Ripe for a Breakthrough

Biopharmaceutical company Urovant Sciences gears up for growth surge based on potential game-changing urology treatment.

Thirty-three million. That is the estimated number of Americans who suffer from overactive bladder (OAB) symptoms. Most do not discuss it with their doctors, according to the Food and Drug Administration (FDA) and many more start treatment only to fall off for one or more reasons. But what if there was a potential new alternative that could provide relief for symptoms that can cause constant physical discomfort, impede quality of life, and be an ongoing source of expense as patients are forced to purchase protective products?


Jim Robinson

The FDA literature states that 30 percent of men and 40 percent of women live with OAB symptoms. Jim Robinson, president and CEO of Irvine, California-based Urovant Sciences, says only about 14 million Americans discuss the issue with their doctors.

"Currently, about 3.5 million people are on pharmacological treatment for OAB and those treatments have historically been in the anticholinergic class," Robinson says. "The side effects of these drugs may include dry mouth, making patients thirsty, and driving a vicious cycle." He notes that in elderly patients, "there is a growing body of evidence that the use of anticholinergic therapies is associated with an increased risk for cognitive impairment."

"Additionally," Robinson continues, "a third of the patients on therapy don't stay on treatment – in some cases because of the time it takes for current therapies to become effective."

A new, differentiated treatment option is potentially on the way in the form of vibegron, a once-daily oral medication that is currently under FDA review. If approved, the medication offers significant potential in a market where patient dissatisfaction and the need for a new treatment is high. Additionally, there hasn't been a new branded oral therapy launched since 2012 and OAB drives significant healthcare utilization and cost. With these factors in mind, the company is mobilizing to deliver on the promise of vibegron.

"Urovant is actively planning for the approval of vibegron – the first product we aim to bring to market," Robinson says. "The PDUFA date is December 26, 2020. If approved, we plan to launch in the first quarter of 2021. Building an organization to move into the commercial stage of planning and execution is a significant endeavor. We are in an expansion phase currently and beginning in the fall we will begin the critical phase of building out the sales force."

A "PDUFA date" is a Prescription Drug User Fee Act date, which is essentially a "due date" for an FDA decision on approval. In late 2019, the FDA approved five drugs ahead of their

PDUFA dates so earlier approval isn't unheard of. The market is ripe for a potential breakthrough – such as vibegron – which is also being studied as a potential treatment to alleviate pain associated with irritable bowel syndrome (IBS) and OAB in men with benign prostatic hyperplasia (BPH), a type of prostate gland enlargement.

"Our drug has been shown to work in two weeks, which is a benefit without question," Robinson says. "If a patient has to wait four to eight weeks for any results, there is going to be a significant drop off in use. For us, it's about ensuring that patients see meaningful benefits quickly after starting therapy."

Urovant is ready to deliver on the promise of vibegron by focusing on leadership, strategy, infrastructure and building out a talented workforce. Fortunately, the fallout from COVID-19 hasn't interfered with these essential processes and the team has been working remotely to make sure every detail is in place for the potential product launch.

The official announcement of Robinson taking over as CEO was on March 23, only about a week into California's shutdown order. At that time, the company had 63 employees and it now has 95.

"As a member of the board since March 2019, I had a running start as I was already very familiar with the company," he says. "Over the span of the four months we've been in lockdown, we've added 32 people and are working at warp speed to make sure we're prepared for the potential approval by FDA and the launch. Fortunately, we've been creatively leveraging technology, which works really well for a company of our size."

Adding to his own extensive experience in the urology space, including overactive bladder, Robinson laid further groundwork with the early -June appointment of industry veterans Walt Johnston and Kenton Stewart to the leadership team. They bring 60 years combined experience, including significant experience in urology. Johnston is Senior Vice President of Commercial, responsible for marketing, sales and commercial operations. Stewart is Senior Vice President of Market Access, with a focus on all aspects of account management, market access, reimbursement strategy, contracts and pricing.



Growth plans anticipate going from 95 to approximately 300 employees by next year with Johnston and Stewart leading that effort. Robinson credits the strength of Urovant's HR team for enabling the company to target such an aggressive pace of hiring. "We are recruiting nationwide with a corporate emphasis on Orange County, Calif., already a hub for biopharmaceuticals that is emerging as a center for specializations including urology. We are looking for talented and passionate individuals to help achieve our mission of improving quality of life through innovations in urology."

Marketing planning for vibegron is focusing on sophisticated digital outreach as opposed to a traditional broadcast television blitz. "Today, we can communicate with patients more directly via the digital realm," Robinson says. "Our plan is to be highly targeted and customized for our patients' needs, with less reliance on broadcast television. Our plan is to leverage digital and all types of new media as appropriate to get the story out about vibegron.

"We also recently launched an educational campaign, Bladder Chatter, focused on women, to advance the conversation around OAB and encourage discussion of this condition with their health care providers," Robinson added.

"We intend to be the leading urology specialty company, first and foremost," says Robinson. "Our vision is very clear, but for me, ensuring the people aspect of the company is right is the most critical. We have a very strong leadership team and that strength attracts other talented people. We will continue to position key players in our organization to achieve our vision of helping patients." — By Susan Belknapp, California Business Journal

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