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Life sciences spotlight

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A culture of innovation: A Q&A with Jeffrey S. Hatfield, CEO of Vitae Pharmaceuticals

Life sciences executive Jeffrey S. Hatfield, president and CEO of Vitae Pharmaceuticals, talks about securing the financing required to succeed in an incredibly capital-intensive industry, the long and risk-laden path to regulatory approval and the desire to change peoples' lives for the better by curing disease. Vitae Pharmaceuticals is a clinical-stage biopharmaceutical company dedicated to discovering and developing a portfolio of novel, small molecule, best-in-class compounds that address important disease areas, including chronic kidney disease, diabetes, Alzheimer's disease, atherosclerosis and inflammation.

Since becoming CEO of Vitae, Hatfield successfully transitioned the company from a platform technology startup to a thriving, product-focused discovery and development engine with a robust pipeline that includes multiple programs advancing in human clinical trials. Prior to joining Vitae in 2004, Hatfield worked at Bristol-Myers Squibb (BMS) in a variety of executive positions, including senior vice president of BMS's virology and immunology divisions; president and general manager, Canada; and, vice president, U.S. managed health care.

Lisa Walkush, principal with Grant Thornton LLP's Life Sciences Practice, recently had the opportunity to sit down with Hatfield to discuss his views on the life sciences market, funding challenges, innovation and tips for emerging-growth companies in today's market.

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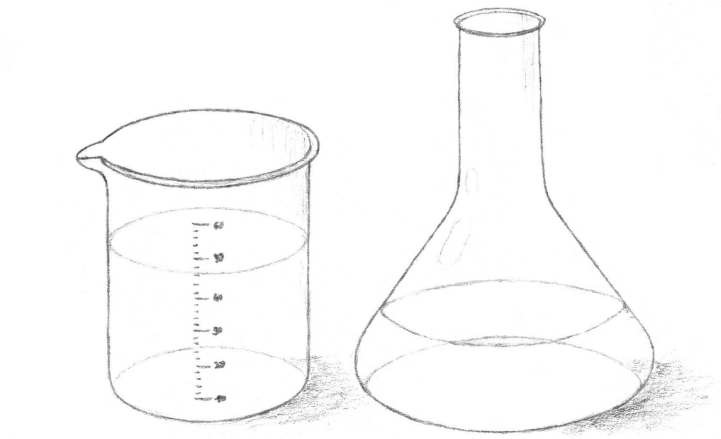

LW: What are some of the top challenges in the life sciences industry today?

Certainly one of the top challenges for our industry right now is being able to finance the work of innovative biotech companies like ours. Biotechs are small organizations — 90% of biotech companies have fewer than 100 employees — but they still must come up with an incredible amount of capital to drive a novel idea forward in the life sciences sector. Even under the best circumstances, a company needs to have access to millions of dollars of capital just to get started, and it then must have a way to get tens of hundreds of millions more if the idea progresses. In life sciences, a cure has to go through an extensive multi-year research phase, then on to a tremendously expensive and long clinical trial phase involving thousands of patients; only after that can it begin with the lengthy and uncertain regulatory process. All that must happen before it can ultimately reach physicians and benefit patients.

Another huge issue is the challenge of making a scientific breakthrough that can be a useful advance in treating disease. The odds are quite low because there are so many ways for a new bit of science to fail. Everything — efficacy, safety, tolerability, dosing, stability, cost, etc. — must meet a very high standard, or the idea fails. It's a long and risk-laden path to turn an idea into a cure that gets delivered to patients where it can be useful.

LW: What is your outlook on the availability of capital for the life sciences sector for 2013?

Unfortunately, the outlook for the availability of capital in the private sector of life sciences is fairly negative across the board right now. Many metrics are down significantly, including the number and size of new venture funds being raised, the number of venture capital financing deals getting done for biotech startups and the number and value of successful IPO market transitions. It's a fairly austere funding environment.

But as we look forward, there are reasons for optimism. The only way that the United States and other countries around the world can really solve their long-term health care funding issues is with novel cures that can alleviate the overall health care system burden. Amazing scientific findings are generating a constant stream of new, high-potential ideas for those cures. When the federal government works through its current broader economic challenges and the nation gets back to some degree of normality and predictability, the markets will likely gradually return to a more functional state, and investors will reacquire appetite for some risk that will boost funding in this sector.

LW: Tell us more about how the regulatory environment affects life sciences companies.

The Food and Drug Administration (FDA) and similar regulatory bodies around the world are responsible for guiding, reviewing and deciding on approval for every potential cure that our industry discovers. One of the key recent challenges facing scientists, sector investors and most importantly patients is the perceived lack of transparency and consistency of the FDA during the review process. This lack of predictability and consistency has caused delays in getting novel medicines to patients and greatly increases financing risk. In turn, this greater financing risk demands greater returns to compensate, and the whole dynamic just piles on top of the other capital-availability problems we've just discussed.

