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THE LIFE SCIENCES EXECUTIVE NETWORK AT 2/13 PARTNERS PRESENTS

Biotech Bulletin | 2023, Volume 13

Tracking The Pulse Of The Philadelphia Life Sciences Industry

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Stay up to date on the pulse of the Philadelphia Life Sciences industry with our Biotech Bulletin. This is a quarterly newsletter, with data and perspectives from local leaders within the industry. Greg Sarian of 2/13 Strategic Partners is the author of the Biotech Bulletin. Each issue will include insight on the latest industry trends, performance metrics on local biotech companies as well as current acquisitions and IPO news in this area.

For Alzheimer's Patients Nationally, There is Reason for Hope But Cause for Concern

BY CHRIS GETMAN, BRAVO GROUP

The recent FDA approval of the Alzheimer's drug Leqembi®, provides hope for patients and families nationally. For the more than 6.5 million Americans suffering from Alzheimer's, the first new treatment in decades offers promise.

But with any promising new therapy, there is cause for concern.

Unfortunately, Alzheimer's patients are not only fighting a fatal condition, but also several regulatory barriers that are stacked against them. Put simply, the Alzheimer's community – whether due to misunderstandings about the nature of the disease or presumed costs associated with it – are victims of systemic discrimination.

The most egregious and recent example of this involves an egregiously cruel decision by the Centers for Medicare and Medicaid Services (CMS) that severely restricts patient access to current and future treatments for Alzheimer's disease. Despite several stakeholders weighing in and approval by the Food and Drug Administration (FDA) on the previously mentioned Leqembi, CMS refused to reconsider national coverage determination for the treatment, effectively limiting access.

Sadly, this decision fits into a pattern we've seen with Alzheimer's. It's a disease that is not treated with the seriousness that other illnesses receive. If this was a breakthrough cancer treatment, it's safe to assume the media coverage and external pressure to ensure patient access would be significant. Too many outside of the Alzheimer's community assume this disease is simply part of the aging process, that it isn't fatal, and that patient care does not require a tremendous amount of time and resources. Not only is this false, but it's also insulting to those battling Alzheimer's from the earliest signs of the disease and those who devote their lives to care for them. Imagine telling someone with stage 1 cancer that they should wait until things get worse before they can access treatments. This thinking goes against everything that new medications and technologies are designed to do.

There is no better time than now for policymakers to focus on Alzheimer's. It is projected that by 2050, the number of Americans fighting Alzheimer's will rise to nearly 13 million. And if policymakers are sincere about correcting health inequities, then the disproportionate impact of Alzheimer's on minority populations is a relevant concern.

While billions of dollars in investment resources and scientific brainpower to improve the futures of those with Alzheimer's continue, health care policymakers have squeezed the other end of this so-called pipeline so that what should be a robust flow of accessible innovation is just a trickle. Financial priorities continue to crowd out the opportunity to mitigate the risk of death and decline.

If policymakers at CMS are to live up to their rhetoric about eliminating health disparities and achieving health equity, they must ensure access to approved treatments. They must put a stop to the ongoing discrimination against a group of people already suffering. They must help to protect this nation's citizens against the risk of death, disability, and debilitating illness.

We have the capacity today to change health outcomes for millions of Alzheimer's patients for the better, so why aren't we?

CEO Spotlight with Jim Barlow, ImmunoGenesis

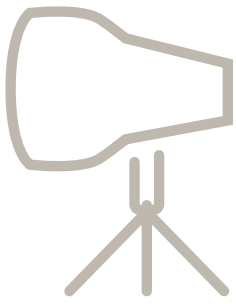
Greg Sarian: Jim, please tell me about the main area of focus for ImmunoGenesis.

Jim Barlow: Sure. ImmunoGenesis was founded out of MD Anderson Cancer Center in Houston, Texas by Michael a Curran. Dr. Curran is a trailblazer in immuno-oncology which is the science of using the immune system to fight cancer. He worked closely with Nobel Prize winner, James Allison, when the seminal discoveries were made that led to the Nobel Prize. Dr. Curran has been focused on how to take the immunotherapy advances that we've seen in hot, inflamed tumors such as lung cancer and melanoma and bring these advances to cold tumors or tumors that have immunosuppressive barriers that prevent immunotherapies from being effective. He has focused his lab at MD Anderson specifically on how to address immune barriers, and that's what ImmunoGenesis' products are all about - how do we overcome immune suppression in these cold, specifically immune excluded tumors? When I refer to immune excluded tumors, I'm describing tumors where there is an immune response, but there are characteristics of the tumor that keep these T-cells that are your killer cells away from the tumor and prevent them from going in and doing their job. We've developed a next generation suite of molecules that can overcome that immune suppression.

