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The Life Sciences Executive Network At Sarian Strategic Partners Presents

Biotech Bulletin | 2022, Volume 12

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 Sarian 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.

Congressional Action Imperative for U.S. Drug Approvals to Move Full Speed Ahead

Among the many deadlines Congress faces this September is the every-five-year renewal of the law that keeps the U.S. Food and Drug Administration's drug review and approval process humming along.

The Prescription Drug User Fee Act (PDUFA) allows the FDA to collect fees from companies that produce certain human drug and biological products, including gene and cell therapies. As a supplement to congressional appropriations, PDUFA funding helps the FDA maintain adequate staffing and resources to keep pace with the rapid increase in the number and complexity of medicines entering the review pipeline. That, in turn, brings new medicines to patients more quickly.

Renewing the act without delay and without major changes is vital to the nation's health, its position as a leader in the biopharmaceutical industry and to the health of our economy.

PDUFA gave legs to the drug review and approval process. Before its passage in 1992, the FDA often took more than two years to review new medicines. With PDUFA, the average approval time fell to 10 months. The power of PDUFA became apparent during the pandemic when FDA staffers continued their regular jobs and then logged long hours to ensure the advances in COVID-19 vaccines and treatments were safe and effective for the waiting public. Imagine the beginning of COVID-19 without those resources.

PDUFA has allowed the U.S. to lead the world in the introduction of new medicines. Over the last five years, about 75% of novel drugs have been approved here before any other country.

That machinery also helps power our economy and keeps the market moving forward. The industry is already responsible for a larger share of business research and development than any other industry in the U.S. economy.

An economic snapshot shows that in 2020 the industry nationwide directly employed more than 900,000 workers, supported nearly 4.5 million jobs and topped an economic output of more than $1.4 trillion. In Pennsylvania, the biopharmaceutical industry supported 271,293 total jobs, with an $82.7 billion economic output.

It is imperative for Congress to protect the health of our citizens and the country by reauthorizing PDUFA and keeping our gold-standard process in motion. In the past, Congress has approved the PDUFA framework before summer recess and worked out the details upon return. That didn't happen this year.

This can open a Pandora's box because this "must-pass" legislation becomes an attractive vehicle for policy insertions. It's not unheard of for toxic, seemingly quick fixes to surface, such as allowing importation of medicines from outside the country to reduce prescription prices. That simply jeopardizes our medical supply chain and increases the chances of counterfeit medicines reaching patients.

At press time, it was unclear where lawmakers were headed because three versions of renewal legislation exist. The House-passed version renews PDUFA, contains changes to the accelerated approval pathway and addresses clinical trial diversity. A Senate committee sent its version to the chamber for consideration, and it contains additional requirements for dietary supplement and cosmetic makers, among other changes. The ranking member of that committee promptly introduced a bare-bones renewal bill without any of the extra provisions included in the other two.

The industry supports reauthorizing PDUFA with a renewed focus on strengthening drug review fundamentals, enhancing accountability and transparency, and advancing innovation for patients.

Ensuring uninterrupted regulatory predictability creates an environment that fosters research and development, serves patients whose lives depend upon those advances and allows the U.S. to continue leading the world in the introduction of safe, effective medicines. Reaching out to your legislators to urge them to reauthorize a clean and timely PDUFA will help to achieve these.

A Spotlight on Pharma Solutions With, CEO, Sumeet Singh

Greg Sarian: Sumeet, tell us about how you started Pharma Solutions and what are you focusing on currently?

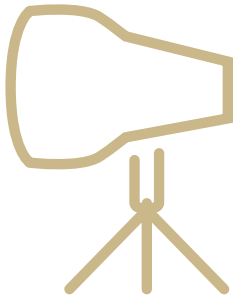
Sumeet Singh: The idea to start Pharma Solutions came about seven years ago as I was trying to get my first drug distribution startup off the ground, after already having spent five years in the industry. The previous startup was essentially an Amazon for pharmaceuticals, connecting wholesalers to independent pharmacies. One of the issues that emerged was that wholesalers weren't great at obtaining and maintaining state licensure – and so our two first clients at Pharma Solutions were actually two wholesalers we recruited for that platform. As we scaled our professional services, I found that it wasn't just small wholesalers struggling to keep up with the immense patchwork of regulation, but really the industry as a whole. The regulatory landscape is extremely complicated, and it's always changing.