The good news here — and there's some truly good news — is that a lot of progress has been made on this in 2012. Leaders at the FDA have recognized the issues and have worked hard to address them. As a part of that effort, when Congress reauthorized the Prescription Drug User Fee Act[1] (PDUFA) this last fall, several new processes were formally established between the FDA and the industry. Hard-wired into PDUFA V are a number of communication-enhancing processes that I believe will greatly lessen the perceived risk of the regulatory process and better serve the needs of patients waiting for novel cures. These changes will be a tremendous help in getting capital flowing back into life science companies.

LW: Can you tell us more about the drug discovery process and how you incorporate innovation despite constraints on capital?

The only way to cure the diseases prevalent in our society is to find ways to continue to fund innovative research. We talked about the government's economic issues earlier — a huge component of the United States' budget debate is around health care costs. How do we, as a society, afford to care for people who are suffering from disease? Offering less money to physicians or charging patients higher deductibles doesn't change the system. The only thing that will change the game is to cure the diseases that are afflicting people around the globe, and that requires true innovation.

When I joined Vitae in 2004, the company had combined capabilities in supercomputing, quantum physics and some other amazing technical ideas in order to accelerate and expand the abilities of drug-hunting scientists in their efforts to discover new cures. The problem, we soon figured out, was that these incredible technologies were not financeable in that marketplace. In 2004, people were getting out of investing in biotech. Platforms, in general, were ice cold. We had to work very hard to construct and communicate a compelling story about what Vitae could become to potential investors so that we could get through the next month. It was a time of real crisis for our company.

We got through it, and at the end of 2004 we were able to close a venture round that brought in $35 million. That capital

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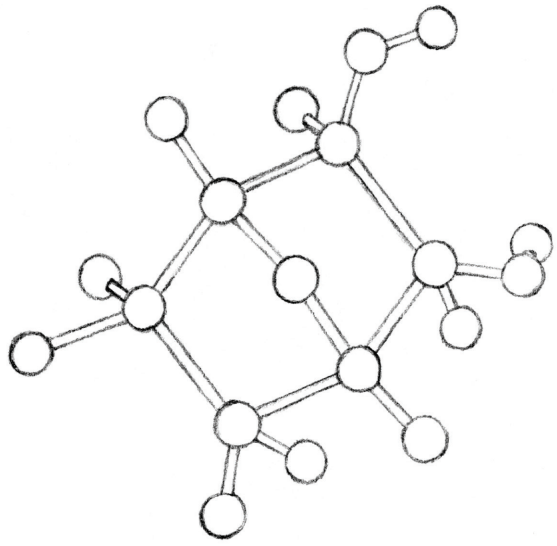
[1] PDUFA was enacted in 1992 (and re-authorized in 1997, 2002, 2007 and 2012) to enable the Federal Drug Association (FDA) to collect fees from companies that produce certain human drug and biological products. These fees play an important role in expediting the drug-approval process.



infusion allowed us to really execute our business plan, and we haven't had to go back to the venture market since that time, which is pretty unusual in this sector. We made a shift in our business model after we closed that venture round. We created a self-sustaining financing model to inure ourselves from financing risk in the future. This new model included a mix of high-value partnering deals on some of our discoveries/assets and the use of capital from those deals to invest in other assets in our portfolio that would create better value for investors. In 2007, we closed the largest preclinical partnering deal of the year, which brought in $37 million of upfront cash for our work in diabetes and metabolic disorders research. In 2009, in a different transaction, we again had the largest preclinical deal of the year, which brought in $42 million in committed cash for our work in Alzheimer's research. Both of those programs continue to advance, and they have earned Vitae additional performance-based milestones that add to our cash resources. To date, over $125 million of largely non-dilutive funding has come into the company as a result of those two deals.

That financing strategy has proven quite successful. Through all the ups and downs of the market we've never had to go back to the venture market for another round, and still have been able to fund innovative drug discovery work in many significant disease areas of global need, like kidney disease, diabetes and Alzheimer's.

LW: To have grown shareholder value without having to go back to the venture market since 2004 is quite a feat. Tell us more about your partnering strategy.

First, we focus on a disease target that has a large global unmet medical need and significant scientific potential — like atherosclerosis for example. We then put our incredible scientific team and technology to work on the generally well-known discovery challenges.

Consistently, Vitae has been able to generate breakthrough science in these important categories. Then, whether we're interested in partnering or not, we begin an extensive outreach process where we share our success and findings with academia and larger pharma companies worldwide. If we find a situation where we believe the discovery could be improved upon or accelerated by partnering, we engage in those discussions to see if we can make a match. People may not recognize it, but there is a truly symbiotic relationship among universities, biotechs and large life science companies worldwide — the life science R&D community typically demonstrates amazing cooperation and collaboration. Vitae has been particularly successful at working within this global network to generate and advance ideas that have the most merit in terms of solving human disease.

LW: Within the life sciences industry, there's so much convergence of providers, payers and life sciences companies. How has increased involvement with providers and payers affected how you approach research?