Greg Sarian: Since you've been at the helm of CEO, Jim, what do you consider your greatest accomplishments and what are the greatest opportunities you're looking forward to?

Jim Barlow: Sure. From an accomplishment perspective, I'd say number one, we've built a really amazing team. When I came in I was very focused on the culture, on taking what my experience taught me both in larger pharmaceutical companies like Merck and Bristol Myers and in biotech, what really makes a great team? What are those components, especially in a small startup where you need to bring in full-time people versus where you can use consultants and how do you balance that? And how do you bring the right type of person? Because not everyone can transition from, say, a large pharma company to a biotech and prosper. And so my greatest accomplishment is building a great team that works well together and has been very creative through this difficult funding environment in advancing our products. I'm really proud of the team we built.

I think second is working through this difficult financing environment and overcoming or looking for ways to be creative. We've raised about $35 million through non-dilutive funding and a grant from the State of Texas, which was about $15.5M, and about $20M in convertible notes. We've used this funding efficiently to bring us to the point where we're ready to start two clinical trials. We're positioned to see these amazing discoveries go into patients and see if we can impact cancer patients. That's been tremendous.



The flip side of that in terms of biggest challenges is the funding environment. It's been since October

of 2021, so basically two years, where there has been an extremely difficult funding environment in biotech. Venture capital firms are making few investments and the bar has become that much higher. And immuno-oncology is a little difficult right now. So it's been a perfect storm in terms of the financing environment and that has been quite difficult.

Greg Sarian: From the patient perspective, what is the main problem? What is the main solution ImmunoGenesis provides ultimately for the end patient, Jim?

Jim Barlow: It's important to step back and look at immunotherapy and the revolution that has taken place in the treatment of cancer by using immunotherapies. What immunotherapies really do is they facilitate the body's immune system to go ahead and kill the cancer. And so what we've seen when immunotherapies work, they can often lead to cures because you're training the body's immune system. Even as the cancer potentially comes back, the immune system can go and kill that again because it's been trained. Whereas if you give somebody chemotherapy or a targeted drug, if the cancer comes back it's likely that they'll have a recurrence. You see these functional cures with immunotherapy and that's the huge promise.

But what we've seen is that immunotherapy works very well in certain tumors like melanoma and lung, but it doesn't work as well in things like colorectal, ovarian, certain types of breast cancer where you have an immune response, but these T-cells can't get where they need to go. And so the problem we're trying to address is to overcome that immune suppression and allow those T-cells to go in and do their work. Our lead molecule has been exquisitely engineered to be a superior version of the market leading PD-1 inhibitors. The revolutionary improvement vs. these drugs is that our drug not only provides superior blockade of the PD-1 pathway and activates T cells but it can also kill immunosuppressive cells. This multitasking ability can allow this drug by itself to drive a very strong response rate in some of those difficult cancers.

Greg Sarian: Fast-forward to the future, Jim, it's the middle of 2026. Where is ImmunoGenesis and where do you see the company in three years?

Jim Barlow: That's a great question. So that's really going to be the time when we're going to get data from these assets that are going into patients. And so at that point, I see us in a strong position to show where these drugs work, how they work, and then set up the pivotal trials that will then bring them to approval and to patients. So that three-year mark will create an inflection point for us where we'll build the company further. We'll have to ramp up to start doing those more pivotal trials. We may end up signing a partnership with a large pharma because some of these late-stage large trials, you really need that big organization to help you with. So I see us on a parallel course where we're going to be growing a lot internally, but we'll also be looking for strategic partners to help drive some of our products to the finish line.

Greg Sarian: You're a Philadelphia native or you're a Philadelphia resident now, what advantages do you see being based in the Greater Philadelphia Region?

