Industry Snapshot reveals new records

Venture capital investment in Massachusetts biopharma industry reached $2.9 billion

MassBio’s annual Industry Snapshot report, released in October, highlights the growth of the state’s cutting-edge life sciences companies, showing venture capital dollars continue to flow in at an astounding rate.

Venture investment in Massachusetts biopharma companies was $2.9 billion in 2016, up from $2.3 billion in 2015, and more than triple the $900 million in 2012, according to the data. Even more, 30 percent of all U.S.-based biotech IPOs were from Massachusetts companies in 2016.

To meet increased demand from new and growing companies in the industry, Massachusetts biopharma employment grew 4.8 percent in 2016, adding more than 3,000 new jobs. Many of these positions are supporting new research, as data shows the R&D segment grew by 9 percent in 2016. Massachusetts also continues to outpace other states in terms of NIH funding per capita and ranks second in total NIH dollars, only after California, with five of the top six NIH-funded independent hospitals located in the state.

“MassBio’s Industry Snapshot makes clear Massachusetts is the no. 1 biotech cluster in the world, home to the best universities, hospitals and biopharma companies, along with the brightest minds in the industry.

See SNAPSHOT Page 7
MassBio’s commitment to gender diversity

As we near the end of 2017, I can’t help but reflect on all the amazing jobs our industry has made in the last 12 months, from broadening cell and gene therapy to milestone achievements that were taken to market by the venture capital community in Massachusetts. One area that continues to attract the heat and brightest minds in the sector and our member companies’ boards is improving gender parity both here and abroad. But we cannot look back and assume progress will continue as expected when we have a very real problem within the life sciences companies – the lack of diversity at the highest levels of management.

I don’t pretend there’s a silver bullet to fixing the gender diversity problem, but I do say that as CEO of MassBio, I’ve fully committed myself to this endeavor, and I can confidently say that our entire leadership team and I are fully committed to this. We’ll see our leadership position as the voice of the life sciences industry and take the lead, computing MassBio to several recommendations from the report, some of which we’re already doing, and others that we’re implementing as formal company policies moving forward.

We’re going to publish data relating to gender representation within MassBio and our Board (recommendations #31), actively promote mentorship and sponsorship programs (recommendation #32), and create a more formal policy to ensure MassBio panels are gender balanced and our key events do not end up on an outside panel (recommendation #48). Using the report as our guide, we will get a pull our recommendations we can implement, and will share our progress. MassBio cannot ignore changing the culture of our number companies and the industry at large to join us, and publicly commit to taking action. I want to hear from you about what your companies are doing to improve gender diversity in the life sciences industry. Help MassBio lead by example and share your stories.

Robert K. Coughlin is President & CEO of MassBio.

Q&A with Katie Brandt
Former Brandt
Rare advocate

Director of Caregiver Support Services
at Massachusetts General Hospital's Frontotemporal Disorder Unit

What elements of the patient’s journey should life sciences companies keep in mind when collaborating with rare disease patients and advocates?

When a life science company has the opportunity to collaborate with a rare disease patient or advocate, it is essential that you acknowledge the unique experience and perspective that a rare disease experience presents. Patients may be able to illustrate symptoms in a way that improves diagnostic tools, shortening another family’s quest for a diagnosis. Participation in a clinical trial may yield information to develop the next generation of disease-modifying treatments. In these instances, the individual outcomes and perspectives are critical to moving forward.

For many life science professionals, recognizing these elements of the rare patients’ voice comes as second nature. In fact, it may be impossible to adequately take stock of the whole patient without understanding the rare experience.

What are some tips for patients who wish to effectively engage with policy makers to impact legislation?

For the rare patient or family member who would like to engage with their elected officials and policy makers, the good news is that you don’t have to have all the knowledge you need to make an impact. You are a citizen with a rare experience and we want to take our side of the story to our elected officials. If you wish to write your representative or senator or share your story with legislative committee chairs, you must be prepared to share your story and how it affects you and your family. They may bring ideas to the table that are products of their research and understanding of the disease, but they are also the human journey, life science companies can offer rare advocates.

