COVER STORY



Self-starters outline what it takes to succeed as an entrepreneur in the life-sciences industry.

ife-science entrepreneurs face seemingly insurmountable challenges every single day, yet studies show that they are some of the happiest and most optimistic people in the workforce. That's because entrepreneurs have a tendency to view challenges as opportunities, not drawbacks. It is in their DNA to defy the odds and succeed with ideas and innovations that others have not thought of. They take a "big idea" and transform it into a revenue-generating, life-altering product or service through passion, perseverance, and strategic planning.

Self-starters from several sectors of the industry, with companies in varying phases of development, outline what it takes to succeed in the life-sciences industry. They share their tips and personal stories to encourage others to join them on the intense ride of the entrepreneur's journey. (Editor's note: If you are an entrepreneur and would like to share your experience, please send your start-up story to tgrom@pharmavoice.com.)

Find a Need, Fill a Need

An entrepreneur with a lot of experience, Alfred Mann, chairman of the board and CEO of MannKind Corp., offers perhaps the most succinct and crucial piece of advice: find an unmet need and solve it. Mr. Mann is an entrepreneur, scientist, inventor, and philanthropist who has devoted his professional life to developing innovative medical products designed to satisfy the unmet needs of patients challenged by health issues ranging from diabetes and heart disease to hearing impairment and chronic pain. He has successfully established 17 companies and brought many novel products to market.

Mr. Mann is currently working on bringing Afrezza, an ultra rapid-acting inhaled insulin product, to market. When he saw the pharmacokinetics and bioavailability of this drug, it was clear to him that it had the potential to address an unmet need in diabetes therapy and change the way that the disease is treated. (For more on Mr. Mann's and other featured entrepreneurs' personal success stories, visit our digital bonus content.)

In October 2013, MannKind resubmitted an NDA for Afrezza, after being asked by the FDA in 2010 for two more Phase III clinical studies. The drug device's PDUFA date is April 15, 2014, and Mr. Mann is hopeful his product will earn FDA approval this time around and calls it a great opportunity in healthcare today."

"My success has come from finding a need and creating a solution for it," he says. "I think that people who try to make a simple improvement or to make some variation of a technology don't solve enough of a problem to make for a great opportunity. I advise finding a poorly met or unmet need and then find a technology that offers a solution."

Mr. Mann says starting a company today is much more difficult compared with when he started his first one 58 years ago.

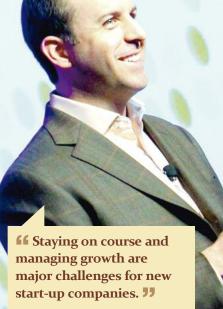
"Today, it's harder to find a truly unmet need, and it's harder to raise money," he says. "It also takes much more investment today to bring a product to success."

Building credibility helps with fundraising and paving a pathway to success, Mr. Mann says.

"You've got to do what you say you're going to do and develop credibility, which enables you to raise the money you need to make the project successful. It takes a lot of money and a lot of time to develop a product, especially in the pharma business."

Building a Better Fire Extinguisher

Business partners Rick Morrison, CEO, and Jud Gardner, chief technology officer, of Comprehend Systems, a provider of cloudbased clinical data insight tools for clinical researchers, add that discovering a unique problem, or a really big problem, helps with success. They joke the message should be: "your hair is on fire, and I'm selling a fire extinguisher."

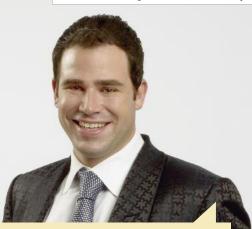


MATT WALLACH / Veeva Systems



44 Being a successful entrepreneur requires being able to make good decisions with limited information. **37**

> JUD GARDNER Comprehend Systems



44 The most important element to success has been applying a certain level of critical thinking to every business problem that presented itself and that's very different from blindly following best practices or what somebody teaches you in a business school.**??**

LEEROM SEGAL / Klick Health

"The customer is not going to care what the extinguisher looks like, as long as it works," Mr. Morrison says. "As an entrepreneur you want to make sure you are tackling a really big problem, and at the same time make sure you have a really good solution."

Knowing when someone's hair will be on fire comes from fully understanding customer needs through listening, and not assuming, he adds.

Comprehend Systems was formed in 2010 in Mr. Morrison's garage, which the company moved out of in December 2013. The partners have known each other since elementary school, where at recess they shared a computer to code for fun. The two are now having fun managing their expanding life-sciences data analytics company.