Jim Barlow: I'm very passionate about growing the Philadelphia ecosystem. There is tremendous talent here. When I came in as CEO, one of the things that I worked out with the founder is that I wanted to be based here. We have our lab operations and we're technically headquartered in Houston, but I wanted a significant presence in Philadelphia because I believe this area has unparalleled talent in terms of developing drugs. With all of the people that have come out of Merck and GSK and Bristol Myers and the strong biotech community, you have people that really understand the clinical development process, how to take a drug from the bench, the lab and transform it into a clinical product that can benefit patients.

I've already seen that pay off. Our head of clinical development is from GSK. Our head of manufacturing is from GSK. Our clinical operations team has extensive experience across both pharma and biotech. Our CFO, Freddi O'Brien has worked at five different life science companies in this area. So you have this tremendous pool of talent that really understands how to get a therapy approved. And you have a really beneficial, I'd say, cost structure and stickiness of employees here. It's really an ideal place to build a biotech and I believe the Philadelphia ecosystem will continue to grow and prosper.

Comprehensive Cybersecurity Considerations and Solutions from the Eliassen Group

BY: BARBARA ELIAS, DIRECTOR OF BUSINESS DEVELOPMENT, THE ELIASSEN GROUP

Let's Get Started

Did you know that the average cost of a data breach is around $9.44 million? Safeguard your business, enhance your security posture, and gain peace of mind in an increasingly complex digital landscape. We bring deep industry-focused experience across a broad range of cybersecurity domains to help you improve your cybersecurity by planning ahead and outlining important steps for any life sciences organization.

**Cost of a Data Breach 2022 – IBM Security & Ponemon Institute*

Plan, Prevent, Respond: Strengthening Your Cybersecurity

PLAN: Effective planning is key to minimizing cyber threats. At Eliassen Group, we offer comprehensive cybersecurity solutions to help you proactively safeguard your business. Our services include assisting your organization with common compliance requirements, including NIST, HIPAA, PCI DSS, SOC 2, NYDFS, GDPR, CCPA, and more.

PREVENT: We prioritize a proactive approach to cybersecurity by designing and deploying effective security controls that support your business objectives. Our expertise includes implementing robust solutions such as IAM, PAM, DLP, Zero Trust Architecture, and third-party security capabilities. By leveraging our expertise, you can establish a robust security framework based on zero-trust architecture principles.

RESPOND: In the event of a cybersecurity incident, a swift and well-coordinated response is crucial. Our team of cybersecurity experts can help you design programs to respond quickly, minimize downtime, and reduce potential damage to your business. We can help you implement effective incident response strategies to ensure your business can quickly and safely resume operations during a cybersecurity incident.

Have questions about cybersecurity in the life sciences, or would like to speak to an expert? Contact Barbara Elias, belias@eliassen.com.

ELIASSEN GROUP®
Your Success, Our Talent

Holistic Evolving Life Planning for Life Sciences Executives

BY: GREG SARIAN CPWA® | CIMA® | CFP® | CHFC® | CEPA®, CEO AT 2/13 STRATEGIC PARTNERS

Our team seeks to create value for life science executives on a myriad of fronts beyond pre- and post-transaction planning.

Over the past several years, we have received numerous questions from life sciences executives and founders seeking an optimal way to organize and store their most important financial documents and data points, especially in situations when caring for an aging loved one. This is due to the Life Sciences industry's work to enable a longer and better quality of life. To help meet this need, we recently created a new resource, Holistic Evolving Life Planning (H.E.L.P.).

In this comprehensive guide, our team will take you through different stages of planning that come along with helping aging loved ones.

We have identified four stages where our team frequently helps navigate senior clients. Within each stage, we have gathered supportive steps according to your loved one's stage of life. We hope this information helps you, your family, and your loved ones be proactive and prepared for the later chapters in life.

Your legacy does not have to begin with sorting through daunting paperwork. Preparing with your family and trusted advisors in advance can help minimize the administrative burden and emotional toll of dealing with the matters of aging loved ones.

Navigating the final seasons of life is challenging. In this incredibly stressful time, it is critical to have a plan

in place. As emotions rise, deviating from your loved one's wishes can be easy. Having a plan in place will help mitigate extra worry and ultimately allow you to focus on carrying out your loved one's last wishes as intended.

