the Medicine Maker S P E C I A L S E R I E S : Women in P b a r m a

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ARTICLE

Notes on Disparity from a Female CEO

Do investors scrutinize CEOs more closely when they are women? It may not always be intentional, but research shows that subconscious bias does exist.

By Vineeta Tripathi, CEO and CSO, Vitarka Therapeutics

I have a vision for my company. I want us to be the market leader for non-viral drug delivery technology. We've already used synthetic biology to deliver therapeutic cargo into solid tumors. But I want our RNAi technology to target cells beyond solid tumors and deliver therapeutics to intracellular targets.

We raised our first investment within six months of setting up the company – and we are still raising investments today. This story ought to be nothing out of the ordinary – but there's an unfortunate reality we must consider: Life sciences companies with female founders often have a harder time securing funding.

Looking in the mirror

At Vitarka, the three biggest problems I initially faced were not connected to my identity as a woman. The first major problem lay in a perception among investors that Vitarka was "unrooted," simply because we weren't a university spin-out. Providing the level of confidence necessary to mitigate that perception was a challenge. The second problem was time – and how long it can take to progress from a commitment to invest to closing the deal. The third challenge was how to tell a compelling story about the problem we are solving and the technology we are developing. "Some investors have doubted whether I can run a company while also being a mother. And I wondered what that meant. If a man can run a company while being a father, why is it different for a woman?"



Most of the venture capitalists that I have engaged with have looked beyond my gender and ethnicity. However, there have also been a small proportion of investors who made me realize that I am a brown, female start-up CEO - not just a start-up CEO. When I started out, I had never considered this. I never thought of myself as a brown female.

Fundraising made me realize both aspects of my existence! In the past, I had always thought "I am a CEO, period." I did not relate with being labeled as a "brown, female CEO founder," and indeed, across 20 years in the professional world I had never thought of myself in terms of gender or ethnicity. However, the fundraising journey made me look in the mirror and see that I am brown and I am female! Compared with my male counterparts, I feel that a small number of investors asked me more questions on all aspects of the business. For example, despite having letters of support from KOLs, some VCs asked to speak directly with the KOLs and thereafter declined the investment opportunity, offering only irrelevant feedback..

VCs should look at the competencies of the CEO, the track record of the team, the science, and the commercialization strategy; the gender or ethnicity of the person or people leading each of these functions should not be a consideration. I understand the need to have specialist funds supporting female founders. However, even within such funds, there is disparity – several are targeted towards "black female founders." So, what about other people of color, like South Asians? This problem can only be solved from the top level down.

Family, mentors, and society's expectations

My family is the foundation of everything I do. Be it my children patiently waiting while I present to VCs or my husband taking on the entire household responsibilities when I have a grant submission deadline, they share my vision of bringing RNA therapeutics to untreated and vulnerable patients. The support from Martino Picardo and Mayer Schreiber from Discovery Park Ventures in the UK as our

first investors is unmatchable. Their belief in the team and the science has been truly empowering. They looked beyond my race and gender.

Martino joined me on this journey from day one. Having a chairperson who is also an excellent mentor with good emotional intelligence should be on every CEO's wish list. I remember my first meeting with Mayer, when he had already heard about Vitarka and checked out my track record. This level of modesty is commendable from an investor. After undergoing due diligence, Mayer committed the investment, saying that he believed in my ability to bring together a team and trusted that the science will work. Put together, he feels that these elements will make our company successful.

Some investors have doubted whether I can run a company while also being a mother. And I wondered what that meant. If a man can run a company while being a father, why is it different for a woman? But this mindset is deeply embedded in our society; women are expected to do it all. Initially, I used to apologize if my children jumped into my lap during a late evening meeting. This used to make the investors on those calls slightly distracted, and doubt my abilities. And that's when I asked myself: Why apologize? I am being an excellent role model for my children; at the age of 3 and 7, they are already learning essential skills for entrepreneurship. And so, now, when my son comes into my lap during a meeting, I say that a little learner has joined us as an apprentice. This change of tact shows the investors my confidence and leadership skills. Therefore, I would say that, before changing the societal mindset, female founders must first accept their own strengths as leaders and mothers.

Moving away from bias

How can we improve the investment process for female-founded companies? First, we need to stop identifying and labeling a female founder as a female. A founder is a founder, regardless of their gender or ethnicity. There has been a study called the Implicit Association Test – and I would encourage everyone reading this article to take the test. The test, featured in Malcolm Gladwell's book Blink, the Power

of Thinking Without Thinking, demonstrates that, if interviewees are asked to fill in an equality and diversity form before an interview, it puts them at a disadvantage because they carry a subconscious bias towards their own gender and ethnicity. Likewise, the moment a founder is labeled as female, it is likely to put their pitch presentation at a disadvantage at a sub-conscious level.

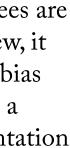
This issue must be tackled at all levels – and there needs to be a cultural change that sees more women sitting at the board level, especially within investor teams. To date, about 95 percent of the investors that I have met and spoken with have been (white) men. There are several forums that discuss the problem of gender disparity in fundraising and the support required for female founders. Ironically, the organizers of such forums invite predominantly male founders or male investors to talk. In fact, forums discussing disparity for people of color still have white male speakers! We need change.

