Neal Kaufman and Josh Riegelhaupt: Health Care investing in a slow-growth environment

This is an edited transcript of an August 2, 2022, Q&A with Neal Kaufman, portfolio manager of Baron Health Care Fund and Assistant Portfolio Manager Josh Riegelhaupt. To access the full recording, please visit our website.

Executive Summary

- Biotech, and innovation in general, is as exciting as ever. We went through a period of over capitalization, now we're in a period of rationalization.
- We think Health Care should do well in a recessionary environment because it's less discretionary and less cyclical. It should also do well in a higher-inflation environment because many of these companies have pricing power.
- Overall, despite some headwinds and some uncertainty, our long-term outlook for the Health Care sector remains bullish.

Can you give us a review of Baron Health Care Fund's performance during the second quarter?

Neal Kaufman: During the second quarter, macro concerns continued to weigh on stocks. Investors rotated out of life sciences tool stocks, which had been strong performers, out of concern about peaking COVID testing and vaccine production revenues. Stocks in health care facilities, supplies and equipment were weak as well, based on the impact of staffing shortages on medical procedure volumes. The best-performing sub-segment was pharmaceuticals because of its defensive characteristics. The Fund's lower exposure to large-cap pharma was a headwind to relative performance. Overall, this quarter, the Fund declined around 10% while the Russell 3000 Health Care Index declined around 7.43% and the S&P 500 Index declined 16.1%.

Which stocks were the biggest contributors and detractors?

Neal Kaufman: The top three contributors to performance were **argenx SE**, **Eli Lilly and Company**, and **Vertex Pharmaceuticals Incorporated**.

- argenx is a biotech company focused on autoimmune disorders. The company is in early stages of a commercial launch for their drug Vyvgart, a treatment for generalized myasthenia gravis, a chronic autoimmune disease that causes muscle weakness. Thus far, the launch has been successful with sales beating expectations. Clinical data from its trial for another indication was positive as well. We think this drug could generate well over $5 billion in sales over time with its expanded indications.
- Eli Lilly did well this quarter due to positive study results for its glucagon-like peptide 1 (GLP-1) drug Mounjaro, a diabetes and weight loss drug. We think this drug could generate well over $10 billion in sales over time, given the millions of people struggling with obesity and the drug's impressive efficacy.

- Vertex, a leader in the treatment of cystic fibrosis, was a new addition this quarter. The stock rose based on progress with the company's new product pipeline.

The top three detractors were **Bio-Techne Corporation, Intuitive Surgical, Inc.**, and **Alexandria Real Estate Equities, Inc**.

- Bio-Techne sells life sciences reagents and other tools to the biotech and pharma industry. The stock was down despite strong fundamentals. We continue to think this is a stable business with multiple drivers that will enable the company to grow revenues by double digits over the next five years.
- Intuitive Surgical sells the Da Vinci robotic surgical system. The stock was down due to concerns regarding hospital budgets – which turned out to be valid. The company reported weak sales in its Q2 earnings, but the stock reaction was interesting – it initially went down but has since recovered and is now trading higher than when it reported. We continue to think Intuitive Surgical has a long runway to expand the number of procedures performed using its robotic system.
- Alexandria Real Estate Equities is a leading owner/operator of life science office real estate. The stock was down due to concerns about weakness in biotech funding potentially leading to rent delinquencies and lower demand for Alexandria's properties. We think these concerns are overblown and that Alexandria's business will remain resilient.

Bio-Techne Corporation is a large holding within the Fund. What do you like about the stock?

Neal Kaufman: Bio-Techne is a roughly $15 billion market cap life sciences tools company. It's a classic picks and shovels company with stable organic growth, high margins, and the ability to compound earnings over the long term. Its biotech reagents are high-margin consumable products; the company mass produces them at scale with high purity and launch a couple thousand new reagents every year. Bio-Techne has a reputation for high quality, reliable products, and has a loyal following in the research community – once scientists start using these research reagents in their experiments they continue to use them, which provides recurring revenue.

The company has multiple growth drivers beyond its research reagents business. It has a platform technology that uses exosomes to detect changes in the blood, such as cancer. Using this platform, the company has a diagnostic test for men with ambiguous PSA tests, used to screen for prostate cancer, who are trying to decide whether to get a painful biopsy. The company is developing other diagnostic tests with this technology as well.

It has entered a distribution agreement with **Thermo Fisher Scientific Inc.** for a kidney transplant rejection test and is developing a bladder cancer test. Another growth driver is BioTechne's GMP proteins business. It recently built a new manufacturing facility for proteins and other products that will be used for cell and gene therapies. This could be a $300 million product category for the company, up from roughly $50 million in revenue today. Finally, it has a proteins analysis business through which it sells various instruments, such as an automated western blot device, which gives a sample-to-answer in three hours versus days for a manual process.

