

## Brian O'Callaghan - CEO, ObsEva

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*Biotech veteran Brian O'Callaghan introduces ObsEva – a Swiss-based firm focused on women's health –, his motivations to join the company – which is on the verge of transforming into a commercial-stage outfit –, and the strategy he has put in place moving forward. O'Callaghan also shares his insights on the Swiss biotech innovation ecosystem's progress at large and the challenges of taking on a new CEO role in the midst of a pandemic.*

**Brian, you joined Swiss-based women's health-focused biotech ObsEva as CEO in November 2020, and rather notably, this is your fifth biotech CEO appointment, along with stints at Big Pharma players including Bayer, Pfizer, Novartis and Merck Serono. Can you give us a recap of your career highlights pre-ObsEva?**

Looking back, I can break my career down into two phases. The first phase was spent with large pharma companies like Bayer, Pfizer, Novartis and Merck GmbH (as well as a year with Covance, a global CRO). That phase began back in 1990, when Big Pharma was king and we were launching blockbusters year after year. It was tremendously exciting, and the experience was incredible. During this phase, before moving into Biotech, I learned how to do the job right. In the second phase of my career, I learned how to do the job differently, very differently.

Some of the motivation for the shift into biotech, was the feeling that Big Pharma was too focused on developing guaranteed blockbusters, instead of developing truly innovative therapies and

addressing real unmet medical need. In addition, after I found myself working in biotech, I realized that there were many advantages to the biotech industry, including the ability to become involved in every stage of development—from concept to commercialization. In comparison, at a Big Pharma company, you tend to have a much narrower perspective, with very strict lines of demarcation. Even when I was reporting directly to the CEO of big companies, it sometimes felt like it didn't really matter whether I came to work in the morning, knowing the company and share price would remain unaffected. However, in a biotech company, it truly matters that everyone shows up every day and always performs to the best of their abilities. Success or survival can never be taken for granted in a biotech company. Most Biotechs are dependent on one or two programs and live off less than 12 months of cash runway. Knowing that you're contributing to true innovation as well as improved therapeutic options and outcomes for patients, provides the stimulation and fulfillment I crave.

While doing all of the above, I have also had the opportunity to work and live in five different countries, (including Switzerland) as well as both sides of the US. I've been a biotech CEO multiple times, as well as GM of divisions of pharma multinationals. I've worked within most major therapeutic areas, including anti-infectives, cardiovascular, the central nervous system, immunology, oncology and women's health, and across all stages of development. I've led public and private companies and experienced successful IPOs, M&As and trade sales. All of these experiences have given me a uniquely broad and global perspective, that not all US-based biotech CEOs have.

This was actually what appealed to the board of ObsEva when they were looking for a replacement for the founding CEO, Dr Ernest Loumaye. As a European company, they wanted someone who understood Europe but was based in the US, had CEO experience both in the US and Switzerland, had public company experience, women's health experience, and late-stage clinical and commercialization experience. Fortunately, I happened to tick all of those boxes and therefore joining ObsEva was an incredible opportunity.

### **From your side, what motivated you to join ObsEva?**

I felt personally drawn to ObsEva and even felt an element of fate being involved, because of how great the fit was. Perhaps for the first time in my life, I felt myself to be the right person, in the right place, at the right time.

I feel strongly about women's health as I worked on clotrimazole when I was at Bayer and fluconazole when I was at Pfizer. I always wanted to return to this space because the medical needs are much more obvious, than some other areas, where it sometimes feels like you're trying to convince people that indications and patient populations actually exist. We know half the population are women and we know women suffer from very specific disease states. We know diseases like endometriosis and uterine fibroids exist, we know that preterm labour and IVF outcomes are an issue. We also know there are very few treatment options available to women and they, therefore, need and deserve new and more innovative treatment options.

Despite all the above, women's health is still underinvested, undervalued and underappreciated. To put it in perspective, my last biotech company was a New York based, private, early-stage company, focused on oncology. We raised the largest Series A in New York Biotech history and 3-4 years later, sold the company for USD billions (in biobucks) to Big Pharma. In comparison, ObsEva is a company that has a product in submission, a product in Phase 3, as well as a product expected to advance to Phase 2B in the fourth quarter of 2021, yet we are incredibly undervalued. That being said, I think the perception of this therapeutic area is changing gradually and will improve significantly.

