Director, Worldwide Human Health Marketing, Arthritis and Analgesia/Vioxx and New Products, Merck

**1999 – 2000.** Associate Director, Maxalt, Worldwide Human Health Marketing, Hypertension/Heart failure/Migraine, Merck

**1995 – 1997.** International Marketing Manager, Diagnostics Division, F. Hoffmann-La Roche Ltd.

**1992 – 1994.** International Product Manager Cobas, the professional in vitro diagnostics laboratory systems, F. Hoffmann-La Roche

**1989 – 1992.** Senior Medical Technologist/Infectious Diseases/Oncology/Fertility, Biotechnology Production/Diagnostic Division, F. Hoffmann-La Roche

### EDUCATION

Executive training, Insead, Fontainebleau, France & Management Centre Europe, Brussels/London

Masters Degree in Medical Technology & Immunochemistry, University of Saarbrücken/ Medical School, Institute for Hygiene and Infectious Diseases

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BY KIM RIBBINK



**Taris Co-founders: Michael Cima, Ph.D., Christine Bunt, and Robert Langer, Ph.D.**

IT'S A LONG WAY FROM WORKING AS A DIAGNOSTIC BENCH SCIENTIST TO CO-FOUNDING AND RUNNING A SPECIALTY PHARMACEUTICAL COMPANY, BUT CHRISTINE BUNT HAS REVEALED IN THE RIDE THAT HAS TAKEN HER THUS FAR.

## → Professional ADVENTURE ←

**C**hristine Bunt's eclectic background began well before she even entered the lab as a young scientist in a diagnostic lab at Hoffmann-La Roche in Basel, Switzerland.

With an eclectic upbringing and professional background, Ms. Bunt perhaps understands better than most the vital importance of diversity. She speaks several languages — German, English, and French — and has lived in a number of countries, including France, the Netherlands, North Africa, Germany, and Belgium.

Ms. Bunt acquired her degree in medical technology and immunochemistry with a specific focus on infectious diseases, mainly Hepatitis C and HIV, from the University of Saarbrücken in Germany.

It was her research on the first enzyme immunoassay for HIV that led to an interview with Hoffmann-La Roche because the company was commercializing immunology-based diagnostic tests.

But she soon grew disillusioned with diagnostic lab work.

"Scientists have their theories, their research assignments, their budgets, they may even have a successful project, and then somebody

in business operations calls to say the project won't be commercialized," she says.

This frustration with the process prompted her decision to study business. Her plan initially had been to leave Roche to study full time, but the company encouraged her to stay, study at night, and work her way through the business, from sales to marketing and into product management.

"It was great to learn on the job," she says.

Perhaps what was most exciting for Ms. Bunt was watching Roche emerge from a small player in diagnostics to become one of the top 10 diagnostic companies.

"When I started at Roche, the company wasn't on the radar screen as a serious diagnostic player; it was exciting to be part of that organic growth," she says.

The company made a couple of strategic acquisitions that gave it access to polymerase chain reaction (PCR) technology, which is a primary diagnostic technology used for research purposes. Ms. Bunt says Roche was the first company to commercialize kits in the fields of HIV and Hepatitis C.

It was this work that led to Ms. Bunt becoming involved with the pharmaceutical division, which was developing protease inhibitors.

"For the first time, because of the PCR technology, we had the ability to quantify viral load," she says. "In other words, through a diagnostic test we were able to determine whether the new medication would work in patients or not."

Ms. Bunt was instrumental in getting the pharmaceutical and diagnostic divisions together.

"This was a very difficult task because these two divisions had never communicated with one another before, which was common in big companies," she says. "Up to that point there had been no incentive for the two divisions to work together, and here, for the first time, was a very strong incentive from a commercial perspective for cross-functional interaction."

Ms. Bunt also played an instrumental role in Roche's purchase of Boehringer Mannheim, which put Roche in the No. 1 worldwide diagnostic spot.

"Ironically, on the day the merger was announced I resigned from Roche because my

Coming from big pharma, I knew it would be a big change moving into a startup environment, so I was advised to spend some time with a startup company, learn the trade, and see if I enjoyed life outside of big pharma.

husband had been recruited by Merck in Whitehouse Station, N.J., and it wasn't reasonable for me to stay in Switzerland with him being in the United States," she says.