Now that we can afford to look forward to our future, we see a lot of opportunity in automation and enablement for the compliance journey. Identifying and maintaining compliance requirements is a manual and error-prone process as it requires individual research by lawyers and compliance professionals, and is typically tracked in Excel docs. Our new ATLAS® platform is designed to capture the entire compliance journey and remove the guesswork.

Greg Sarian: What are your greatest challenges, and what are your biggest opportunities over the next 6 to 12 months?

Sumeet Singh: I think everybody's a little bit hesitant about macro-trends that point to interest-rate growth and even a possible recession. Capital is tightening and that's a challenge for any company looking to scale and grow. That being said, we are still fully focused on growing and further developing our ATLAS® platform. We have a major product release scheduled for quarter four of 2022, and we're incredibly excited about our transformational approach.

Greg Sarian: Sumeet, how does Pharma Solutions ultimately help the end patient?



Sumeet Singh: I think the most important thing to remember for us is that the intense regulatory landscape is ultimately designed to ensure the life science supply chain is a net positive. Regulations protect the patient by promoting quality, preventing diversion, and preventing counterfeits. Regulations also ensure efficiency

by creating price transparency and preventing fraud.

Greg Sarian: If you had a blank canvas, and fast forward three to five years, where is Pharma Solutions? What is the company doing? How is it different than it is today?

Sumeet Singh: We plan to stay wholly committed to the compliance space, as it is mission-critical component for billions of dollars of business. We are incredibly excited about our product and corporate development roadmap - in short, we are hoping you find us on the New York Stock Exchange in the next five years!

To learn more about Pharma Soltuions, visit https://pharma.solutions/

A CFO's Checklist for Life Science Companies in Today's Climate

Barb Carlin, Danforth Advisors, Mid-Atlantic Managing Director

Following the record-breaking growth in 2020 and 2021, the capital markets have cooled, forcing the life science sector to adjust to a new paradigm. Many companies who were preparing to access the private and public markets are now finding themselves having to do more with less. With our view inside hundreds of such companies, Danforth Advisors understands the challenges and is actively engaging with management teams to build a blueprint for weathering uncertain times.

Here are some of the ways the Danforth team is supporting our clients today.

Extending the runway. This is one of the top concerns our team is discussing with our clients. There are many factors to consider in terms of preserving cash. With delayed or cancelled plans to access the public markets, our clients are evaluating discretionary versus non-discretionary spend as well as with portfolio prioritization. There are often opportunities to identify near-term operational efficiencies and to consider longer-term decisions, such as delaying or out-licensing assets.

Effective budgeting and forecasting. In planning for financing, it is critical to have a handle on how much capital is needed and how long it will fund operations. Life sciences expertise is a must, given the cost and complexity of manufacturing and clinical development initiatives and the roles they play in supporting future financings. We work with our clients and their investors by providing meaningful financial analyses to support crafting strategic plans.

Examing clinical contracts. Working with clinical research organizations (CROs) and related vendors brings tremendous expense. Smaller companies typically lack a dedicated internal resource and rely on clinical operations staff, whose primary focus is trial planning and execution – not contract structure and negotiation. Even when a trial is underway, sponsor companies can take a strategic approach to renegotiation. Our Clinical Business Operations team of clinical contracting specialists collaborate with clients to both structure contracts and evaluate cost-cutting measures that incentivize CRO performance and ensure accountability – with payments based on meaningful results vs. time spent.