Last but not least, I really love Switzerland. I actually built a house in Switzerland when I lived there in the early 2000s and my second child was born there. I have a Swiss driver's license and even a Swiss boating license, so am also licensed to navigate all Swiss waterways.

**This is a really critical period for ObsEva, which is on the verge of transitioning into a commercial-stage company with your lead asset Yselty®, currently under evaluation by the European Medicines Agency (EMA). What do you see as the most critical opportunities and challenges you face in your first year or so as CEO?**

The founding CEOs of biotech companies are typically pioneers and renowned scientists or clinicians, who understand the unmet needs of the landscape. However, developing new therapeutic approaches with exciting new mechanisms, is only half the battle. Turning their breakthrough ideas into prescribed products and getting new assets primed for the market, is a tremendous challenge and a science unto itself. Therefore, seasoned industry executives with the ability to attract investors as well as strategic partners, combined with late-stage development, pre-launch and commercialization experience, can be critical to success. Interestingly enough, a large part of my career has involved taking over from founding CEOs of biotech companies, this

was also the case with ObsEva. Dr Ernest Loumaye felt that it was time to retire and entrust the company to another. As with many founders, Ernest is a luminary in his field, and is an extremely hard act to follow.

Since joining ObsEva, it's become apparent to me, that to take the company to the next level, will require focusing on two key areas of corporate strategy: capitalization and commercialization. This is perfectly normal and predictable for a company of this size and stage of development.

Therefore, since joining ObsEva, I have prioritized these two critical objectives, and thankfully we are now making significant progress on both fronts. We recently released our 2020 earnings report, where we highlighted that we are entering 2021 well-funded and stronger than ever. We have raised USD 55 million since January 2021 through our prior At-The-Market (ATM) program and upon exercise of previously issued warrants, which we believe now gives us a cash runway of over 12 months. As was recently announced, we have entered into a new ATM program with SVB Leerink, via which we may currently raise up to another USD 50 million.

We have also created a lot of optionality and momentum on the commercialization front, with numerous negotiations having reached an advanced stage, with a number of potential strategic partners across all programs in our portfolio. With current momentum being maintained, we expect to be making announcements in due course.

### **What can we expect to see in the commercial strategy that ObsEva will develop?**

Yselyt<sup>®</sup> is our lead candidate being investigated for uterine fibroids and endometriosis. For uterine fibroids, the EMA has recently validated our Marketing Authorization Application. This is a major milestone toward making Yselyt available in the EU and marks the beginning of ObsEva's transition into a commercial-stage company. We will continue to work closely with the EMA to achieve marketing approval, projected for the fourth quarter of 2021. Our New Drug Application submission in the US is expected in the second quarter of 2021 and we plan to provide an update on the next steps, as we advance further in the regulatory and commercialization process.

To achieve our commercial ambitions, we are currently evaluating two potential commercialization routes. The first is the classical partnership with a Big Pharma. The second is less classical and more contemporary and would involve partnering with a commercialization services partner who can provide all the commercialization core competencies and resources required. The advantages to this second strategy being the retention of far more value in our assets, the option to play a role

in the commercialization process, as well as the flexibility to bring the assets back inhouse at a later stage if desired.

Ultimately, it's all about creating optionality, so that we can choose the best potential partners and strategies for each of our programs.

To summarize all of the above: We understand the value of our pipeline. We have options and high expectations. We also have the cash runway to let all scenarios play out. So, stay tuned!

**So far ObsEva has pursued in-licensing as a portfolio strategy. Will this remain the go-to strategy for ObsEva as you continue to expand your portfolio?**

Yes it will, as we currently don't have the bench science and discovery capabilities, to generate assets internally. We will therefore continue to scour the world for innovative assets, that may be gathering dust on someone's shelf, or that we believe we'd do a better job with.

The benefit of women's health is that it is a relatively underserved area, and so competition for assets is much lower, compared to areas like immuno-oncology. What happens quite frequently, is that companies develop an asset, before realizing it's more suited to women's health, than the original indication they were focused on. That's when we step in, to convince them to pass it on to a specialty player like us.