What actions can both patients and industry partners take to raise awareness for rare diseases?

When my husband passed away from the rare disorder, Frontotemporal Dementia (FTD), I knew that I wanted to be a voice to raise awareness about his experience and FTD. I didn’t have to have a marketing plan or a set media campaign. But, I had contacts from our rare experience. I was able to reach out to individuals and agencies who could help and supported us through our journey with FTD to find solutions for the needs we had. I reached out to the clinicians at MGH, the staff at the nursing home where he lived and the professionals at the Association for Frontotemporal Degeneration. We’re going to publish data relating to gender representation within MassBio and our Board (recommendation #31), actively promote mentorship and sponsorship programs (recommendation #32), and create a more formal policy to ensure MassBio panels are gender balanced, and our key events do not end up on outside panels (recommendation #48). Using the report as our guide, we will get a pull on our recommendations we can implement, and will share our progress. MassBio cannot ignore changing the culture of our number companies and the industry at large to join us, and publicly commit to taking action. I want to hear from you about what your companies are doing to improve gender diversity in the life sciences industry. Help MassBio lead by example and share your stories.

Robert K. Coughlin is President & CEO of MassBio.

MassBio celebrates company openings

New MassBio Members

MassBiotool hosted its second annual Champions of Biotechnology Education Awards Ceremony to celebrate and recognize the outstanding educators and support of biotechnology educational programs in Massachusetts. The event, held on Nov. 8 at the UMass Club, honored Dr. Jeffrey Leiden, Chairman, President and CEO of Vertex Pharmaceuticals, Gloucester High School science teacher David Enos and Eric Leigh, and Sanofi Cytokin.

Each award“s extraordinary efforts have helped advance students in our region toward the incredible opportunities of careers in the life sciences,” said Peter Meunier, Executive Director of MassBio tool.

“Dr. Leiden has been a key partner to us for over a decade, helping us pave the way for innovative education programs in biotechnology,” said Meunier.

“We’re honored to shine a light on Eric’s contributions as a Champion for Biotechnology Education.”

We’ve got some exciting news for you all today, our First Reactor opens in Massachusetts on Oct. 18.

Inozyme Pharmaceuticals

Inozyme Pharmaceuticals opened its manufacturing facility in Lexington on Oct. 18.

New MassBio Members

Astellas

Veeva Therapeutics

New MassBio Members

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Veeva Therapeutics
MassBio’s annual Patient Advocacy Summit puts the patient front and center

**By Meaghan Casey**

If one message could be heard loud and clear at MassBio’s fourth annual Patient Advocacy Summit, it was this: Always put the patient first.

Multiple speakers, from Tekesha O’Neal’s Liz Lexis to Akkus Therapeutics’ Kathy Grant, repeated that sentiment throughout the course of the day-long event, held at Merck on Oct. 27. The summit brought industry leaders together with patient advocates and other stakeholders to examine ways in which life sciences industry leaders together with patient advocates and other stakeholders can more fully incorporate the patient voice into the work they do — not just approaching regulatory affairs for Blueprint Medicines. “How do we keep that idea of patient centricity central to who we are? The executive buy-in is really important.”

“To focus on the patient, you really want to get to know the community,” said Liz Lexis, interim head of patient advocacy and engagement at Alnylan. “What’s the disease impact on a daily basis on the patients and the caregivers? If we’re not taking that into account, our clinical trials won’t be successful.”

The topic of patient-driven research and development was explored in greater depth by a panel made up of patient-inspired entrepreneurs. Often times, it takes an invested patient, relative or caregiver to drive patient advocacy, as was the case with Stuart Sulsdin, who created the Sanfilippo Research Foundation after his son was diagnosed with Sanfilippo syndrome and they were told there was nothing they could do. “We realized we needed to engage with the industry and do our own disease, making it more attractive to companies,” said Stairs. “Now there’s a gene therapy for one strain in clinical trial and a second one in the works.”