Weighing all available financing options. While slower paced, companies are still raising capital and they are doing so based on validated science and proven leadership teams. We have witnessed the decline in enterprise valuations and the structure of financing rounds becoming heavily tranche based. We are anticipating that investors' diligence activities may take longer periods of time, especially for early-stage companies, than what we have witnessed over the past few years. Our clients reach out for support in exploring alternative paths of capital, expanding investor relationships and evaluating liquidity events including collaborations with strategic partners and M&A transactions. For public companies, at-the-market offerings provide a way to raise capital in smaller increments over time. Proven science and platform technologies with expanded application continue to attract reputable investors, entrepreneurs and trusted advisors.

Stage-adjusted people strategy. Apart from financial capital, the life science sector faces an increasingly higher demand for human capital. Competition for talent is intense at companies large and small, despite the continued headcount reductions throughout our industry. Our clients benefit from a right-sized HR function with industry experience who can provide flexible support. This will allow them to attract and retain high-caliber performers, manage workforce planning and implement effective processes for onboarding, benefits and payroll administration, and other operational needs. We have been providing fractional HR resources with life sciences experience who can supplement our clients' internal staff or establish

and manage compliant HR programs on an ongoing basis.

Barb Carlin, CPA, MBA is Managing Director of the Mid-Atlantic region for Danforth Advisors, a consultancy that helps life science companies start, grow and operate at their best. The firm's flexible, scalable services span strategic C-level advisory, operational finance and accounting, clinical business operations, human resources and risk management. Founded in 2011, Danforth has been a strategic and trusted thought partner to hundreds of life science companies, private and public, across all stages of the corporate life cycle. Learn more at www.danforthadvisors.com.

Strategic Planning - Keys to Maintaining Your Financial Independence

Greg Sarian, CPWA®|CIMA®|CFP®|ChFC®|CEPA,
CEO & Founder, Sarian Strategic Partners

As a life sciences entrepreneur or executive, you may be spending most of your time focusing on your company's objectives and overlook planning ahead for your individual goals such as preparing for retirement and maintaining financial independence.

The process for planning a comfortable retirement should begin early in your career. A growing number of Americans are living to age 100. Nationwide, the centenarian population has grown 65.8% over the past three decades, from 32,194 people who were age 100 or older in 1980 to 53,364 centenarians in 2010, according to new Census Bureau data.

By 2050, it's estimated that there will be million centenarians in the U.S., with a growing number in our population living well into their 90s. Today's pre-retirees must consider a myriad of issues, in addition to determining if they have enough capital to maintain their financial independence throughout retirement. While the amount of capital is central to the planning process, other key considerations may be overlooked if they do not have a direct bearing on the spend goal. However, it is critical to discuss these subjective components in detail to help ensure that your retirement plan is both comprehensive and aligned with your long-term objectives. Before making plans to travel the world, lowering your handicap or focusing on your favorite nonprofit endeavor, consider these five key financial matters.

1. Time Horizon & Lifestyle Changes

It's essential to clarify when you're going to begin to draw from your portfolio. While saving for retirement is no small task, the compounding effect of adding to your portfolio as a pre-retiree and benefiting from compounding interest is a significant factor in creating a meaningful nest egg. Your desired timeframe to stop saving and to begin withdrawing money is critically important. Additionally, anticipated lifestyle changes should be factored in prior to retirement. It's ideal to make decisions that will result in large financial outflows—such as moving, renovating a home or purchasing a second home—while you are still earning an income and there is some flexibility in your budget. A significant outflow of capital may deteriorate your portfolio and compromise your ability to achieve other objectives in retirement, especially if the outflow is more significant than anticipated. The clearer your budget and short- and long-term spending goals are before you retire, the more likely a smoother transition into retirement. Lastly, your ability or willingness to work and generate income throughout retirement may have a substantially positive impact on your nest egg. Potential capital outflows and inflows can have a significant bearing on the final outcome of your retirement spend goal, so it's important to include these considerations in early modeling stages.