We have a strong focus on Asia—it is actually one of the biggest markets for women's health products. For instance, China is actually the world's largest IVF market. For this reason, we have established a partnership with a Chinese company, Yuyuan BioScience Technology, to develop and commercialize one of our assets for the Chinese market, and Yselty® was actually in-licensed from a Japanese pharma company, called Kissei.

**As an experienced CEO, how has it been joining and leading a Swiss company in the middle of a global pandemic with restricted travel while you are based in San Diego?**

It has been a little frustrating, because I've not been able to travel to Switzerland since my appointment in November 2020. As a result, I've not actually met anyone from the company face to face. Of course, I know Switzerland very well, having previously lived and worked there, but I am anxious to meet the team in Geneva. In my most recent roles, I ran companies based in New York and Seattle, and in each case would spend at least 30 weeks a year in each place. Therefore I am

one of the ones that's looking forward to traveling again for work.

Despite the challenges of the pandemic, my transition has been exceptionally smooth—thanks to my board and executive team. We have an incredibly accomplished, well-functioning and supportive board. We also have an executive team of seasoned executives with all the right core competencies, as well as a high level of managerial maturity. Therefore, my introduction and integration was effective, immediate, and we were able to hit the ground running together. Much credit for the environment I entered should also be given to the Swiss ecosystem, which is very professional and purpose oriented.

**You were based in Zug in Switzerland in 2000 for four years as president and CEO of BioPartners, the Merck GmbH spin-off company, and now as CEO of another Swiss company, how do you assess the Swiss environment for biotech innovation? Has it changed significantly over the past two decades?**

BioPartners was actually my first CEO position. BioPartners started life as Merck BioPharmaceuticals, which was a division of Merck GmbH. I was general manager of Merck BioPharmaceuticals, as well as part of the founding management team. When we spun it out of Merck GmbH, the investors wanted me and a few key members of management to continue running it. The company was initially headquartered in Germany but based on the advice of some experts and our board, we soon moved it to Switzerland. Initially, it seemed to me like an unnecessary distraction. However, following the experience of relocating and re-establishing a start-up biotech company in Switzerland, then running it for four years, before successfully selling it, I have to say that the Swiss infrastructure and ecosystem was incredible.

One of the advantages is the fact that Switzerland is not part of the European Union. Therefore, without the burden of some EU legislation and regulation, many things can happen much quicker and much more efficiently. As a result, progress can be more rapid and is genuinely seen as a key performance indicator in Switzerland. On top of all that, the educational system, government support, and general infrastructure is all truly incredible. Not to mention the extensive talent pool throughout Switzerland, where you can readily recruit all the qualified personnel required, across all key core competencies. This is essential when building a team and growing a company.

The global perception and appreciation of the Swiss life sciences sector has definitely evolved over the past two decades. When I was heading up BioPartners, I spent a lot of time in the US raising money, and many of the investors I spoke to really didn't know much about Switzerland. However

today, the image of Switzerland has changed dramatically within the US, and across the globe. Of course, a lot of this stems from the Big Pharma players based in Basel, as the ecosystem they generated over the years, produced a plethora of biotech companies, as well as biotech leaders, that have become prominent throughout the world. So, it's now universally appreciated in the US that there is a thriving European biotech scene, with Switzerland at the epicentre of it.

**More generally, how do you see the global landscape for biotech innovation? Any comments you might like to make to our global audience of industry executives, regulators, investors and so on?**

I have two key messages to two different sets of investors.

To the venture capitalists, I would like to say, bring back the 'venture' part of what you do! When I first started raising money, venture capitalists took risks. They invested in companies that represented true innovation and real evolution of therapy. However, the venture spirit has diminished dramatically over the years, and today, most venture capitalists seem only willing to invest in things that are as de-risked as possible and very well understood.

To the public markets I would say, please start looking at the markets more rationally. The markets seem to be completely irrational today. The best recent example occurred on 6 January 2020 when there was an insurrection in the US and the Capitol building was taken by force. Yet the very next day, markets went up. Then despite the global pandemic, IPOs took off last year. Not to mention all the loss-making tech companies and early-stage biotech companies in overcrowded specialty areas, that are valued in the USD billions. This behaviour does not make sense and investors in public markets need to focus more on companies where real value has been generated.

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