"We were an eight-person company working in a garage doing business with a 100year-old company with revenue of \$10 billion a year, but they bought our product because their hair was on fire - badly," Mr. Morrison says. "The most important thing to remember as an entrepreneur is persistence pays off. Sticking to it is the key, especially when you're first starting out and you have to sell to everybody and everybody's telling you no. Everybody includes potential investors, potential employees, potential customers, potential co-founders, and even your spouse. You basically just have to keep at it. It's not easy for any entrepreneurial venture, even if it looks like other people have it easy or they're telling you they have it easy; that's just not

the case. Just keep going and eventually you can make something that's awesome."

Being a successful entrepreneur also requires being able to make good decisions with limited information.

"There is difficulty and uncertainty on every side, but in an innovative environment, a bad decision today is better than a great decision three months from now," he says.

For new entrepreneurs, becoming familiar with the investment funding process is crucial to securing a successful deal, and to protect your business from shark investors that present unfair deals. Creating a network of trusted CEOs and founders to use as sounding boards helps in this regard. It is not unusual for entrepreneurs to reach out to each other even if they are not in the same business or industry.

"Entrepreneurs are typically very keen to help each other," Mr. Gardner says. "Also, when you're pitching to somebody, we learned that you don't have to have all the answers. Good investors might say, 'Okay what about x, y and z.' And it's okay to respond, "Well, we thought about it, but we're not sure.' This a very reasonable answer, especially in the early stages because if you feel like you're forced to give an answer, it won't be well thought out and the truth is, you probably don't know what the solution is yet."

Mr. Gardner adds a formal business plan isn't completely necessary, as long as you can find a pain point, articulate what it is, figure out how to solve it, start showing that you can solve it or that you have a clear path on how you're going to approach it, and then start reaching out to people who you respect a lot.

Leave Fear at the Door

According to Niven Narain, co-founder, president, and chief technology officer at Berg, a biopharmaceutical company with a data-driven, biological research approach, there are two emotions that an entrepreneur will need to stare down time and again: fear and surprise.

"You can't embark on any adventure in life if you're going to let fear stop you," he says. "I can't tell you how many times I've sat in meetings with people who thought my idea was crazy. But just remember the arguments endured by Watson and Crick at the Gordon Conference when they presented their DNA discovery. Be prepared to explain your idea over and over again — it's going to take some patience."

Mr. Narain faced this many times while presenting his big idea of enabling fundamental biology to drive the next generation of drug development and diagnostics. He saw a future of medicine guided by use of big data analytics changing the paradigm of the healthcare system. Ultimately, Mr. Narain developed the proprietary Interrogative Biology platform, which has unraveled key insights into cancer cell metabolism and a robust therapeutic and diagnostic pipeline in endocrinology and CNS diseases. Berg's mission is summed up on its website by a quote from Nobel Laureate Al-

bert Szent-Gyorgyi on scientific discovery: "Seeing what everybody else has seen and thinking what nobody else has thought."

"You may be looked to or looked upon as totally crazy and that's okay because you believe in your idea and you're going to have a lot of proving to do but don't be afraid," Mr. Narain says. "And I would encourage new entrepreneurs to never ever do anything to spoil a potential business relationship. Stay humble, have no fear, and don't hesitate to keep explaining yourself. These are the three key elements to success."

Making Money is Only a Part of the Journey

When it comes to starting a new venture, Chris Behrenbruch, Ph.D., CEO of ImaginAb, says be ready and able to make money as soon as you can, but this doesn't mean that your big idea or innovation should be motivated solely by making money.

"Earn a buck as fast as you can, but don't just do it for money," he adds. "Being inter-

ested in money will sharpen decision-making and a touch of selfishness often helps with selfpreservation, but when money is the endgame, most ventures fail. Besides, you'll probably be poor for a while."

However, sometimes entrepreneurs wait too long before cashing in on their ideas.

Dr. Behrenbruch says he is amazed at how many venture-backed companies have this idea that there's an over-the-horizon event in which they're going to start to monetize their technology. This trend is typified in the majority of business plans he sees and he suggests that often there are early partnerships and research agreements that can bring in revenue without giving away the crown jewels that will form the basis of bigger deals five to seven years down the track. In terms of entrepreneur mentality, early revenue and use of non-dilutive financing usually implies an appreciation for the difference between a dollar hard-earned versus a dollar that somebody else simply wrote a check for.