Roche offered her a couple of positions, but these were either in Indianapolis or California and so Ms. Bunt emigrated to the United States with her husband and waited for her green card before beginning the search for work.

She was soon offered positions with Pfizer neuroscience and Merck neuroscience.

"They were both great opportunities, but I chose Merck because I meshed with that team better," she says.

Eventually, she became director of worldwide human health marketing, arthritis, and analgesia at Merck. Ms. Bunt had oversight for Vioxx and was instrumental in building a highly diverse team.

"We had people from all over the world with different backgrounds on the team and it was an absolute pleasure working in such an environment," she says. "This diversity of talent — people of different genders, backgrounds, experiences, and so on — worked out beautifully. It was one of the best teams I ever worked with, and I am trying to apply this model to the hiring strategy at Taris."

Her career at Merck was a whirlwind of business successes.

She finalized the launch of Maxalt, a treatment for migraine, before becoming the worldwide director of marketing for Vioxx and the follow-up compound in the arthritis and analgesia business unit for Merck.

"Needless to say it was life in the fast lane," she says. "I prepared and launched three indications and two formulations for a \$3 billion drug before being asked to take over the hospital products-cardiovascular business unit for Merck."

Though the venture had its ups and downs, Ms. Bunt thoroughly enjoyed the experience of building the teams.

Ms. Bunt jokes that her husband once again upset the applecart.

"I told myself never to marry a physician, and what did I do?" she says. "I married not only a physician but a surgeon."

Her husband was offered a position as a chief medical officer for a pharmaceutical company in Boston and while the couple tried to commute for half a year, it became untenable.

The couple had a small child at the time, so not wanting to continue the nomad lifestyle, Ms. Bunt resigned. Merck sought to find her a commercial position in Boston, but it became apparent this would not be workable.

Realizing that the life-sciences industry in Boston was more on the biotech and startup side, Ms. Bunt took the time to network with biotech CEOs and venture capitalists to get advice. And she became excited by the prospect of getting involved in a new company.

"Coming from big pharma, I knew it would be a big change moving into a startup environment, so I was advised to spend some time with a startup company, learn the trade, and see if I enjoyed life outside of big pharma."

As a result, Ms. Bunt joined CombinatoRx at the end of 2005 in the capacity of VP of commercial development and later marketing. CombinatoRx creates product candidates with novel mechanisms of action, striking at the biological complexities of human disease.

"This was a great experience for me, and it strengthened my goal to join a startup company," she says. "I started networking again, reaching out also to academia, which ultimately led me to Dr. Bob Langer and Dr. Michael Cima, who introduced me to Taris' technology."

In April 2008, Ms. Bunt, Dr. Langer, and Dr. Cima co-founded Taris and began building the team. In July 2009, the company launched with the announcement of \$15 million in Series A financing.

"We've had a fantastic ride so far, but we recognize development is hard and that inevitably we'll hit a wall at some point, but knock on wood we are preparing to enter the clinic and hope to begin studies very soon," she says.

## FINDING A NICHE

Rather than develop a technology and later find a therapeutic fit, the two scientists gathered physicians together, including urologists, to



## CHRISTINE Bunt

identify areas of high unmet medical need. By focusing specifically on urology, they drilled down into the field of drug delivery through the bladder. There are several bladder diseases in urgent need of new therapeutic treatments, including bladder cancer, interstitial cystitis (IC), urinary tract infection (UTI), and overactive bladder (OAB). After discussions with doctors and careful consideration of effective business plans the Taris founders decided to focus their first program on IC.

"There is significant need in this area because currently patients with severe IC are being treated with a process called bladder instillation," Ms. Bunt explains.

During a bladder instillation, the bladder is filled with a solution that is held for varying periods of time, from a few seconds to 15 minutes, before being drained through a catheter.