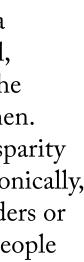
A good example from a VC perspective is SOSV's IndieBio program, which has more than 50 percent cohort companies with female founders and almost 30 percent with only female founders. I have not seen such a ratio anywhere else. At most investor showcases, there are usually only one or two female CEOs out of about 10.

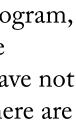
Advice for women like me

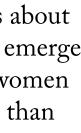
My top advice is simple: Be who you are. Raising investment is about trust and your relationship with the investor, and that can only emerge from personal authenticity. There are no set societal rules that women need to follow. We don't need to be any more or less aggressive than men. We need only be ourselves.

To female founders who are also mothers like me, I have one specific message: Be confident and unapologetic. If your child crawls into your lap during a meeting, there is no reason to apologize. Find pride in being a role model and demonstrating the leadership skills needed to manage the meeting and the child!









IN MY VIEW

Run the STEM World (Girls)

What actions can we take to help women and girls thrive in STEM fields?

By Patrice Jimerson, Associate Vice President of Diversity and Inclusion, Agilent Technologies, USA

Gender diversity in science, technology, engineering, and math (STEM) fields is a conversation we've been having for years. Most people claim to support gender equity, but diversity data doesn't reflect this notion. To resolve the challenges that hold women back from STEM fields, we need to use an intersectional lens that recognizes how other dimensions of identity affect women's experiences. It's time we take a step back to identify what's still driving the lack of representation – and how we can make tangible improvements.

Unconscious bias is by far the biggest roadblock in increasing the number of women in STEM fields. People know what the issues are and what they're supposed to do about them, but when the rubber meets the road, people still make prejudiced decisions based on their gut reactions.

Whether that manifests as a hiring manager thinking female candidates' family goals will interfere with their jobs or a woman being talked over by her male colleagues, this prejudiced behavior can deter women from pursuing STEM jobs. Unless people recognize their unconscious bias and are mindful of its effects, we won't make any progress.

The most prominent example of this signaling starts at an early age; if girls grow up without seeing women in STEM and leadership roles, it can subconsciously make them feel like they don't belong in those roles, either. However, when girls see people that represent them in



"Often, when we talk about diversity and inclusion, it's as an add-on to the rest of the business, rather than an integrated policy. It needs to be part of the performance expectation and talent management"

the roles of CFO or vice president, it gives them hope of a successful future that isn't completely unattainable.

Another key obstacle is that many STEM-related industries don't have an actionable plan or consequences regarding gender diversity. Many companies aren't held accountable for lack of representation and fail to diversify their workforce. If a company's demographics go from 15 percent women one year to 12 percent women the next, what are the ramifications? Who reaps the benefits and who suffers the consequences?

I believe one of the reasons that gender equity continues to be an issue is because we've been thinking of gender in monolithic terms, when we should really be thinking about intersectionality. When you look at this issue across other dimensions of identity, it compounds the problem. Your race and socioeconomic background affect your access to education, your political power, and your pay equity. If your parents weren't in a STEM-related field, you're much less likely to choose that field yourself. Until we take all aspects of identity into consideration, we will continue to see low representation rates.

If we want to start dismantling the cultural and systemic barriers that hold women back from STEM fields, we need to address the problem as early as possible. It's imperative that girls of all ages understand that STEM careers are a viable option for them. We need to weave the love of science and math into the things that girls are interested in; sparking the interest of young women and girls, and continuing to nurture that interest throughout their careers. If this ideology is implemented across the world, we can broaden the pipeline of women entering STEM industries. For example, the Agilent HBCU (Historically Black Colleges and Universities) sponsorship program provides crucial support to historically black institutes. This program ensures that black students have access to high-quality scientific equipment and STEM recruiting opportunities. If these resources are offered to other underfunded schools, we're likely to see more women from marginalized communities entering STEM fields.

To further push this ideology, we need to hold leaders accountable for upholding diversity. For example, encouraging business leaders to make an active effort to spend company money on diverse vendors or serving as a member or sponsor for underrepresented communities. If leaders aren't making these active decisions to improve gender equity, there must be consequences to stop this repeating behavior; for example, a negative impact on their ratings, bonus, or another pre-discussed metric. However, this shouldn't be an exception of performance, which relates to diversity and inclusion.

Another key element includes building awareness for those who aren't a part of these marginalized communities. By educating our male counterparts and those of other ethnic backgrounds of the barriers in place, we can work at breaking down walls and improving diversity and inclusion in the workplace. Without a diverse network, it is difficult to learn things that you wouldn't otherwise know. For

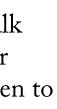
example, have you ever listened to a woman with a disability talk about the challenges that have presented themselves during her career? To move the dial, we need men to make space for women to speak for themselves - and then to listen and understand their experiences.

Women are not monolithic. The reasons women leave their jobs vary greatly, and we need to slice and dice the data to understand those reasons before taking action to reduce it. In 2020, our data showed that women aren't willing to sacrifice their home lives for their work lives (1). Allowing women flexibility gives them the autonomy to create their own schedules, letting home life coincide with work.