We have identified four stages where our team frequently helps navigate someone who is caring for an aging loved one or may be interested in organizing their own financial data and affairs. Within each stage, we have gathered supportive steps according to your loved one's stage of life.

- **ACTIVE SENIOR:** adults 55-75 years of age who are active and healthy but should begin considering some pre-planning steps.
- **ADVANCING SENIOR:** loved ones having trouble with everyday tasks. What should you be preparing for?
- **PASSING ON:** involves the transition to end-of-life care and what to do when a loved one passes.
- **FAMILY LEGACY:** identifies your loved one's wishes and how a legacy can be successfully carried on as intended.

With H.E.L.P., there were two key objectives we focused on accomplishing:

1. Identifying the most critical documents and files that a spouse or loved one would need to access if the primary financial overseer in a household was impaired, lost cognitive abilities, or passed away.
2. An efficient and secure way to digitally store these important documents so that they are easily accessible to loved ones who need to assume governance.

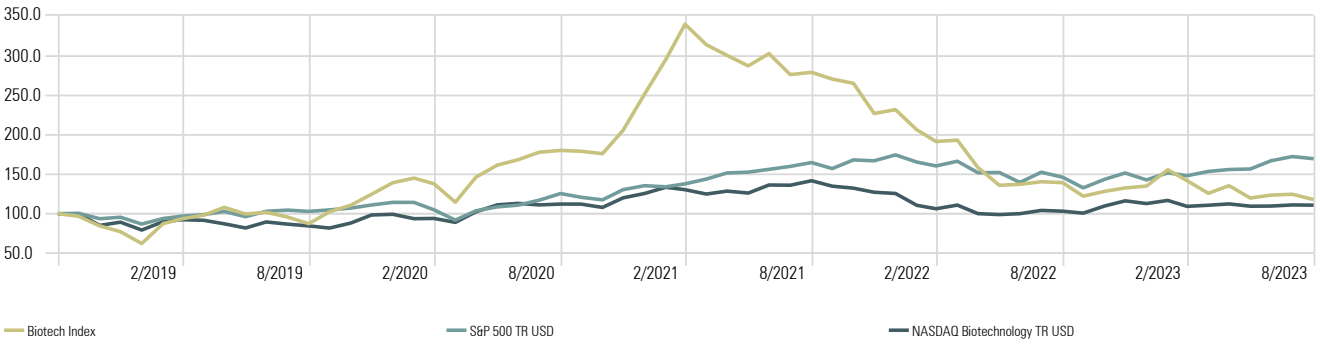
Click here to view or download the first segment of our H.E.L.P. resource. Our clients have found this resource to be a valuable guide to equip them to better organize their financial life. Our team has been helping them to create this cohesive digital living balance sheet, which has increased mental ease and security. My team and I welcome a conversation to share how this may be beneficial to your family as well.

2/13 Strategic Partners Biotech Index*

The 2/13 Strategic Partners Index started in January 2013 to track regionally located HealthCare oriented businesses whose stock is traded above $1 a share against the S&P 500 and the NASDAQ Biotechnology index. It is an equally weighted index of publicly traded life sciences companies headquartered in PA, NJ and DE and is rebalanced monthly. Below is a look at the performance pattern since December 2013 along with a list of the companies that are currently included. Also listed are the Top Ten Companies who have had the largest gains and losses YTD within the index.