"In my experience of launching more than

a dozen start-ups, nothing impresses investors more than companies that generate a small amount of revenue early," he says, "It proves they are transactional."

If the technology cannot be monetized at different phases in the maturation of a venture, this can be a very meaningful indicator of investment risk and may mean that the entrepreneur is unsure of the value proposition, or even fully understands the target market.

"If you know the market really well and understand the technology fully and still don't see a scope for early revenue opportunities, particularly for platform technologies, then forget about it," Dr. Behrenbruch says. "It probably just means the idea is incremental."

Dr. Behrenbruch also offers a tip on making the pitch to potential commercial partners. A solid proposition should focus on how the healthcare product or service is going to cannibalize an existing offering, or disrupt the existing landscape of market share.

"A mistake that a lot of entrepreneurs tend to make — and I am not that smart so it took

THE SAVVY ENTREPRENEURS' TAKE ON SUCCESS

Experts discuss their defining moments as entrepreneurs, how to maintain the necessary determination and passion, and share lessons learned.



DR. CHRIS BEHRENBRUCH CEO, ImaginAb

Lessons Learned From a Life-Sciences Entrepreneur

My passion for achieving a healthcare outcome trumps personal wealth creation. When money is the prime motivator I think a venture has less of a chance of success.

Like, trust, and respect your business partners. If you can't face the prospect of hanging out with your co-founders for 100 hours every week don't go into business with them. My ImaginAb co-founder, Anna Wu, and I went through a lot together, including some friction, tough financial times and some real conflict. But I never stopped truly liking her and appreciating her as a wonderful human being. In fact, I will go so far as to say that my loyalty to Anna got me through some really dark times when I couldn't see clearly for myself.

Don't carve up the "pie" of the new venture and distribute it on day one. Make sure that all partners' equity is vesting and contingent on performance. I promise you that out of the four guys who start a business at least one will turn out to be lazy, or even worse, motivated but ineffectual. Making sure that founders have to continue to earn their keep is vital for success.

A start-up is a marathon effort. Be in it for the long haul. I have never had a start-up that took less than three years to register on the radar of established industry, just because that's how business development cycles work. The "big guys" take time to see "little guys", especially so in regulated environments like healthcare where there may not be a whole lot to talk about until you have a clinical proof-of-concept. Don't raise start-up funds for less than that three-year horizon, it adds unnecessary risk.

f you can't see yourself busting butt for the better part of a decade to realize your vision, then forget about it. Of course we all want it to be faster than that, but the probability is that it won't be.

MELISSA EASY



Chief Commercial Officer, DrugDev **A Dating Agency for Investigators** Working for large and small CROs in

consulting positions for a number of years gave me the opportunity to work with and gain insight into a wide variety of pharmaceutical companies. I was surprised — and continue to be to this day — that the same frustrations and inefficiencies regarding clinical trials are shared across the board, regardless of the size or geographic location of the company.

I liked to challenge people that there must be a better way, but was always told, no "because this is the way we have always done it." I had the idea to build a network of research-experienced investigators and help them learn about the right protocols, a dating agency of sorts to match investigators with protocols. I did my homework and found there were no regulatory or legal reasons to not do it. I wanted more flexibility in my life, we had no children at the time, my husband's job was stable and we agreed it was a now or never decision. So I went for it and started a network that has grown to a databank of more than 80,000 highly qualified investigators.



STEVEN MICHAELSON

Founder, Calcium What I Learned On My Entrepreneurial Journey

My advice to burgeoning start-up advertising agencies is to be relentless — never give up, always look forward, and never except that it can't be done. I would also recommend being extremely resourceful — beg, borrow, steal, do what ever it takes to always deliver the best possible job, no matter how small.

The biggest lessons I would like to share include trust your instincts, if you think there is a problem there usually is one. To combat a problem, be proactive. If you see an opportunity, jump on it. If you think there is an issue, jump on it. Lastly, your business is your baby, take extra care of it. No one will love it more then you do. No one will take care of it more than you will. Trust no one. But since you have to, choose your people carefully. And most of all, have fun. It's advertising, not brain surgery. CALL, CLICK, OR VISIT TRANSFORMED SHOPPING & BANKING Why not life sciences?