The quality of interactions at work are also pushing women to leave jobs. Highly educated and experienced professionals are in demand. If women don't feel supported and empowered by managers or colleagues, they're willing to find alternative employment without having to make compromises. By creating more welcoming environments for women, people of color, the LGBTQIA+ community, and other marginalized dimensions of identity, we can improve the retention of women overall.

Often, when we talk about diversity and inclusion, it's as an add-on to the rest of the business, rather than an integrated policy. It needs to be part of the performance expectation and talent management. Diversity doesn't just happen. It's reflected by our customers, our partners, and our science. For it to be heard, it has to be purposeful.

Diversity can't be a one-and-done training. It needs to be experiential and dynamic. It needs to be reflected in what leaders say, do, and think about those involved in their business. It has to be fully integrated; until we do that, it will continue to be a challenge.



ARTICLE

Four Top Tips for Leadership

The importance of experience, learning, collaboration, and dealing with environments dominated by men.

By Angela Osborne, CEO, eXmoor Pharma

Each stage of every career comes with a different set of challenges. Early in Angela Osborne's career, she wanted to move forward fast but grew to understand that experience and learning were key to making a mark. Here, Osborne – founder and CEO of eXmoor Pharma–shares her top four career tips.

1. Experience is a learning curve

The questions I hear most when I mentor young people are "how do I get promoted fast?" and "how do I become CEO?" I was once like them; I was looking for my ideas to be taken seriously when I didn't yet have the experience to warrant that respect. Frustrating as it is, there's just no direct substitute for experience.





After moving from a biotech SME to a mature engineering company, I found myself pushing to be taken seriously in an environment dominated by older men. I had more self-confidence by then and I knew my point of view was valuable, but it sometimes took more effort than it should have to convince others of my credibility. However, that experience made me a stronger person and gave me the skill set to convince, persuade, and cajole to sell my ideas.

Developing support networks is also beneficial. By mid-career, I was fortunate to have senior-level support. I have since spoken to young women who finally get a seat at the table, then worry as they look around and realize it's all men. Imposter syndrome is a genuine challenge, but I like to remind these women that, generally speaking, any negative interactions they experience tend to be due to ignorance, not malice. It's important to try to move on.

Thankfully, I remain motivated to try to succeed in whatever I do. More recently, my challenges relate to leadership approaches. At eXmoor, we have been a relatively small organization for 15 years, but

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the time came in 2017 to build bigger. As we have transitioned, I've needed to redefine my role because it's impossible to be hands-on with everything! My goal now is to set a strategic direction. I leave it to my very capable team to perform. I'm lucky to have such great support.

2. Pick your battles

More experience has also taught me to choose my challenges more carefully. I'm competitive by nature, but I'm learning that sometimes you just need to let things go.

At my core, I am a positive person who generally expects things to turn out well. You could call that brave (or perhaps stupid!) but it's led to attempting – and succeeding – at what is commonly viewed as impossible. Although I have certainly learned from experience, I don't necessarily think I have handled each experience well. I remember trying to compete against colleagues with more experience but less competence (or so I thought!).

When I consider my initial, more confrontational approach, I think I should have found a way around people who I felt were holding me down, rather than going head-to-head. If I had handled things differently, then perhaps both of us would have benefited. I was in a hurry to get up the career ladder, but I realize now there are so many different routes – nobody has to follow a traditional, structured path. If I'd understood that, I might have put less pressure on myself. I remember being offered a ski season that I declined because I felt I needed to focus on my career and rush forward. There may have been missed opportunities.

3. Collaboration over competition

We played a game once during a management training program. The group devolved into two teams with both trying to outdo the other.

Neither team won. And the group lost. Looking back, the obvious strategy was to maintain focus on the collaboration. We would have all succeeded if we had done that.

I reflect on this all the time in the cell and gene therapy manufacturing space. CDMOs have a nasty habit of disparaging each other, but the reality is that, for the sector to thrive, we need a good number of CDMOs to be successful or the entire industry won't work. Collaboration is required, not competition – it's better for patients if we all do well.

4. Come prepared to learn

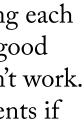
Spend the early part of your career learning everything, getting as much experience as you can. It can sometimes be hard to recognize opportunities when they come along, but keep an eye out and be prepared. If you're given a moment in the spotlight in front of senior people, you're going to get noticed – for good or bad. I've seen young people thrive after approaching these interactions with enthusiasm and focus; I've seen others spend entire meetings scrolling through emails. It says a lot about you.

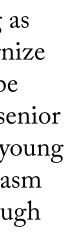
Know when to take opportunities. If you're put to work under someone with more experience, learn what you can and then move on.

Some young people ask me what the best place to start at an organization would be. I say it doesn't matter; everything has experience to give you. Once you're inside an organization, you can more easily look for other areas and move around.

When hiring young people with the prerequisite technical background, we value energy, enthusiasm, and the ability to think critically above all else. A willingness to learn and high energy must come across in an interview. Everything else can be taught.











FEATURE

Hello – From Women in Pharma

The Women in Pharma network aims to inspire, empower and shape the pharma industry to better serve women. Meet the minds behind the mission.

By Miriam Kenrick, VP marketing EMEA and Sarah Sowerby, Owner, WordBird.

Empowering to unleash potential

We both feel we love working with "masculine energy." So if anyone thinks we're out to man bash – rest assured we love you!