2. Liability Management

As you approach retirement, it is important to analyze your debt in terms of the outflow it represents, in addition to determining if you will continue to maintain the same levels of debt after you retire. There is a tax implication to consider as well, as mortgage debt may provide a modest income tax deduction. It is also vitally important to make sure that your future borrowing facilities are in place before you retire, even if you don't anticipate using them. Given the tax law changes, you will not be able to deduct home equity line of credit (HELOCs). Consider setting up a security-based loan against your non-IRA portfolio—it may be more tax-efficient than a home-equity line of credit. At this time, net investment interest expense is a deduction up to the amount of taxable investment income your portfolio generate.

3. Wealth Transfer

Focusing on wealth transfer planning can also help you align your financial affairs with your retirement goals. Despite the recent increase in the unified credit provisions per the 2022 tax law changes to 12 million per person, it's important to review and update key wealth transfer documents as you approach retirement. Remember also that even if your assets are below the level of exposure for federal tax, states have their own inheritance taxes. Pennsylvania charges direct heirs 4.5%. Make sure that your beneficiary designations are still consistent with your wishes, and that your living will, healthcare directives and powers of attorney are up-to-date and relevant in the state in which you reside.

Many people who change residences when they retire fail to recognize that each state has specific nuances when it comes to these documents. Lastly, review your wealth transfer plan with your financial advisor to help ensure that your assets are set to move to the people, and entities in the portions that you desire.

4. Benefits in Retirement

There are numerous income tax and state tax issues that come into play as you transition employer-sponsored plans and benefits into your own individual retirement accounts. You should also have a very clear understanding of the benefits, if any, that will still be available to you as a retiree. These could include insurance plans and deferred compensation payment schedules. However, the two primary areas of focus should be Social Security and Medicare benefits. Many people are not eligible for Medicare until age 65, and the earliest they could access Social Security is age 62, with most receiving a full benefit after age 66. Marital status, your level of past compensation, as well as your spouse's, will influence a number of pre-retirement decisions. It's also vital to understand your Medicare benefits as you approach your early 60s. For many, Medicare will provide only a portion of the benefits that were provided under a robust employer-sponsored healthcare plan. For this reason, it is wise to research Medigap policies in your early 60s that will help bridge the gap between your existing needs and what Medicare will cover.

5. Portfolio Construction & Risk Tolerance

When you get closer to the point of needing regular income from your portfolio (about two or three years before you retire), the portfolio should be positioned in such a way to help minimize risk and volatility so that your standard of living is not compromised. This defensive posturing should be in conjunction with a retirement income withdrawal strategy to help you replicate your income stream as you begin to live off of your portfolio. The composition of your portfolio may also change if there is a change in your tax status. Many retirees are in a slightly lower tax bracket than while they were working, so a detailed review of your asset allocation and asset location strategies, as well as the fixed income portion of your portfolio, is important. The goal is to achieve high returns with the least amount of risk, so if you have investments in tax-free bonds or tax-sheltered investments, your needs may change in a lower income bracket.

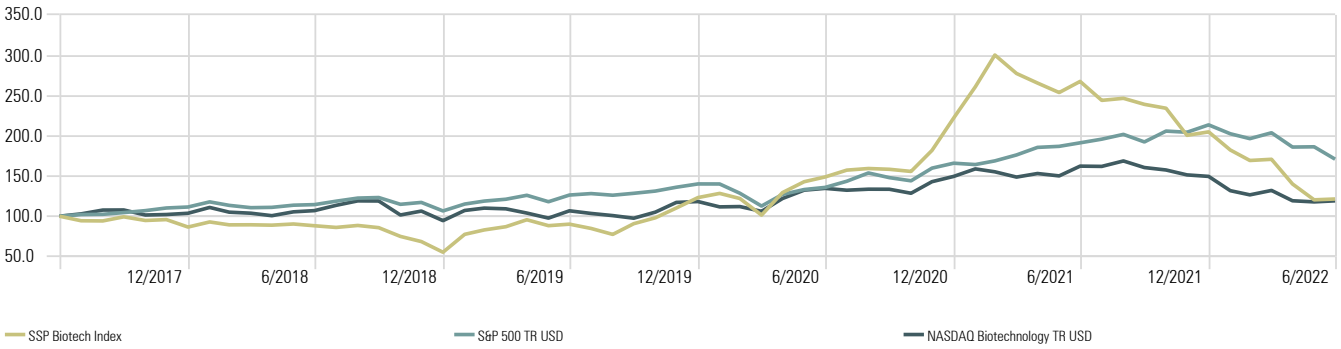
Retirement readiness involves more than capital accumulation. At Sarian Strategic Partners, our experienced financial advisors can help you navigate critical planning issues and integrate subjective considerations into your overall plan. Contact us today to start preparing for the retirement and future you envision.