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Global Entrepreneurship Monitor Report

Entrepreneurs are among the happiest individuals across the globe when it comes to personal wellbeing and satisfaction with their work conditions, according to the Global Entrepreneurship Monitor 2013 Global Report.

In 2013, more than 197,000 individuals were surveyed and about 3,800 national experts on entrepreneurship participated in the GEM study across 70 economies, collectively representing all global regions of the world and a broad range of economic development levels. A similar report published in 2013 concluded that more than 43% of Americans believed there were good opportunities for entrepreneurship, the highest level recorded since GEM began in 1999. Additionally, the U.S. level is onethird higher than the average of the 24 developed (innovation-driven) economies that participated in GEM in 2012.

In the same report, 56% of Americans believed they had the capabilities to start a business. This measure has remained remarkably stable despite severe economic volatility during the past five years. It stands at one-third higher than the average among the 24 innovation-driven economies.

Source: Babson College

me almost 10 years to work it out myself — is how to gently sell a threat," he says. "All too often entrepreneurs pitch a business partner on how their idea is going to change the world instead of telling them how it is going to take X% from their current market share. If you can't articulate this, then you might not have a story worth listening to."

Build a Trusted Network

As an entrepreneur of a new venture, building a strong team and being open to advice from those with more experience is key, says Brian Neman, CEO of Sanguine. Sanguine employs a unique direct-to-patient approach for sourcing non-invasive biospecimen blood, urine, saliva, etc. — and associated medical data from patients for biomedical research.

Sanguine uses crowd-sourcing for recruiting mobile nurses and phlebotomists to collect samples directly from patients' homes.

"At first I far underestimated the value of a board of directors and an advisory board, so I would definitely recommend that a new entrepreneur employ both early on in the process," Mr. Neman says.



ff As an entrepreneur you want to make sure you are solving a really big problem, like someone's hair is on fire. **J**

> **RICK MORRISON** Comprehend Systems

your brand successfully to your Gran, you need to start over. **!!**

ff If you can't articulate

JON GWILLIM CreateHealth.io

Building a strong trustworthy team is also crucial to success and one of the first challenges an entrepreneur faces.

"As a first time entrepreneur you may not understand what you need in a co-founder or partner; what you need is someone who is going to help you build an organization from scratch," Mr. Neman says. "I have discovered that this person can't be someone who is just dedicated and very excited about the idea. You need to feel confident that this person has the presentation and social skills, emotional equilibrium, academic intelligence, market understanding, and maturity to do exactly what you would do when representing the company."

Flexibility and Agility Are Key

Serial entrepreneur Jon Gwillim would advise fellow entrepreneurs to be flexible and open to understanding patient needs.

In short, PatientsCreate was a start-up to build a digital bridge between patients and pharmaceutical companies. Although the company's technology and vision remains the same, the branding and language has taken on a major re-fresh.

"At first, PatientsCreate seemed like a good name to drive this mission forward," Mr. Gwillim says. "The more work we've done with patient groups and pharma companies, we realized that patients are more than patients they are people with careers, friends and family, doctors, and nurses. By calling ourselves PatientsCreate we almost create a barrier to adoption. So what seemed like a good idea and a year's worth of work — projects, sales, etc. pushing PatientsCreate, we decided to bin it and relaunch. We are now CreateHealth.io. We're going with the .io instead of .com or .org because we thought it's quite powerful as a platform, and as a business we wanted to take insight and turn it into outcomes. Create-Health does what it says on the tin and .io lends itself very nicely to what we do — this is the rationale behind the name change."

Mr. Gwillim also has evolved the company's mission in a more succinct manner.

"There is a big problem, overall, if you can't articulate your brand to the everyday Joe Public, or to Gran," he says. "We cut our original mission back until it was as simple and as straightforward as possible."

Mr. Gwillim also tweaked the language to a level that everyone can relate to, as he feels in the life-sciences space messages can become too complex.

"In the healthcare and pharma space, we tend to talk like robots and no one knows what we're about," Mr. Gwillim says

Having this type of flexibility and attitude toward making changes along the start-up journey will move you closer to success faster, Mr. Gwillim says.

"I see everything as an evolution; you hear about people who are able to let go of businesses or change things, but to me, we want to build a successful company that makes a real difference and has value to everyone involved. To keep the momentum going, you need to be able to pivot and evolve and to realize when something is wrong you need to bin it and bin it quickly. The ability to make necessary changes to ensure success is actually one of the luxuries of a start-up company."

