Insights from the C-Suite:

Biotechnology Companies

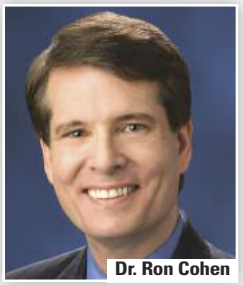
Biotech executives address the need for regulations that address the specific needs of biotech and how funding challenges can impact innovation.

According to a recent report by US Biotech Market Analysis, the United States represents the world's largest biotechnology market, leading with its innovation, extensive R&D, and company developments in various spheres of the biotechnology sector. On the back of rising instances of innovations in information technology, world-class healthcare infrastructure, and active participation by private players, the U.S. biotech industry has grown in the past few years.

According to the report, biotech funding has been a major source of growth in the U.S. biotech industry as venture capital and financing by other sources continue to provide the momentum. The structure of financing has been strengthening over the past few years with IPOs, FPOs, public and private sectors, and venture funds contributing significantly to the industry developments.

Other analysts say one of the major problems in recent years for emerging biotech companies has been funding for research. With the signing of the Jumpstart Our Business Startups (JOBS) Act, emerging biotech stocks will be allowed five years to focus funding on research before having to allocate funds to costly regulations, saving companies up to $2 million per year.

RON COHEN, M.D.
President and CEO


Dr. Ron Cohen

Acorda Therapeutics Inc. *is a biotechnology company whose mission is to develop and market therapies that restore neurological function and improve the lives of people with multiple sclerosis (MS), spinal cord injury (SCI), and other disorders of the nervous system.*

For more information, visit acordatherapeutics.com.

The U.S. biotechnology sector is poised to deliver many important advances in medicine in the years ahead. To keep the sector growing, we must carefully review and, wherever possible, improve flawed regulatory processes that inhibit our ability to innovate and compete on a global scale, while still providing the needed assurance that approved drugs are safe and effective. Several regulatory processes and systems should be top priorities for reform in efforts to improve our ability to advance important development programs.

The FDA has had five commissioners in the past 10 years alone. This level of turnover makes it very difficult to establish effective leadership and focus on long-term planning. Commissioners should be appointed to fixed terms of six years to insulate them from political influence.

In many cases, essential information from the FDA takes far too long to reach companies with drugs under review. In many instances, the communications are overly cryptic or open to wide interpretation, and in other cases, the information is never transmitted at all. Both formal and informal communications between FDA and drug developers must work better to provide the guidance required for developing innovative new drugs and to keep them on track.

The growing FDA focus on risk over the past several years has slowed down or resulted in discontinuation of many development programs, without taking into account one of the key risks: the devastating effects on patients when access to new drugs is delayed.

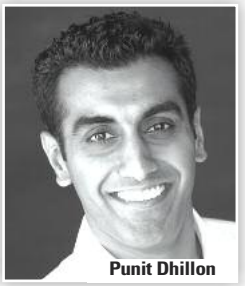
The accelerated approval pathway has proved effective in delivering drugs to patients more rapidly, but this pathway has been applied primarily to drugs for HIV and cancer. This pathway should be made available for treatments across a wide range of serious diseases for which there are unmet needs.

There is no mandate at the FDA to promote or support innovation. FDA decisions and delays have discouraged companies and investors from investing in several areas of medical innovation where they perceive FDA decisions have been unduly capricious or hostile. The agency mission statement should state that support of medical innovation is part of FDA's mission.

Congress often hears from patients desperate to see new drugs approved, but patients do not have an active role in FDA processes related to drug and device approval decisions. The voice of the patient is a critical element in determining what is acceptable risk compared with the benefit of new treatments.

In addition to streamlining the review process, reforms in these areas might also attract more investment to the biotechnology sector, fueling many new research and development efforts.

PUNIT DHILLON
President, CEO, and Co-Founder


Punit Dhillon

OncoSec Medical Inc. *is developing novel, localized anticancer therapies against solid tumors to overcome the significant cosmetic, functional, and other side effects associated with surgery and other nontargeted therapeutic approaches.*

For more information, visit oncosec.com.

We cannot avoid the current economic climate and its impact on the increasing costs of healthcare in the United States. Therefore, the biggest challenge facing the biotech industry today is developing new and innovative therapies that not only provide a better treatment outcome for patients, but also provide improved quality of life at an affordable cost.

It is expensive to develop and gain approval for new drugs and medical devices from regulatory agencies such as the FDA, and for a company to recuperate those costs it must charge a premium for treatment. However, in today's global economy, there appears to be a paradigm shift and backlash against new and expensive therapies. Doctors are more aware that there is no single treatment that can benefit the patient, especially with reimbursement implications in mind. Meanwhile, patients are more educated about available therapies, and many are unwilling to sacrifice their last days suffering through a treatment that might or might not provide a few more months of survival.

The solution, then, is for biotech companies to

focus on developing innovative treatments that integrate breakthrough technologies. These technologies may fall in areas such as genomics and drug delivery, with the goal of improving patient outcome and quality of life through personalized and customized medicine.

We are developing a novel drug delivery device that harnesses a process called electroporation. Derived from the words electric and pore, this involves applying a brief electric field to a cancerous cell. The electrical pulse triggers the temporary creation of pores in the cell's outer membrane — pores that close again within seconds once the electric field is discontinued. These transient pores can improve uptake of various drugs more than a thousandfold, thus reducing the amount of drug required to induce therapeutic benefit while also improving the safety profile of the therapy. In addition, OncoSec is implementing a strategy to decipher molecular markers that may indicate whether or not a patient will respond to the therapy, in effect personalizing the treatment.

By taking advantage of our current scientific understanding, and integrating it with tomorrow's technological advances, the biotech industry can revolutionize medicine through targeted and personalized new therapies. In doing so, we will have the ability to improve patient outcome and quality of life, and as a result, decrease the burden on the healthcare system by reducing the need for pre- and post-treatment care. In the end, a healthy, cost-effective, and sustainable healthcare system is a benefit to us all. It reduces the cost for the payer and makes available funding for research and development of even more innovative and improved treatment options.

YUICHI IWAKI, M.D., PH.D.
President, CEO, and Founder


Dr. Yuichi Iwaki

MediciNova *is a biopharmaceutical company that acquires and develops novel, small-molecule therapeutics for the treatment of diseases with unmet need with a commercial focus on the U.S. market.*

For more information, visit medicinova.com.

The greatest challenge facing today's biotechnology companies is the need to secure long-term investments, and this involves looking far beyond the next clinical milestone. Ultimately, in the eyes of investors, it is the enduring value of a drug to patients and prescribers that counts.

Smaller biotech companies, which can be more innovative than their larger counterparts, are uniquely positioned to take risks by fulfilling unmet clinical needs. However, they will not succeed in the marketplace unless they can succinctly state why a long-term investment in their drug makes sense, and communicate this value to potential investors. Of course, with any challenge comes an opportunity.

A biotech company can overcome the initial barrier to success if it demonstrates that its pipeline products are safe and efficacious — the clinical goal. But to really distinguish itself among competitors, the biotech must keep in mind the business goal, which is showcasing a drug's true economic value for both patients and prescribers. Once they understand the value of the drug in these ways, investors are more likely to take notice, because there's a greater chance the drug will be prescribed and used over a long period.

At MediciNova, we are testing bedoradrine sulfate (MN-221) as an intravenous treatment for acute exacerbations of asthma. The data we are developing can be of great value to hospitals to help employ cost avoidance strategies for improved asthma patient care and reduced inpatient admissions.

Only by taking these types of measures is a biotech company assured of securing long-term investments and ultimately staying in business. PV