Sarian Strategic Partners Biotech Index*

The Sarian 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.

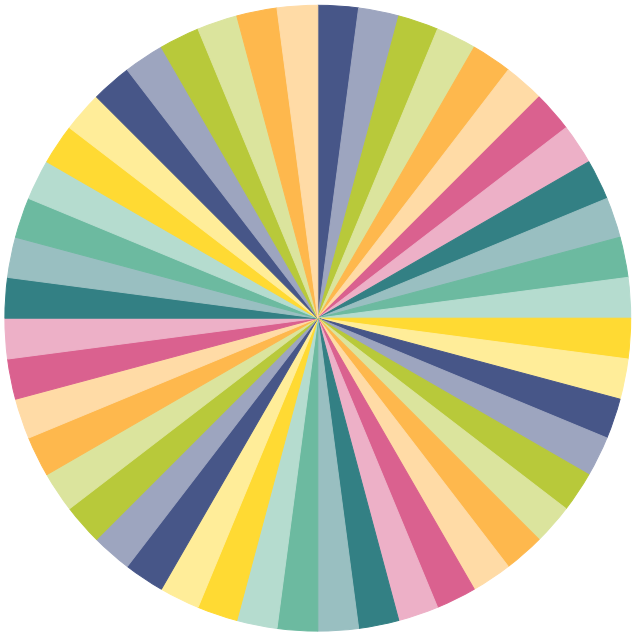
Investment Growth

Time Period: 7/1/2017 to 6/30/2022



Portfolio Holdings - SSP Biotech Index

Portfolio Date: 6/30/2022



	%
Aclaris Therapeutics Inc	2.1
Adaptimmune Therapeutics PLC ADR	2.1
Advaxis Inc	2.1
Agile Therapeutics Inc	2.1
AmerisourceBergen Corp	2.1
Amicus Therapeutics Inc	2.1
Arbutus Biopharma Corp	2.1
Avantor Inc	2.1
Baudax Bio Inc Ordinary Shares	2.1
Cabaletta Bio Inc Ordinary Shares	2.1
Cyclacel Pharmaceuticals Inc	2.1
Eagle Pharmaceuticals Inc	2.1
Endo International PLC	2.1
Enzon Pharmaceuticals Inc	2.1
Galera Therapeutics Inc Ordinary Shares	2.1
Globus Medical Inc Class A	2.1
GSK PLC ADR	2.1
Helius Medical Technologies Inc	2.1
Idera Pharmaceuticals Inc	2.1
Incyte Corp	2.1
Inovio Pharmaceuticals Inc	2.1
Insmed Inc	2.1
IVERIC bio Inc	2.1
Johnson & Johnson	2.1
Lannett Co Inc	2.1
Larimar Therapeutics Inc	2.1
Madrigal Pharmaceuticals Inc	2.1
Marinus Pharmaceuticals Inc	2.1
Merck & Co Inc	2.1
Neuronetics Inc	2.1
Ocugen Inc	2.1
Onconova Therapeutics Inc	2.1
OptiNose Inc	2.1
OraSure Technologies Inc	2.1
Pacira BioSciences Inc	2.1
Passage Bio Inc Ordinary Shares	2.1
PhaseBio Pharmaceuticals Inc	2.1
ProPhase Labs Inc	2.1
PTC Therapeutics Inc	2.1
Societal CDMO Inc	2.1
Strata Skin Sciences Inc	2.1
TELA Bio Inc Ordinary Shares	2.1
Teleflex Inc	2.1
Trevena Inc	2.1
Verrica Pharmaceuticals Inc	2.1
West Pharmaceutical Services Inc	2.1
Windtree Therapeutics Inc	2.1
Zynerba Pharmaceuticals Inc	2.1