Be Laser Focused...At the Start

Maintaining a sharp focus on your purpose and managing growth is another major challenge for new start-ups, says Matt Wallach, cofounder and president of Veeva Systems.

"New entrepreneurs are met with many opportunities to veer off the chosen path," he

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If Be prepared to explain your idea over and over again — it's going to take a lot of patience. J

> NIVEN NARAIN Berg Pharma



44 A promising start-up has to show early business development acumen and be able to clearly articulate a commercial threat.**9**

DR. CHRIS BEHRENBRUCH / ImaginAb

cause the experience was very positive with our

early customers and we're just in one industry, the life-sciences industry, word got around very quickly. Staying focused on one product line and one geography was really important for our ability to execute. Some companies in our position might have expanded more rapidly, tried to win every deal they heard about, and they would have risked the success of those early customers."

Culture and Commitment Are Imperative

Serial entrepreneur Leerom Segal, president and CEO of Klick Health, and co-author of New York Times best-selling business book The Decoded Company, has been creating businesses since he was 12 years old. Entrepreneurism runs in his family and his blood, but he credits great mentors and strong partners with his success. He also believes in investing in team development to maintain a strong, fearless culture that thrives on critical thinking.

"I certainly had inspiration and good guidance and coaching but if I reflect on the past 20-something years, I think the most important element to success has been applying a level of critical thinking to every business problem that presented itself and that's different from blindly following best practices or what somebody teaches you in a business school."

This means thoroughly researching the marketplace, and then using organic ideas on how to solve problems and develop market plans.

"We don't follow templates," he says. "We apply critical thinking and make a decision on what makes sense for us, solving the problem our way." **44** I underestimated the value of having a board of directors and an advisory board, so I would recommend employing both early on in the process.**J**

BRIAN NEMAN / Sanguine

The most important advice Mr. Segal would share with new entrepreneurs is not to tie the business up in leases, and to leave your ego at the door each day.

"The most important mindset and management advice that I can share is that we have found there are only two things that stress us out: the first one is leases and the second one is egos," he says. "Stay fiercely independent. We never borrowed a cent because that would have shaped how we'd behave. By having this deeprooted belief that egos and leases are the only things that can slow us down, we were able to really build a business model that allowed us to put the most experienced people directly in front of clients and allowed us to make decisions that were tempered by the realities of our economics without ever borrowing from the future."

Not all big ideas start with technology or science. Sometimes just a different way of doing business can differentiate you from the pack. Klick Health is built on providing a culture that rewards brilliant people to do great work.

"I believed that if we started first with the people and the culture, then everything else would fall into place and that has served us very well so far," Mr. Segal says.

Providing this culture requires building a strong team that has more experience and knowledge than he has, he says.

"As a leader, as an entrepreneur, it makes your life so much easier when you can stand on the shoulders of giants," he says. "Every single day I learn from my team and the team is learning from each other. This exchange has had a huge hand in shaping our success."

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ff My success has come from finding a need and then creating a solution for it.**?**

> ALFRED MANN MannKind Corp.

says. "It's tempting to take the \$100,000 deal that takes you in a different direction. The companies that are able to focus on the core innovation and what they're doing over time are the ones that do better."

Veeva Systems started seven years ago in a the global market of pharma CRM, but instead of expanding globally as soon as possible, Mr. Wallach and his partner decided to focus only on the U.S. market for starters.

"There were people on the team who thought we needed to get to Europe and Japan immediately, but we decided to just stay focused on the United States and to make sure that we had enough big, large, happy customers that could prove that the product worked and the product could scale. We believed we needed to do this before we went into other markets."

Veeva maintained that focus for three years before expanding globally and in the past four years the company has amassed a \$4.6 billion market capitalization on almost \$210 million in revenue, and has 33 out of 50 of the largest pharma companies as clients.

"If you get it right the first time, then you build confidence among your customer base and then you can upgrade and enhance the product over time," Mr. Wallach says. "Be-

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CHRIS BEHRENBRUCH, PH.D. ImaginAb

Dr. Behrenbruch is a serial entrepreneur with a diverse background in developing and commercializing biotechnology, healthcare IT, and medical devices from both the operational and executive perspective. Dr. Behrenbruch was a VP at Siemens Molecular Imaging following the acquisition of Mirada Solutions and CTI Molecular Imaging, where he was responsible for advanced medical imaging research for life sciences and clinical use.