However, we often feel as if many senior roles are announced out of the blue, with decisions made behind the scenes at the golf course, the bar, or a rugby match. This is something we have seen with our own eyes. For example, Kenrick was clueless how to navigate upwards after making it to director level. We need more stories that can inspire



"In reality, every cell of our body is biologically gendered. The way our bodies work, what can go wrong, the diseases we get, the symptoms we experience, and the way treatments actually work (or not) can differ based on our biological gender, but the pharma industry has not focused on this."

women so that we can learn how to break into the highest levels of leadership – and somehow do it without burning out. As we ordered our second mimosa, the plan for WiP was already taking shape. Women need to do more than just inspire each other. There is significant evidence showing that we women tend to undervalue our achievements - focusing on what we could, or should, have done better. We often don't apply for jobs because we don't tick all the boxes. There are a catalogue of ways we hold ourselves back.

We need more than online modules of unconscious bias training to get more women into leadership. We need to let go of the disempowering beliefs and habits that we've unconsciously allowed to dictate our lives and stop trying to be "Superwomen." We need to learn how to prioritise our own wellbeing, create and manage boundaries, ask for and receive help, and start saying no.

We have a lifetime of cultural and societal expectations infused into our brains to be perfectionist people pleasers, helpers, carers, and, increasingly now, breadwinners. We need to help our women learn how to break the habits of a lifetime so that they can empower themselves, lead by example, and coach the next generation, so that they can learn to do this before they are in their 50s.

Shaking things up

The day after the mimosa brunch, Kenrick went to a bookshop (another post-COVID-19 thrill). By chance, she purchased "Invisible Women" by Caroline Criado-Perez. The book analyzes publicly available data through a female lens. From product and service design, such as cars and public transport planning (women are the majority of public transport users and they 'trip-chain' to the variety of places they need to go. Timetables and routes are designed by men for the work commuter), to the financial and legal worlds, to healthcare and medicine; the world is designed for – and in the interests of - men.

Since Aristotle, medicine has assumed all bodies are the same (except for reproductive parts), with females assumed to be just smaller males. In reality, every cell of our body is biologically gendered. The way our bodies work, what can go wrong, the diseases we get, the symptoms we experience, and the way treatments actually work (or not) can differ based on our biological gender, but the pharma industry has not focused on this.

Sowerby initially couldn't believe it. A lifetime of pharmaceutical grade evidence-based work made her very skeptical, but then the Women's Health Strategy for England was published. Over 100,000 women contributed evidence to the government review on the health challenges faced by conditions that only affect women, and those that affect men and women equally. The findings were sad and deeply shocking.

SIDEBAR S&M or M&S?

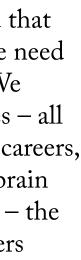
M is for Miriam Kenrick. With 25 years in commercial roles in companies including GSK, Roche, Allergan, and now Santen, as VP marketing EMEA, I am on a mission to unleash potential in the pharma industry, particularly for women who hold themselves back, burn themselves out, or beat themselves up (or all three).

S is for agency entrepreneur, Sarah Sowerby. After years as a copy chief in agencies such as Paling Walters (now known as TBWA) and consulting with over 30 agencies, I set up my own boutique creative agency, WordBird, which has enjoyed 11 years of partnering with many different brands looking to make an impact in the healthcare world.

Together, we launched Women in Pharma, an industry-agency partnership seeking to activate positive change in the pharma/ healthcare world.

Women are not taught about menstrual wellbeing. We are told that pain, erratic emotions, and heavy periods are just something we need to live with. We don't understand our own bodies and cycles. We might struggle to get pregnant, go through IVF, and lose babies – all of which is hidden from view. As we approach the peak of our careers, we go through perimenopause, which can be accompanied by brain fog, overheating, itching, becoming more anxious, not sleeping – the list goes on. And again everything is done in secret with partners unsure how to offer support.





"Let us reiterate; none of this is about bashing men. It's about recognizing that we all need to ask more questions. When we care for women's health, everyone in society benefits."

We soldier on, until we are literally collapsing and are seen by a doctor. However, doctors are not taught about women's health either, and we are treated by a system often designed by (and for) men. Women are passed from pillar to post, struggling with health whilst keeping up all responsibilities in life. The treatments we are given often started out based on male rodents. Even when there is a split of genders in clinical studies, do we disaggregate it to look for differences? Do we always ask if a drug works differently in male and female bodies? Do we ask what the effect of the menstrual cycle is? Or the effect of hormonal contraception? Or the menopause?

#workinprogress #weignitepotential #weinspirepossibilities

Let us reiterate; none of this is about bashing men. It's about recognizing that we all need to ask more questions. When we care for women's health, everyone in society benefits.

The challenge is to change the system. This is something that WIP wants to do. To help companies ask more questions. To understand both male and females biologically and develop treatments

accordingly. To encourage different conversations in areas such as R&D and regulation. To educate and empower everyone (whatever their gender) in the industry to make the necessary changes for the sake of our whole society.

Of course, neither of us know exactly what to do with some of the biggest challenges, which is why we are building a community. A sisterhood perhaps; however, sisters have brothers too. All supporters of our mission are welcome! It's only together that we can solve these huge issues, and do it fast enough to help daughters, wives, if not grandmothers.