Investment Growth

Time Period: 9/1/2018 to 8/31/2023



Portfolio Holdings - Biotech Index

Portfolio Date: 8/31/2023

	%
Aceragen Inc	2.2
Aclaris Therapeutics Inc	2.2
Adaptimmune Therapeutics PLC ADR	2.2
Agile Therapeutics Inc	2.2
Amicus Therapeutics Inc	2.2
Arbutus Biopharma Corp	2.2
Avantor Inc	2.2
Baudax Bio Inc Ordinary Shares	2.2
Cabaletta Bio Inc Ordinary Shares	2.2
Cencora Inc	2.2
Cyclacel Pharmaceuticals Inc	2.2
Eagle Pharmaceuticals Inc	2.2
Endo International PLC	2.2
Enzon Pharmaceuticals Inc	2.2
Galera Therapeutics Inc Ordinary Shares	2.2
Globus Medical Inc Class A	2.2
GSK PLC ADR	2.2
Helius Medical Technologies Inc Class A	2.2
Incyte Corp	2.2
Inovio Pharmaceuticals Inc	2.2
Insmed Inc	2.2
Johnson & Johnson	2.2
Larimar Therapeutics Inc	2.2
Madrigal Pharmaceuticals Inc	2.2
Marinus Pharmaceuticals Inc	2.2
Merck & Co Inc	2.2
Neuronetics Inc	2.2
Ocugen Inc	2.2
Onconova Therapeutics Inc	2.2
OptiNose Inc	2.2
OraSure Technologies Inc	2.2
Pacira BioSciences Inc	2.2
Passage Bio Inc Ordinary Shares	2.2
PhaseBio Pharmaceuticals Inc	2.2
ProPhase Labs Inc	2.2
PTC Therapeutics Inc	2.2
Societal CDMO Inc	2.2
Strata Skin Sciences Inc	2.2
TELA Bio Inc Ordinary Shares	2.2
Teleflex Inc	2.2
Trevena Inc	2.2
Verrica Pharmaceuticals Inc	2.2
West Pharmaceutical Services Inc	2.2
Windtree Therapeutics Inc	2.2
Zynerba Pharmaceuticals Inc	2.2

Leading Contributors - YTD

Time Period: 1/1/2023 to 8/31/2023

	Return
Zynerba Pharmaceuticals Inc	150.94
Marinus Pharmaceuticals Inc	78.64
IVERIC bio Inc	76.32
West Pharmaceutical Services Inc	73.20
Verrica Pharmaceuticals Inc	65.45
Cabaletta Bio Inc Ordinary Shares	53.08
OraSure Technologies Inc	34.02
Onconova Therapeutics Inc	22.22
Insmed Inc	9.56
Cencora Inc	7.11

Leading Detractors - YTD

Time Period: 1/1/2023 to 8/31/2023

	Return
Lannett Co Inc	-98.78
PhaseBio Pharmaceuticals Inc	-96.68
Aceragen Inc	-93.57
Windtree Therapeutics Inc	-90.00
Baudax Bio Inc Ordinary Shares	-86.41
Galera Therapeutics Inc Ordinary Shares	-85.91
Endo International PLC	-85.88
Agile Therapeutics Inc	-77.09
Neuronetics Inc	-76.13
Inovio Pharmaceuticals Inc	-71.16

* Information provided by Morningstar Direct

Philly Funding

September 8 - BlueWhale Bio Inc.

A University of Pennsylvania spinout founded by immunotherapy pioneers Dr. Carl June and James Riley came out of stealth mode Friday with its announcement it has raised $18 million in seed financing. BlueWhale Bio Inc. was founded with a technology platform to address and overcome bottlenecks in the cell and gene therapy manufacturing process. June and Riley co-invented technology they say could bring the benefits of cell therapy to more patients faster and at lower costs.

September 8 - Trevena

The Chesterbrook biopharmaceutical company received a $15 million payment from a royalty-based financing deal triggered by the first commercial sale of Olinvyk in China. The sale was made by Jiangsu Nhwa, the company's licensee in China. Olinvyk has regulatory approval in the United States and, as of May, in China for adults with acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

September 6 - Imvax

Imvax, a Philadelphia biotechnology company developing a personalized and whole tumor-derived immunotherapy for brain cancer, has raised $23 million in fresh capital and added the former CFO of Spark Therapeutics to its board. Since its inception in 2015, Imvax has raised about $175 million including the $112 million it raised in 2020. The company, headquartered in the Curtis building, plans to continue additional fundraising over the next several months.

August 23 - Fore Biotherapeutics

A Philadelphia precision oncology company has raised $75 million to advance its lead new drug candidate and also announced the upcoming departure of its CEO. The Series D financing round for Fore Biotherapeutics was led by SR One and Medicxi. The round also included existing investors Wellington, OrbiMed, Novartis Venture Fund, Samsung Securities, HBM Healthcare Investments and Cormorant Asset Management. Fore Biotherapeutics has now raised $166 million in funding.