Anna Hehenberger, general counsel for Lyfebulb, spoke about the practicalities of early engagement with patients. “The patient is the consumer of the drug and is the only one who can tell you if they’ll use it.” She said that while side effects are worth the benefits, “It’s not just about the treatment. It’s also about developing the device or consumer product that’s going to help make their lives more comfortable.”

During a panel that focused on the patient voice in discovery, Lily Stairs, head of patient advocacy at Clara Health, brought up a similar point by looking at consumer research in other industries. She used the example of Airbnb, which struggled to get off the ground before it became the giant online home-sharing marketplace that it is today. “The early stage and the turning point for that company,” said Stairs. “How do we take that example or look at the number of focus groups dedicated to consumer products and ask ourselves why we wouldn’t be doing that in bench?”

Other panels addressed the issues of navigating the regulatory process abroad and how patient and advocacy groups can partner with pharma companies to support awareness campaigns.

Closing out the event, Lee Cooper of Moderna Therapeutics gave a thought-provoking keynote presentation on the benefits of genetic testing. Cooper, who was diagnosed last year with Long QT Syndrome, a rare genetic heart condition, argued that carrier screening could help eradicate diseases. He is a proponent of anyone of child-bearing age getting tested early, rather than waiting until pregnancy, and for those with risks to consider in vitro fertilization treatment. Through parent germline genetic diagnosis, embryos can be tested for genetic disease or chromosomal defects, allowing fertile, specialist to transfer only healthy embryos.

-MassBio News
Building a more diverse industry

New report uncovers causes behind the gender gap within the life sciences

To order biopharma in Massachusetts to continue building a more diverse industry and to ensure your company is at the front of the game, check out the “Massachusetts Industry Snapshot: Life Sciences 2.0” initiative. It should be the backbone of company culture — reflected in recruitment, retention and promotion strategies for leadership roles. To download the full report, visit www.massbio.org/industry-snapshot.

In September, MassBio and executive recruiting company LifeSource released the findings of a comprehensive study examining the causes behind the lack of gender diversity within the Massachusetts biopharma community. “Opening the Path to Diversity Futures,” explores the experiences, motivations and attitudes of companies and employees to evaluate why gender gaps exist at every level of an organization, and what can be done to help companies increase diversity and inclusion.

The data reveals that women are underrepresented in leadership roles, but the gap at all career stages is equal proportions to men, but the gender gap grows at all career stages, despite women aspiring to the C-suite and board positions at the same rate. As the women reach the C-suite, they account for just 3% of senior leadership, the board level, just 14%. Women who hold EVP or VP positions, a prime talent source for the C-suite, are even more affected, with only 1% or women in these roles.

“This does not provide quantitative evidence of the visible gender inequality in the life sciences industry, it only explains how much of a factor women’s career advancement at all stages despite women entering the pipeline with equivalent education and motivation,” said Lihitamn CEO Karl Simon. “The findings challenge some longstanding assumptions and expectations and raise awareness of why the gender gap exists. The industry needs to tackle these issues so women are not marginalized and that the pipeline, thereby, we disparity the leadership at the top of companies is gender diverse and fully includes women.”

Some of the report’s most interesting findings include:
• 60% of women say they’re at a disadvantage because as an all-male board and advanced management, and because women interviewed only by men.
• Companies do not necessarily receive feedback when recruiting women while women report facing career development as a trend for joining their companies.
• Women value flexible working significantly more than men (77% vs. 25%).
• Women, 74% of men say they are fairly compensated.
• 33% of women state the performance evaluation/review process is biased, 13% of men.
• 67% of C-level women change careers regularly to scale what in these tripartite relationships.
• 33% of women view the performance evaluation/review process as biased vs 73% of men.
• 64% of women say men’s offer is working to improve diversity and that women are not as satisfied as they are in this regard.
• 57% of women believe they are not advancing in their careers as they face same rate in 2016. Women make up 24% of C-suite positions, a prime talent source for the C-suite, they account for just 24% vs men, and at the most senior levels, they account for just 6%. While there are no universal solutions to improve the gender gap, the report suggests that all companies should:

To download the full report and sign up for future updates, visit: https://www.massbio.org/diversity.