Leading Contributors - YTD

Time Period: 1/1/2022 to 6/30/2022

	Return
OptiNose Inc	125.93
ProPhase Labs Inc	91.90
Merck & Co Inc	20.99
AmerisourceBergen Corp	7.13
Johnson & Johnson	5.10
Incyte Corp	3.50
GSK PLC ADR	0.96
PTC Therapeutics Inc	0.58
Pacira BioSciences Inc	-3.11
Aclaris Therapeutics Inc	-3.99

Leading Detractors - YTD

Time Period: 1/1/2022 to 6/30/2022

	Return
Agile Therapeutics Inc	-94.03
Baudax Bio Inc Ordinary Shares	-88.99
Endo International PLC	-87.61
Larimar Therapeutics Inc	-81.84
Verrica Pharmaceuticals Inc	-79.04
Helius Medical Technologies Inc	-77.26
PhaseBio Pharmaceuticals Inc	-77.02
Advaxis Inc	-73.92
Windtree Therapeutics Inc	-73.40
Cyclacel Pharmaceuticals Inc	-72.22

* Information provided by Morningstar Direct

Philly Fundings

September 14

A French gene therapy company that established its U.S. headquarters in Philadelphia earlier this year has raised $75.2 million in a venture capital financing. SparingVision's Series B financing was co-led by Jeito Capital of Paris and Pittsburgh-based UPMC Enterprises. Other investors participating in the round were 4BIO Capital, Bpifrance, the RD Fund, and Ysios Capital. The financing extends SparingVision's cash runway to the second half of 2025. The company plans to use the proceeds from the private stock sale to fund first-in-human trials of its lead gene therapy products, SPVN06 and SPVN20, and to advance its CRISPR-based genome editing portfolio in collaboration with Intellia Therapeutics (NASDAQ: NTLA). CRISPR, an acronym for clustered regularly interspaced short palindromic repeat, is an emerging technology used to edit parts of the genome by removing, adding or altering sections of DNA sequences.

September 14

A University of Pennsylvania spinout emerged from stealth mode Tuesday, announcing it has raised $165 million to develop a new type of CAR therapy that incorporates mRNA. Capstan Therapeutics, which has offices in Philadelphia and San Diego, was created to build on the research conducted in the laboratories of Penn's leading cell therapy and mRNA scientists including Drs. Drew Weissman, Carl June and Bruce Levine. The company just closed a $102 million Series A financing that was led by Pfizer Ventures and included Leaps by Bayer, Eli Lilly and Co., Bristol Myers Squibb, Polaris Partners, Alexandria Venture Investments and all its existing investors. In November, Capstan raised $63 million in a seed financing round led by Novartis Venture Fund and OrbiMed. RA Capital and Vida Ventures also participated in the seed round.

September 12

Main Line health care analytics firm PurpleLab Inc. has raised $40 million in funding to accelerate investments in product development and human capital. Cleveland private equity firm Primus Capital led the Series B round, joining existing investor Edison Partners of Princeton, New Jersey. PurpleLab raised a $3 million Series A round in August 2019. The Wayne health tech company's no-code analytics platform is used by life sciences companies, health plans and health care providers to develop real-world evidence that novel therapeutics or clinical strategies are performing and leading to cost savings. The company says it has experienced triple digit growth for four consecutive years. PurpleLab says the fresh funding will enable the company to continue its growth.