Dr. Behrenbruch completed his undergraduate studies at Monash University, received his D.Phil (Ph.D.) from the University of Oxford, and received his MBA jointly from New York University and the London School of Economics.

ImaginAb's mission is to transform the clinical management of cancer and autoimmune diseases via targeted molecular imaging. ImaginAb re-engineers therapeutic antibodies against biologically important targets into small proteins optimized for diagnostic imaging with positron emission tomography (PET). In the era of targeted molecular therapy, there is a major unmet need for true companion in vivo diagnostics to help realize the promise of personalized medicine. ImaginAb is redefining therapeutic management by harnessing the power of antibody technology for in vivo imaging. The company's proprietary antibody fragment platform yields actionable molecular information to guide treatment decisions in cancer and immunology. ImaginAb also collaborates with select biopharmaceutical partners to design imaging agents as companion diagnostics for therapeutic antibodies. ImaginAb's technology is positioned to deliver on the promise of precision medicine by improving patient outcomes and reducing the cost of healthcare.

The genesis of ImaginAb started seven years ago when Dr. Behrenbruch was an entrepreneur-in-residence at UCLA. He had previously experienced two consecutive postmerger integrations totaling \$1.1 billion and was "fried." And he thought UCLA would be a nice change of pace.

"At UCLA I had the coolest job in the world," he says. "All I had to do was wander around the corridors and help faculty members spin out companies. This is where I became familiar with ImaginAb technology and I became enamored with it. This how the company started.

"The company takes antibodies and reengineers them into imaging agents," Dr. Behrenbruch continues. "Everybody in the antibody space is trying to prolong serum kinetics, make antibodies more potent and last longer in the body. ImaginAb does the exact opposite. We reengineer them into very rapidly targeting, rapidly clearing fragments that carry a little bit of radioactivity so they can be imaged."

ImaginAb has about 30 collaborations with 15 global pharmaceutical companies where it is reengineering antibody drugs and ADCs into imaging agents to aid in patient selection as part of a precision medicine strategy. The company's lead product is for prostate cancer.

The product, which is in Phase II trials is for men who have had a prostatectomy and who have a rising PSA post-prostatectomy; 98% of those men will have an imaging study such as a CT or a bone scan.

According to Dr. Behrenbruch, there's a real need to know where the disease is so that it can be staged and managed properly.

"My aha moment actually occurred at Siemens before going to UCLA," Dr. Behrenbruch says. "Siemens, like a lot of the big imaging companies at the time, was developing imaging tracers but in complete isolation from pharma. I remember we used to spend \$20 million or \$30 million a year developing a small molecule or peptide against an oncology target and do first-in-human studies or have an academic collaboration. Then we would go to a pharma company with a new imaging agent for breast cancer and ask them why don't you use it? Pharma's response would be: why and how is this going to derisk our programs? We almost never had an answer to these questions. We were always trying to push things on to pharma, then I got to UCLA and I saw what Anna Wu was doing, which was to take assets out of pharma and reengineer them into imaging agents. People then realized that the flow of technology had been wrong."

Through its technology, ImaginAb is going to literally be able to image immunology.

"We have an imaging agent against activated T-cells and cytotoxic T-cells so when a patient is given a cancer immunotherapy we can actually watch T-cells get recruited to a tumor without sticking a needle into a patient," Dr. Behrenbruch says. "There is this crazy idea that disease is heterogeneous and metastasis are not the same as primary lesions yet we still manage patients on the basis of archival tissue specimens. This is big idea stuff, but I think the really big idea here is that we reverse the flow. Sometimes an area that has struggled for decades can become really relevant again if the business model is changed."

Dr. Behrenbruch in thinking about his career says he has always been interested in healthcare.

"It's nice to get out of bed every day as a commercial animal knowing that you're building a business, you're building value, you're employing people, and that you're involved in wealth creation, but it's also very satisfying to know that the products and the services that you're developing are also beneficial to people," he says.

The Heart of an Innovator



The success with pacemakers was so exciting that it motivated me to change my focus to healthcare.

ALFRED MANN MannKind Corp.

With years of experience and 17-plus companies under his belt, Alfred Mann is a one-of-akind octogenarian. A life-long entrepreneur, his first medcical opportunity presented itself back in the 1960s, when Johns Hopkins asked him to develop a pacemaker that would last up to five years. He was working in the aerospace field at the time, and his success with this project is what turned his passion from space to healthcare.