MassBio President & CEO Robert K. Coughlin addressed the crowd gathered at the CRO/CMO Symposium.

The symposium’s second panel focused on how service providers, sponsors and consultants can ensure seamless communication and strike a balance between micro-managing and allowing full autonomy. Not surprisingly, the conversation often boiled down to trust and transparency.

“The most important piece is defining your needs up front and having really good communication with your consultants and CROs through frequent phone calls, Skype meetings and in-person visits,” said Jim Reckel, head of molecular biology for ThermoFisher, a virtual company. “Make sure you’ve aligned and everybody’s on the same page.”

And project. How do you and the CRO partners align around what that milestone should be, and what is the value of that milestone? How do you make sure the partners are comfortable with the risk of a program they don’t have control over? It’s important to align incentives across both organizations.

Each of the panelists agreed on the value of clearly defining project scope, establishing key performance indicators and having a steering committee to manage communication.

The program also included roundtable discussions on developing strong provider–CRO relationships; leveraging the maximum value of your CRO relationships; looking both globally and locally to find the right sourcing partners; searching for startups; how to get a new CRO, CMO business plan off the ground and manage a complex CMO network. Additionally, attendees had the opportunity to network at a well-trafficked exhibit hall.
By Meaghan Casey

As the demand for accelerating drug development continues to grow throughout the biotech industry, so does the need to outsource research and manufacturing.

MassBio’s 6th annual CRO/CMO Symposium explored the ways in which sponsors and vendors can better partner to advance efficient outsourcing and drive forward new treatments and cures. Through a series of conference-wide panel discussions and breakout sessions, speakers examined the evolving strategies in outsourcing, as well as strategic partnerships in pre-clinical, clinical and manufacturing and commercialization.

The event, taking place on Sept. 28 at the Hynes Convention Center, was held in conjunction with Biotech Week Boston. Set up as a festival of events spanning the drug development value chain, the week was dedicated to accelerating the business of biotechnology through new ideas, science, technology and partnerships to make a positive impact on patient health. More than 300 attendees gathered on the Biotech Week Boston floor for the MassBio event, joining the conversation about the CRO/CMO community.

The opening panel presented different perspectives on partnerships. Panelists evaluated the risks and rewards and discussed how consolidation affects the industry landscape.

Organix CEO Peter Meltzer reflected on the evolution of the CRO/CMO industry, having gotten his start in it 30 years ago. Organix, established in 1986, is a pioneer of contract research in synthetic organic and medicinal chemistry.

“We did what everybody advises you not to do and that was start a company for which there was no marketplace,” said Meltzer. “It turned out, things changed radically. If you look around Boston, there are myriad small companies and virtual companies, and of course every large pharma has a presence in the area. It’s night and day from 30 years ago to now.”

According to MassBio’s annual Industry Snapshot, Massachusetts now has 34,000 biotech R&D employees—the most in the U.S. The sector has grown by 40 percent in the past decade and 9 percent in just the last year alone. Meanwhile, the trend in transitioning from in-house R&D to strategic CRO partners also continues to gain momentum, as CROs are helping to get new products to market faster.

“Part of our strength is that within our own staff, there are people who have been with us for the life of the company,” said Meltzer. “There’s a huge knowledge base, which allows us to solve problems of real complexity. Then we’ve had research programs of our own, which contribute to that ability to solve substantial problems that have occurred in really tricky areas.”

When talk turned to the challenges and benefits of partnering, Helen Ho, head of corporate development for TCR2 Therapeutics, discussed the differences between the traditional fee-for-service model and a milestone-based structure. She advised building flexibility into any fee-for-service agreement, so that scientists can deal with the experiments critical to the project rather than the accounting logistics. She also warned that it can take more time to get the milestone-based deals done.

“For a small company, you’re focusing on a broader milestone or goals for your project, while the CRO is generally only focused on one aspect of