WiP has been going for over 12 months and we have almost 700 supporters in our LinkedIn group. We've run webinars, launched a podcast and run a couple of events in London (INSPIRE! and EMPOWER!). We have also launched some empowerment programs.

We are doing this alongside our day jobs, so we need other people to get involved to help run events and to expand our reach; people who can bring their own ideas of how we can inspire, empower, and shake up healthcare for women.

People ask us how we do all of the things we do. But the funny thing is how much energy it gives us. Having a bigger purpose and making a bigger positive impact is very energizing.

We hope you've enjoyed getting to meet us. We hope even more you want to get involved. Most importantly we hope we've shaken you up a little and inspired you to make a bigger impact.

The idea for Women in Pharma (WiP) came about as the world was reawakening from COVID-19 lockdowns. We had planned a brunch in the spring London sunshine to catch up on the last two years.

Home alone with her two teenagers whilst leading her business through COVID-19, Kenrick had reinvented herself from stressedout perimenopausal superwoman to yogi empowerment coach (a major overhaul to say the least!).

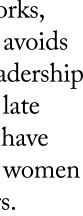
In parallel, Sowerby had transformed her wellbeing habits through an app called Second Nature, whilst running Wordbird with her husband (executive creative director, Andrew Nicholson) and being the best possible mother to a young son living with severe mental health issues.

There was a lot to catch up on. Amongst other topics, Sowerby talked about an exclusive female entrepreneur evening she had attended called Diamonds. The aim of the event was to create opportunities for female entrepreneurs and to provide a safe space for mentoring and encouragement. Initially, Sowerby had a large dose of imposter syndrome amongst the CBEs and OBEs, but when she heard the human stories of kitchen table businesses she realized that these people were just like her. Walking away inspired, she felt that this kind of networking event was needed in the pharmaceutical industry. If you can't see it, you can't be it. And we just don't see enough of the incredible women in our industry and the stories behind them.

Meanwhile, Kenrick had never thought about gender at work. She considered herself 'just a person,' and admits that she had always found it easier to be one of the lads, enjoying the banter and relative simplicity of male relationships. Sowerby had a similar mindset.

Though Sowerby had always valued strong female support networks, Kenrick admits that groups of women filled her with dread. She avoids hen-dos like the plague and has noted that the few women in leadership she does have experience with seem to always be sending emails late and on weekends, and traveling like crazy. Many are childless or have stay-at-home partners. Not everyone can relate to these types of women so more role models are needed, particularly for working mothers.





ARTICLE

The Journey of Founding a Company

Lessons learned in starting up a company – and navigating an industry dominated by men

By Stacy Blain, Co-Founder and Chief Scientific Officer of Concarlo Therapeutics

I can't remember a time when I didn't want to be a scientist, and as a kid, I always imagined that I would have a lab in the back of my house. I was the kid who took the frog home at the end of the summer to continue dissecting it, irradiated fruitflys in the back of the classroom to see if I could change eye color in future generations, and built a model of the human body complete with veins and arteries. I wanted to know how things worked, so I asked a lot of questions.

My grandfather gave me a biography about Marie Curie when I was 7 years old. No one in my immediate family was a doctor or scientist, but I was fortunate to have exceptional science teachers from my earliest days. Ms. Hartsook was my first-grade science teacher, and she started me on this path. Dr. Crabtree, my high school science teacher – and the first person I met with a PhD – opened new aspirations for me. Before our introduction, I had only considered going to med school to do research. In high school, I realized I could get a PhD and do experiments all the time, and I went to Princeton because they had just opened a molecular biology department, distinct from the traditional evolution, ecology, and behaviour disciplines.

Concarlo's origins

After my PhD at Columbia, I went to Memorial Sloan-Kettering Cancer Center to finish my training, and worked in the lab of Dr. Joan Massague. Along with Drs Andrew Koff and Jim Roberts, he had just discovered this new protein, p27, and I essentially took up the mantle to continue working on this protein to figure out how it functioned. I have continued working on this protein for the last 25 years and I became a faculty member at one of the state universities of New York. From the beginning, we had envisioned that if we could figure out how p27 regulated the kinases CDK2/4/6, we could harness that power to turn these kinases off in cancer. We sorted that out around 2013, and I started Concarlo in 2017. But while my entire career was probably headed towards the development of p27targeting drugs, I hadn't focused on starting a company; I simply wanted to understand how p27 worked and how we could leverage its regulatory power.

A few things happened that really pushed me to start Concarlo Therapeutics and as a scientist, I was able to see that these forces were leading me in one direction. First, I submitted a large RO1 grant from my academic lab to the NIH in 2015, which was not funded. When I spoke to my program officer, he said that it was a great grant, but it was clear that I wanted to make a drug, which is something academics can't do. He suggested that I start a company, and get an SBIR grant to fund that work, and I applied to the NYC economic development corporation to get help with this.

Second, the tech transfer office at my university took me to a few meetings to meet with venture capitalists. I naively thought they would just fund my lab so I could continue studying the target and develop the drug. When they said that the tech was still too immature for their investment, they suggested that I start a company instead. I didn't know anything about the business of running a company, but I knew that I needed to find people that did and I found two cofounders. One was a 20-year veteran in the financial industry, who had decades of experience running and founding companies, and (importantly) raising money. The second was a fractional COO, who had started and operated companies for decades, albeit in a different industry. My university had an incubator on campus, and a recent graduate student from my lab joined. And so we began Concarlo.