"The success in developing the pacemaker was so exciting for me it really motivated me to change my focus to healthcare," Mr. Mann says. "I left the military and aerospace technology business, and since then have devoted my life to medicine, trying to solve unmet or poorly met needs."

The second surgery performed using his new pacemaker was on an 8-year-old girl in 1973. In 2011, Mr. Mann discovered that after 37 years, the woman was not only still living, but also still using the same pacemaker.

"I guess it lasted more than five years," he quips.

After that success, Mr. Mann wanted to identify other unmet medical needs that needed solving.

"I sat down with my chief technology officer and we brainstormed and made a list of some 14 possible applications," he says. "I decided that one of the greatest unmet needs is a way to better treat diabetes."

So Mr. Mann set about pioneering insulin pumps and continuous glucose sensors and even an artificial pancreas system.

While his innovative team was looking for a way of stabilizing certain drugs to deliver via

the pumps, it occurred to Mr. Mann that maybe that same technology might solve a major problem with prandial insulin, which took too long to break down in the body and lasted far too long.

DIGITAL EDITION — BONUS CONTENT

"That was in 1999 and I was very excited about this innovation because when I saw the kinetic and dynamic profile of the formulation, it seemed clear to me that this could revolutionize diabetes therapy," he says.

He has been committed to this goal ever since. In 2001 he sold his company MiniMed, the insulin pump and glucose sensor business, to Medtronic, and spun off the continuing commercialization of the drug, Afrezza, to a new company, MannKind Corp.

Rapid Identification of Therapeutic Targets



We're using the body's own machinery to discover ways to fix itself.

NIVEN NARAIN Berg

Niven Narain is cofounder, president, and chief technology officer of Berg, a vertically integrated healthcare solutions company that houses the Interrogative Biology Discovery platform that arbitrates leading-edge discovery and health analytics initiatives.

Mr. Narain invented the Berg Interrogative Biology Discovery platform that serves as the engine of innovation driving rapid identification of therapeutic targets and biomarkers for diagnostic development. The company has produced six INDs in less than four years among numerous validated biomarker panels in cancer and drug toxicity.

He is also the discoverer of a novel cancer technology, BPM 31510, which is going into Phase IIb trials for skin cancers and currently in late Phase Ib trials indicated for solid tumors and hematological malignancies.

Mr. Narain has more than 375 U.S. and international issued and pending patents that cover technologies pertaining to drug discovery platforms, cancer, wound healing, pain, fatigue, burns, diabetes, chemotoxicity, metabolic diseases, and corresponding diagnostics in cancer, heart failure, and CNS diseases.

Mr. Narain was director of cutaneous oncology and therapeutics research at the University of Miami, Miller School of Medicine when he had his aha moment.

"We had the most active dermatology department in the world, so we were in constant interaction with pharma companies and we had a very high patient pool," he says. "The thought process was this is the drug, this is the prescription, and this is the way to treat the disease. In the lab it was how do we come up with a hypothesis to drive toward a greater understanding in the science of that disease. But in my heart I fundamentally knew that we needed to develop drugs by going back to the biology, but I did not have all the answers. Interrogative Biology as a platform didn't exist, but what I did know is that philosophically we had to take a different approach. My partners Carl Berg and Mitch Gray were on the same page, and Carl was at a point in his life where he wanted to do something big in healthcare. So we connected and the rest is history, or at least where we are today.'

The biotech firm recently expanded and now has almost 200 employees.

Currently, Berg is working with the Parkinson's Institute and Clinical Center to identify potential biomarkers that may lead to breakthroughs in the research, diagnosis, and treatment of Parkinson's disease. Using Berg's Interrogative Biology platform to analyze multi-omic tissue samples — skin fibroblasts, blood, urine — supplied by the Parkinson's Institute, this collaboration will identify the differences between healthy and diseased tissues in an effort to unravel the mysteries of the disease.

Berg and the Parkinson's Institute together are the first teams to approach biomarker discovery by looking at proteomics, metabolomics, and lipidomics, in addition to clinical data, simultaneously in human patients and controls from the same cohort.

"Berg is really taking this bold approach of engaging human biology to use as a foundation to discover the next generation of medicines, and doing so in a cheaper, faster, more effective manner," Mr. Narain says. "We're using the body's own machinery to fix itself."