When I first started working in this industry in the mid-80's, we only considered the questions of whether a new drug treatment had a positive effect in its disease area and whether it was generally safe to take. Now, you're right, Lisa, there is a much broader set of issues and dynamics to consider up front as we search for new medicines. One dynamic is that there are much higher standards on all fronts for what we discover today — just being safe and effective is no longer in any way satisfactory.

There's the managed care context that has to be considered. To gain a reimbursement listing so that physicians can prescribe a new medicine, the expectation is that we have to prove clinical advantage over existing therapies available to their patients. Then there's the pricing question to consider — is there enough economic incentive to take the risks and do the R&D work necessary to try for approval? For Vitae, we go out early on in the process and get feedback from managed care physicians who are sitting on the pharmacy and therapeutics committee. We share a target product profile of what our discovery work could look like as it advances, and ask what the reimbursement issues and questions are likely to be, whether they are likely to reimburse our therapy if it achieves the target profile, or whether they will restrict it. Those questions need to be fleshed out in order to know whether we should keep investing in our program. If it doesn't offer enough benefit, we scale back investment accordingly.

The other convergent factor that I think is a huge benefit to the entire health care system is that patient advocacy groups are getting much more involved in the R&D system. Patients are the ultimate stakeholder in what we, as an industry, are working to achieve — better cures that can make a real difference in people's lives. These patient organizations are learning how to provide feedback to the industry on the most pressing needs of their respective patient group, to monitor the industry's progress and to help ensure rapid access to important new breakthrough medicines.

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Among the most rewarding things I have done in my career is sitting at the table with people suffering from a disease and hearing directly from them about how they experience the disease and how it affects their work, their family, their psyche, etc. so that when we do our drug discovery, we know exactly what we're chasing in terms of patients' needs.

LW: You've had a number of different roles in the industry over the course of your career. Tell us about how the industry has changed during that time.

It's a more complex and challenging time to try to discover important new medicines that can benefit patients around the globe, but that's still what it's all about. I was so enthused recently while having a series of lunches with small groups of Vitae employees, which included bench scientists, computational chemists, structural biologists and more. I was curious about what had motivated them to join a small biotech like Vitae when they could work for one of the large life sciences companies, like Johnson & Johnson, GlaxoSmithKline, Merck or BMS. What surprised me was that their independent answers were more or less identical — everyone said they were working in life sciences with the specific lifetime goal of discovering a new therapy that could make a difference to patients around the world, and they all felt their best chance to accomplish that goal was to be working here at Vitae. That's the essence of the best of this industry — incredibly inspired and committed people who are willing to accept the long hours and daunting odds of success because they so passionately want to use their scientific talent to change the world in a positive way.

LW: To me that speaks to culture. In fact, at Grant Thornton we've adopted the saying, "Culture eats strategy for lunch." Tell me about the culture at Vitae.

I think that culture is the number one thing that matters at a company. Culture is the way we interact every day. It's what we do. It's what we say. It's how we think and act.

When Vitae was just getting going everyone there decided to work together to explicitly define a roadmap for our culture — what we wanted the organization to look like and feel like — so that employees would be happy and excited when they drove to work every day. A team of our bench scientists led the process of identifying and codifying what was most important. These values — innovation, urgency, results, enthusiasm and teamwork — became the cultural pillars of our organization. We try to bring those values to all that we do, and every year since then we've given a peer nominated Vitae Values award based on these cultural values.

LW: What has been your most difficult decision to date at Vitae?

There have been so many challenges we've overcome. It is always very difficult when we've started a program that got quick traction and looked really promising, but then we realized, through interactions with the external environment, that while our science had promise and was potentially better than what patients have today the benefit still wasn't necessarily strong enough to merit financing. It's very hard to stop quality innovation when it's the business case that's the 'no go' decision

LW: If you were advising the CEO of an emerging life sciences company, what guidance would you give?

I have four pieces of advice.

First, build a great team of the best people at every position. Consider talent, motivation and style equally for each person.

Second, have a plan for continuously gaining capital. Financing is a really big issue, and it is important to have a clear plan for how to get money, how to efficiently generate positive results and then how to get more money to keep things moving forward. Ultimately, you can get capital if you can build a compelling argument for how your investors will earn a suitable return from investing in your work.

Third, expect failure. This is a challenging industry with long odds for success, and it seems to always be getting harder. I've never had a year in my career when in December, I thought, "It's going to be easier next year." The challenges and the failures, are always going to be there, so accept them and expect them. Do the 'killer' definitive experiments as quickly as possible, and when you encounter disappointment, one of the most important decisions to make is whether to press on or kill the program. Making the right decision is what makes or breaks companies.

And fourth, have hope. There will be several novel and hugely impactful discoveries made over the next decade. Being one of those successes — curing disease and changing the world for the better — is what we all strive to achieve, and it's what drives the energy, passion and commitment for us all.