Combatting cancer

Cancer is caused by uncontrolled cellular proliferation. The signals that normally regulate this process are controlled by a family of three kinases: CDK2, CDK4 and CDK6. In cancer, these kinases push the cancer cell into the proliferative phase. One of the goals in oncology for decades has been to turn these kinases off, but it is difficult because these three kinases look very similar to a large family of kinases. Most of the biotech industry's attempts to drug these three specifically have met with unacceptable levels of toxicity, by inhibiting targets in nontumor cells or inhibiting the wrong target completely. Only CDK4/6 inhibitors have been approved by the FDA, but drug resistance is a common problem.

p27 is the master regulator that normally controls all three kinases, acting as a switch to turn them on and off. We believe that targeting p27 can help us to fight resistance, by inhibiting all three targets simultaneously, not leaving room for resistance to develop. p27 is not a traditional drug target because it is not a kinase nor a cell surface receptor, making it difficult to drug by small molecule kinase inhibitors or monoclonal antibodies. However, we followed nature's lead and co-opted the endogenous p27 inhibitor. Nature had already performed thousands of years of high throughput screening to find the best way to inhibit p27, forcing it to inhibit CDK2 and CDK4/6.

Concarlo is developing medicines that will convert p27 into its inhibitor mode to turn these three kinases off. Our approach will specifically inhibit only CDK2 and CDK4/6, producing a therapy with low toxicity. Since p27 targeting inhibits all three kinases, it will work in drug-resistant cells as well as treatment naïve cells. We have validated the p27 target as a way to inhibit CDK2 and CDK4/6 in numerous tumor types and animal models. We have developed our lead product, completed preliminary CMC, have assembled an amazing team and are ready to move this lead asset to the clinic in less than 2 years.

Our initial focus is metastatic, Ibrance-resistant breast cancer, but we will move on to other cancers driven by CDK2 (those that are a priori resistant to CDK4/6 inhibitors), such as ovarian. We will also look at cancers that involve mutations in the RAS/MAPK pathway, such as non-small lung cancer or melanoma.

The challenges of building a business

In 2017, there was little support for academics for start-up companies. In fact, most of my colleagues wondered why I was doing this. For me, however, staring Concarlo Therapeutics was the logical next step both in my research and my personal evolution as a scientist.

If I had been in Boston or San Diego, it might have been easier, but New York was a very juvenile biotech ecosystem, with limited support. Today, New York is much more mature, with numerous incubators and accelerator programs, so I think the transition would be easier today, but academics will always face challenges. Academics do not have a rolodex filled with venture capitalists, so getting intros and raising money is difficult. Venture funds like to fund serial entrepreneurs or people they have backed in the past, which makes it difficult for anyone new to break into this funding space. p27 was a new target and our approach using a peptide was less traditional, so we had to do a lot of convincing.

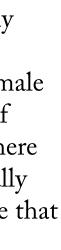
Studies have shown that women-lead companies yield better returns on investment, but women-led companies only receive ~2 percent of venture funding. Those two stats seem incongruous and might discourage women to start companies. Honestly, the latter would have discouraged me if I had known that! As a female CEO, I have a depressingly low chance of raising funding for my company. But that has to change, and women need to continue to put themselves and their technologies out there. Find an accelerator or mentorship program to build a network of other women in the industry. Representation matters and learning from the talented women who have gone before will help during this journey.

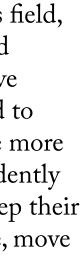
Women in STEM

STEM is still a male dominated field, although this is hopefully beginning to change. There are more male faculty members in academia, more male members of pharma C-suites, and more male board members. However, we graduate nearly equal numbers of women and men with science PhDs, raising the question of where these talented and interested women go. I think we need to really figure out what the discouraging factors, policies, or systems are that make it difficult for women to stay in these industries.

Even for women like me – that have chosen to continue in this field, bias (both conscious and unconscious) - exists, and I have faced unnecessary obstacles during my path. For example, studies have shown that women that speak with more passive language tend to fare better in the workplace, get bigger promotions, and receive more funding and advancement, compared to those that speak confidently and with conviction (1). So to be successful, women tend to keep their mouths shut, making it difficult for bold women to gain tenure, move into C-suites, and on to boards.

Women and men enter science careers because they want to solve problems and be a part of solutions. My advice to women starting out is to follow your passion without going into this field blindly. Recognize that this is still a male dominated profession and be on the lookout for bias and obstacles. Find mentors that are familiar with the challenges associated with being a woman in a male-dominated profession. Make sure that you work in an environment where women are respected, promoted, valued, and encouraged. If you find yourself disrespected, speak up. This can be difficult as a junior person starting out, but if you don't stop that or call out the behavior at the outset, it will not disappear. You need to make sure that your gender does not become an obstacle.