This intensive treatment is both difficult for patients and less than ideal therapeutically speaking. In response, Dr. Cima and Dr. Langer, in collaboration with urologists, developed a device based on specific criteria: it needed to be lighter; it needed to be able to carry different drugs; and ideally it should float in the urine. The result was the Taris lidocaine-releasing intravesical system (LiRIS), a passive non-resorbable system whose primary mode of action is the controlled release of lidocaine in the bladder. Lidocaine has been shown in clinical practice and reported in scientific literature to decrease symptoms such as bladder pain and urgency. The LiRIS system is designed to be inserted into the bladder via cystoscope or catheter. Over a period of weeks, the LiRIS system will deliver therapeutic agents directly to the bladder and can then be removed by conventional, nonsurgical cystoscopic procedures.

"Currently, there are a lot of bladder instillations being performed for IC and intravesical treatment for bladder cancer," Ms. Bunt says. "Other companies have attempted to develop devices and failed. Either the devices were too big or the coating intended for the entire bladder lining was washed off. The bladder is a very challenging organ to work with."

Ms. Bunt says when she met Dr. Cima and Dr. Langer to discuss their invention, she was fascinated by what they had achieved and their thought processes.

"I presented the device to some urologists I knew and the feedback I received was overwhelmingly positive," she says.

The company has filed its IND for IC with the FDA and is ready to enter the clinic once it receives the green light from the agency.

In fact, one thought leader told Ms. Bunt that Taris had an ethical obligation to the urology community to make the device available.

The company has filed its IND for interstitial cystitis with the FDA and is ready to enter the clinic once it receives the green light from the agency. Ms. Bunt anticipates that Phase I clinical trials will be ready to begin in late 2009.

Ms. Bunt says the company expects the development pathway to be somewhat lower risk because lidocaine instillations in the bladder are already being conducted in clinical practice for IC.

"When a patient arrives at a urology office with an IC-related flare up, it can't be controlled with oral medication," she says. "Urologists are using lidocaine and there are scientific publications documenting its effectiveness for the treatment of IC. But there are no good delivery methods and this is where Taris comes in."

Taris is already determining its second program and is weighing choices, including bladder cancer and OAB.

Ms. Bunt believes Taris has an ethical obligation to consider development of a treatment for bladder cancer.

"Bladder cancer is one of the most expensive cancers to treat, and it's an area where treatments are desperately needed," Ms. Bunt says.

The company will also look to evolve the technology. Currently, the device is a removable system, but researchers are evaluating the path set by the developers of drug-eluting stents and would ultimately like to develop a drug-eluting biodegradable product.

"We also have IP for other devices that we haven't yet fully explored, so we have many choices, which is a nice problem to have," Ms. Bunt says.

## A FLEXIBLE MANAGEMENT STYLE

Recognizing that the road ahead will no doubt be bumpy, Ms. Bunt knows it's impor-

tant to be flexible and is the antithesis of a hands-on manager.

"I don't want our people to burn out; they need balance and they need to have flexibility," she says.

This management philosophy is a far cry from the world she entered as a young scientist at a diagnostics laboratory in Basel, Switzerland.

"There was a clocking system at Roche even for executives," she says. "There were certain lock out times that employees had to be in the office and there was paperwork to be filled out during business trips. That does not reflect the current times anymore."

Unlike many company leaders, Ms. Bunt is also highly supportive of those who choose to work part time.

"These individuals are some of my best resources," she says.

Balance is important to Ms. Bunt. In her own life, Ms. Bunt ensures she is home at a reasonable hour to spend time with her children before often taking out her laptop later in the evening to deal with work issues.

An avid runner, Ms. Bunt finds that her early morning workouts help her to recharge and prepare for the day.

While many hobbies that were once prevalent in the lives of Ms. Bunt and her husband have gone by the wayside with raising a family, she has in recent years taken on an exciting new pursuit: building houses.

"When my husband was relocated to the United States in the late 1990s, I could not work for a year while I waited for my green card applications to be approved," she says.

To avoid becoming completely bored because she had always worked, she built a house, supervising the entire project from scratch.

"The house turned out fine and hasn't collapsed yet," she says.

It's a passion that has stuck. Today, Ms. Bunt and her family are living in the third house she and her husband have built.

"We've got the itch again, so we'll start to look at land toward the end of the year and begin building again," she says.

Most people might consider building a company to be enough of a challenge, but then again it's that energy and that always-on-the-go approach to life that perhaps has enabled Ms. Bunt to put Taris on solid ground at a time of deep uncertainty. ♦

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