

Debbie Hart - Founding President & CEO, BioNJ, USA



Much of the research, the development and the manufacturing that is happening in [the cell and gene therapy] space is happening right here in New Jersey

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BioNJ's president and CEO Debbie Hart reflects on the association's mission of creating a robust and engaging life sciences ecosystem in New Jersey. Hart also outlines how BioNJ is hoping to continue to grow the region's reputation as a hub that stands out for its level of expertise, favourable geographic location, and supportive governmental initiatives.

Who are the members of BioNJ and what ties them together?

Our membership is comprised of the full spectrum of companies including large and small biopharmaceutical companies, academic institutions, economic development organizations, government, and service providers such as CROs, CMOs, attorneys, and accountants. It is a microcosm of the continuum of what it takes to discover and bring a drug to market in New Jersey.

What services do you provide to your members?

We believe that BioNJ has the preeminent model for a robust life sciences innovation ecosystem where Science is Created, Innovators are Valued, Medicines are Delivered and Patients can Live Longer, Better Lives. We're working to ensure that in four specific ways.

The first area is by advocating good policies on behalf of the industry and making sure that the contributions that our industry is making to innovation and to healthcare are recognized. This

includes as the cure for Hep C – which was developed in New Jersey; reducing cancer rates with innovations such as CAR-T therapies and bringing hope for rare disease Patients where previously there was none with innovations coming from New Jersey companies such as Amicus Therapeutics, Insmed and PTC Therapeutics.

The second area is education and networking. We know that people join BioNJ to expand their knowledge and to meet others in the ecosystem. So, we organize 35 events a year focused on topics such as cell and gene therapy, clinical trials and supply chain management; where our members can share best practices, meet a partner, find a funder or secure a job.

Thirdly, we offer a series of high-value purchasing agreements for our members where they can save precious dollars on lab supplies, insurance, delivery services – to name a few.

And finally, talent, which is the number one reason companies come to New Jersey. We have a robust offering to make sure that employers and job seekers get connected.

How has the association's agenda evolved over the years?

Our agenda has evolved and expanded to mirror the growth and evolution of the industry and the environment. We are particularly proud of our commitment to Patients and to making sure that their voices are heard. We are also using our own voice to tell the industry's story and talk about the medical innovation which is allowing Patients to live longer more productive lives. Additionally, we have taken a lead in educating the community on the challenges presented by the Institute for Clinical and Economic Review (ICER) and other value frameworks and to proposing better cost-effective solutions.

What are some of the biggest challenges companies face in the policy arena?

We are particularly concerned about some of the proposals coming from Washington...proposals that will put the brakes on innovation and have a devastating impact on our State's biopharmaceutical economy. Early-stage life sciences companies rely heavily on early investment to usher a treatment through the complicated FDA approval process. And 90 percent of all drugs never receive FDA approval. The existing system helps to ensure that the small biotech with a recent drug or biologic approval has the opportunity to provide a return on investment. Artificially limiting the ability of a company to appropriately price a new therapy through price controls will

have a chilling effect on investment and potential employment disruption for thousands of New Jersey's life sciences employees.

You recently organized the Cell & Gene Therapy Manufacturing Briefing. Are you trying to focus the association's efforts into identified key areas of expertise?

We are committed to telling the industry story and in New Jersey that includes the growth and expansion of cell & gene therapy from discovery to manufacturing and commercialization. The first CAR-T therapy approval was received by a New Jersey company. Much of the research, the development and the manufacturing that is happening in this space is happening right here in New Jersey. Companies from around the world are looking at New Jersey as the place to be if you want to be in cell and gene therapy. In fact, at the Cell & Gene Therapy Manufacturing Briefing, we had a waiting list to register. It's very exciting...for the industry, for New Jersey and for Patients.

In your own words, what makes New Jersey competitive?

Hands down it is our talent. In particular, no place else in the world has the depth of development and commercialisation expertise.

And we have the good fortune of geography that allows non-stop travel anyplace in the world from any of five nearby international airports. The Food and Drug Administration (FDA) and the National Institutes of Health (NIH) are a train ride away and Wall Street is just across the river. When you compare our costs to other ecosystems, you will find that New Jersey rents are 40 to 60 percent less expensive than other hubs. We're very competitive. The cost of talent is less expensive, too.

Moreover, each and every governor since we started has recognized the value of the biopharmaceutical industry and has put his or her stamp on how to support and grow our industry. Governor Murphy is no exception. Since taking office in early 2018, Governor Murphy brought back the State's Commission on Science, Innovation and Technology and announced a grant program that will help companies applying for SBIR/STTR grants. The Governor supported and signed an increase in the Angel Investor Tax Credit from 10 percent to 20 percent with an additional five percent for minority and women-owned businesses and instituted a free rent program for start-ups. These are tangible and concrete initiatives that are already making a difference for the biopharmaceutical industry.

J&J, Merck (MSD), Novartis, BMS and many other companies all have either their global or their US headquarters in New Jersey. Are you satisfied with the input of these enormous companies into the New Jersey bio community or do you want to see more?

New Jersey is so fortunate to have these leading pharmaceutical companies in our state and that they are so engaged with BioNJ on every front — from policy to partnering.

On the opposite side, what is the life of an early-stage New Jersey biotech company? What might be the typical flow and what are the issues that you think could be addressed in a better way?

It's a long hard road with endless ups and downs. It takes 10-12 years and USD 2.6 billion to bring a drug to market and most never make it. The struggles of raising capital, keeping shareholders content, regulatory challenges, finding talent and a rocky road to approval are not for the faint of heart.

How have things changed in the way New Jersey looks at the biopharmaceutical ecosystem?

New Jersey has been the beneficiary of the work of the industry since the Johnson brothers founded J&J in 1886 in New Brunswick. And the industry has expanded ever since, now including more than 3,200 life sciences establishments supporting more than 400,000 jobs. The size and scope of the industry has helped to ensure that government is committed to its growth and expansion.

Most recently, under current Governor Phil Murphy, we have seen an increase in the number of incubators and accelerators inciting start-ups as well as the migration of companies from other states and countries.

We work closely with our partners at the New Jersey Economic Development Authority (NJEDA) and Choose New Jersey to ensure that companies from anywhere in the world are aware of what New Jersey has to offer and that our door is open to them.

What is your vision for New Jersey's life sciences industry and what are your goals for the next 3-5 years?

Our vision is that the industry continues to grow and expand here...that New Jersey companies continue to lead the country in drug approvals and innovation...that Patients around the world will be able to access the therapies and cures that they need when they need them. We are committed to that and will do all we can...on every front...to make it so. "Because Patients Can't Wait®."

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