SITTING DOWN WITH

Leading with the Heart

AskBio CEO Sheila Mikhail shares the story behind her success and her strength

It has been said many times that we should never forget what or where we've come from. Back in June, we sat down with AskBio CEO and Co-Founder Sheila Mikhail, who continues to leverage her success for the benefit of those at her roots, those she meets on the way, those she inspires, and those she is inspired by – despite her own personal challenges. Now acting in the capacity of advisor, Mikhail spends her time focussing on the challenge of battling cancer, and raising awareness of ongoing inequality for women in cancer screening and diagnosis. Here she shares how to steer companies, employees, and herself through challenging times.

How did you keep employees motivated during difficult times?

We kept the focus on the patients and our mission. I always liked to tell our employees that we were revolutionaries changing the way that medicine is being practiced! Instead of treating the symptomology, we were trying to figure out what is causing the disease at the molecular level. From there, you can go in and fix it. I am still a firm believer that this is the future of medicine. Nobody benefits by just treating the symptoms, but if we can tweak whatever is wrong at the molecular level, and do that effectively and precisely, then the quality of life change will be amazing. We would be giving people back their lives, and giving children their childhood.

How important is it to have the right people around you in difficult situations?

It's incredibly important. Being a CEO is a very lonely place, and sometimes you're very uncertain about if you can achieve things, but

you always have to project confidence, even at your lowest point. You don't want a bunch of yes people around you. You want people to challenge you and to help shape your ideas.

I love people who are committed and who work passionately. It's so much fun to work with people who are trying to do breakthrough science and genuinely achieve something new. Those people are dynamic and incredible. When you reach for the stars, maybe you won't get that far, but you'll get a lot further than if you set the expectations low. I've been very fortunate to have worked with people who are pioneers in their fields; people with big vision and who have stretched and pushed me to get gene therapies into the clinic for pathway diseases.

How important is it for CEOs to juxtapose altruism and philanthropy with business?

It is extremely important. Jude Samulski was approached by parents from all over the world who had kids with ultra rare diseases. It is very difficult for these patients and their parents to get attention from anyone in the for-profit sector. We find that our technology at AskBio works extremely well for many of these diseases with single-gene defects. If you can just replace the defective gene with a therapeutic gene, it works extremely well.

We believed that these children should not be left behind. Although we couldn't make the business case, we formed a non-profit, Columbus Children's Foundation (CCF), to focus on developing gene therapies for children with ultra rare disease. We focused first on amino acid decarboxylase deficiency, which is an incredibly "Being a CEO is a very lonely place, and sometimes you're very uncertain about if you can achieve things, but you always have to project confidence, even at your lowest point."

devastating neurological disease where children essentially end up strapped into a chair. They can't lift their heads. They can't talk, or use their hands, or feed themselves. They were treated with our therapeutic and, a year later, they are talking, walking, and feeding themselves. I have videos of kids skiing, dancing, and going to school. I've met some of these kids and it really makes you realize that every life is valuable.

But when you look at the numbers, you can't make a business case to go after that disease. It's really unfortunate because you're refusing to help because of an inadequate return on investment. I've seen how devastating disease impacts families. It's very stressful. We shouldn't think in macro, and dehumanize what we're doing. We have to think about everyone's potential. They are on this Earth and if we can make their quality of life better and allow them to make their contributions, then it is extremely valuable. If you're in possession of a technology that can make the blind see and make the deaf hear, you have an obligation to unleash that technology.

How did your career change in 2023?

I stepped down as CEO of AskBio earlier this year because I was diagnosed with bilateral breast cancer. I was very surprised because I went for mammograms every year. They missed two sizable tumors. I've had a lot to learn. I've been working to understand why a very reputable institution (Duke University) missed the tumors, and I've been learning about cancer and cancer treatment as I navigate the options that I have. I've learned a lot about the flaws of breast cancer screening and I have spent my time educating other women by working with the legislature in North Carolina, and at the federal level, to pass laws that mandate insurance coverage or supplemental screening because, unfortunately, in my case (and many other cases), the doctors follow insurance coverage as the standard of care rather than looking at the patient's needs. Convincing insurance companies to expand coverage is not easy.

My tumors were found in time, so I have pretty good outcomes, but the whole process has been enlightening. I had to fight to get the

proper screening and I was told that my insurance wouldn't cover it when I pushed for a chest CT.

Now I'm advocating for women because if I had to struggle this hard to get diagnosed, then God help other women. This is an example of equitable access. I'm doing my part to try to make changes in talking to and educating women, but it's always about insurance. You can cure disease by giving women the right screening tool for their breast type.

I've been trying to make something good from my experience and help others. Everything happens for a reason. I was the first in my family to go to college and I've always been driven by all the opportunities that came my way, as well as how I can help others along the way. A lot of people are not so fortunate. I have a big voice; I have opportunities, and I have resources, so I will apply those where I can to help others.

What are your hopes and expectations for the future of advanced medicine?

I'd like to see more diseases treated at the molecular level rather than just treating symptomology. Gene and cell therapy has it right: fix, rather than ameliorate, the problem.

I'd like to see more preventative measures using cell and gene therapy to prevent disease from occurring. It's also important to broaden access and affordability by driving down the manufacturing costs. I want to make sure people around the world get what they need. Part of this challenge is about having compassion. It cannot always be about return on investment.

When you lead with your heart, good things happen. I always tell people not to think about returns as return on money invested. Instead, think about the number of lives positively impacted. Guess what? It's a pretty good measure for both buyers and for returns.

ROUNDTABLE DISCUSSION Women in Pharma

What can the pharma industry do about the glass ceiling in women's careers?

In all industries, there is a lack of women in leadership positions, including the pharma industry.

If we look at healthcare; around 80 percent of the workforce is female, with nursing roles, in particular, being dominated by women. However, only 26 percent of C-suite positions in healthcare are held by women (with women of color lagging even further behind than white women).

And then in Silicon Valley companies, women hold only around 11 percent of executive positions.

So there isn't a question of IF there is a glass ceiling for women. We know that this does exist. The question is, what do we do about it? Watch the discussion below. Featuring:

- Paula Casalino from IPS-Integrated Project Services, LLC
- Melissa Berquist from Resilience
- Sarah Odeh from Women In Bio









SPONSORED CONTENT

We're Here to Change Everything

Resilience is a technology-focused biomanufacturing company dedicated to broadening access to complex medicines

While many biopharmaceutical companies are built to fulfill a need, Resilience was built to serve innovation. In recent years, the biomedical industry has made incredible strides in developing increasingly complex medicines. However, large-scale biomanufacturing processes have struggled to keep pace with the ability to produce these new, complex therapies. Recognizing this gap, the mission of Resilience reflects this challenge – increasing access to complex medicines across the world.

With a sustainable network of high-tech, end-to-end manufacturing facilities supported by a team with decades of experience, Resilience is dedicated to providing solutions to help ensure the treatments of today and tomorrow can be made quickly, safely, and at scale.



By continuously advancing the science of biopharmaceutical manufacturing and development, Resilience seeks to free its partners to focus on the discoveries that improve patients' lives and protect biopharmaceutical supply chains against future disruptions.

Partnerships and collaborations

Resilience has collaborated with numerous institutions, including Mayo Clinic, MD Anderson Cancer Center, California Institute of Regenerative Medicine, Parker Institute for Cancer Immunotherapy, The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, and Harvard University, to accelerate innovation in the creation of impactful therapies and technologies to benefit patients.

Markets served/facilities

Resilience serves global customers through its sites located in six states across the US, as well as in Canada. With our initial mission to broaden access to complex medicines in mind, we have upgraded digital, quality, and capacity at our sites across North America. This approach has begun to expand internationally as well.

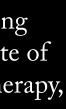
Products, services, and capabilities

With more than 50 active customers across its network, ranging from large pharma to small and mid-size pharmaceutical and biotechnology companies, as well as government and NGOs, Resilience works across all stages of five primary modalities: biologics, vaccines, nucleic acids, cell therapy, and gene therapy.

Resilience offers several ways to engage, including incubation, collaboration, and manufacturing to support the development of more than 70 molecules across its portfolio. The company's offerings include Platform Technology & Development, Process & Analytical Development, and Drug Substance and Drug Product Manufacturing from Clinical to Commercial, geared toward increasing access to medicines around the world and democratizing manufacturing.

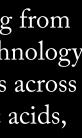
LEARN MORE AT: RESILIENCE.COM















Meet Navneet Dhesi: Engineering Trailblazer in **Innovation and Collaboration**

Navneet shares strategies, skills, and mentorship experiences to thrive in engineering company dedicated to broadening access to complex medicines

Navneet Dhesi AMIChemE, recently nominated for an ISPE award, is a chemical engineer with seven years of experience spanning pharmaceuticals and fast-moving consumer goods. Her journey began at PepsiCo, where she developed project management skills and a deep understanding of food manufacturing technology. Transitioning to GlaxoSmithKline, she specialized in bulk sterile manufacturing processes. At Procter & Gamble, Navneet served as a process engineer, technical leader, and line manager, refining her technical expertise and leadership skills over two and a half years. For the past four years at IPS, she's been a process engineer in design, overseeing design documentation, engineering studies, and safety assessments with unwavering dedication to innovation and efficiency.

In male-dominated industries such as engineering, what strategies have you found effective in advocating for yourself and your ideas and fostering a collaborative and inclusive work environment?

When advocating my ideas, I prioritize confidence by thorough preparation and clear structure. This approach boosts acceptance and inspires younger females to enter the field.

enhance team performance or project outcomes?

One skill that women are particularly good at is multitasking. Multitasking is a skill women excel at. Juggling multiple tasks improves time management, fosters stronger team relationships, and enhances overall performance.

Have you had a mentor that helped you? If so, can you share some wisdom they imparted to you?

My mentor, the Process Lead at IPS, guides me toward IChemE Chartership. She emphasizes the importance of asking questions, knowing when to seek expertise, and instilling confidence. Continuous self-review fuels motivation for career improvement.

How do you navigate and bridge potential communication or cultural gaps that may arise in multicultural or multidisciplinary teams within the field of process engineering, and can you share any strategies you've found effective in fostering understanding and collaboration across different perspectives?

What underappreciated qualities or skills do women often bring to engineering roles, and how have you leveraged these attributes to

"When advocating my ideas, I prioritize confidence by thorough preparation and clear structure. This approach boosts acceptance and inspires younger females to enter the field."

> During a project in Denmark, a clienthosted session highlighted cultural disparities between Denmark and the UK, particularly in humor and communication styles. This awareness improved client interactions and fostered better relationships.

> > LEARN MORE AT: WWW.IPSDB.COM