Overall, we think Bio-Techne can generate organic revenue growth in the mid-teens. We think the company can double its revenue over the next five years to roughly $2 billion dollars. If we assume 40% to 45% EBITDA margins on $2 billion of revenue, that gets us to around $800 to $900 million of EBITDA. We think the business is worth a very high valuation given its stable recurring revenue, high margins, and low capital intensity. If we assume a 30x EBITDA multiple, this should yield roughly a $27 billion enterprise value; add back the estimated cash, and we're seeing roughly a $29 billion equity value versus $15 billion currently. We see additional upside from mergers and acquisitions (M&A) activity that we expect they should have a cumulative $4 billion to make acquisitions. Ultimately, we think the company would be a valuable asset for a consolidator in the life sciences tool space.

Were there any notable stock purchases or sales?

Neal Kaufman: Two of the top net purchases during the quarter were additions to existing positions.

First, we added to **Novo Nordisk A/S**, a leading biopharma company headquartered in Denmark that specializes in treatments for diabetes, obesity, and other chronic diseases. Novo Nordisk and Eli Lilly are leaders in the GLP-1 class of diabetes treatments; these drugs stimulate insulin secretion and inhibit glucagon secretion, which helps lower blood sugar, they also slow stomach emptying and increase how full you feel after eating, which reduces appetite and leads to weight loss. Nova Nordisk currently has a drug called Wegovy, which was approved for diabetes and should receive an anti-obesity label next year. In the next few months, the company expects to report interim results from a select study, which is evaluating whether Wegovy reduces the risk of cardiovascular events in patients with obesity. If the study is positive, we think this could convince non-insured people to pay for these drugs and expand access. The market is very large with over 650 million people worldwide living with obesity and only 2% are treated with an anti-obesity medication. We think we're in the early innings of a multi-year growth opportunity.

Another top net purchase was **Illumina, Inc.**, a longstanding investment across multiple Baron Funds. Illumina has become controversial in the investor community. The two big concerns are increased competition and an uncertainty about the outcome of the GRAIL acquisition. We acknowledge that some market share losses are inevitable, but we also think it will be difficult for competitors to overcome Illumina's dominant position. We believe Illumina will continue to innovate and introduce new products to stay ahead as the company spends roughly $1 billion on research and development. As for the uncertainty with GRAIL, we think Illumina has a good argument that the market has become more competitive, and the deal should be approved. If the company unwinds the deal, earnings will go up substantially because GRAIL is highly dilutive to near-term earnings. We think Illumina can still participate in the growth of the liquid biopsy market through minority investments and can still make acquisitions in other emerging growth areas like synthetic biology or proteomics. At this valuation, and with everyone negative on the stock, we think the risk/reward is good.

Can you share your perspective on Biotechnology?

Josh Riegelhaupt: The Biotechnology (Biotech) subsector was trading in the lows for both 2018 and 2020. Here are a few recent statistics:

- Clinical data in Q2 was 76% positive, yet only 35% resulted in one-day stock appreciation and only 27% sustained positive momentum.
- M&A seem to be on track even though stock performance is potentially down. The public M&A count stands at seven through June 30, representing about $21.3 billion in value. This would annualize to 17 or so, about $51 billion for 2022, which is about the same as 2021.
- At the low, 25% of all SMID-cap Biotech companies, those below $5 billion in market cap, were trading below cash. About 60 stocks are down over 90% in the last two years. About 60% of stocks under the $15 billion market cap are down 50%. This has led to restructurings and reorganizations.
- The fundraising window is mostly closed, although there's a discrepancy between the public and private markets. Private market financings year-to-date through June are about $14 billion,

which isn't far off from the $18 billion in the same period of 2021. Year-to-date follow-ons in the public markets, about $5 billion versus $20 billion the year prior. Therefore, there's a huge discrepancy there. To give you a sense of this, IPOs have raised less than $1 billion this year.

Applications for FDA drug reviews are up four to five times, whereas employee count is barely up. Thus, the FDA is over-strained, which has led to more delays, more extended reviews, and more rejections. They're trying to hire and trying to get their new budget through; we'll see what happens with that.

On August 2, 2022, there was a push in Washington, D.C. to come to an agreement on what is being called The Inflation Reduction Act of 2022. This legislation contains some major provisions relating to the pricing of prescription drugs in the government channel – Medicare and Medicaid to a degree. Should this legislation pass, we will of course review the details and potential implications and share our thoughts in our Q3 discussion.

Overall, we think Biotech, and innovation in general, is as exciting as ever. We went through a period of over capitalization, now we're in a period of rationalization. We believe Biotech is going to keep improving the human condition and it's going to be beneficial to all of us.

With more than four years on the books, what do you feel sets you apart from other investors in the Health Care sector?

Neal Kaufman: Our strategy is to identify competitively advantaged growth companies that we can own for years. We own around 40 to 50 stocks. The top 10 holdings typically represent over 40% of assets. It's a growth-oriented, all-cap portfolio. We can invest in both U.S. and non-U.S. companies.

To ensure diversification and help manage potential risks, we loosely group the portfolio into three categories: earning compounders, high-growth, and Biotech. Earnings compounders are companies that we believe can grow earnings at double-digit rates over the long term. High-growth companies are those we expect to generate mid-teen or better revenue growth – they may not be profitable today, but we believe they can be highly profitable in the future. Biotech companies are self-explanatory. The portfolio will have a mix of these three categories, with allocations based on our view of the opportunity set and market environment.

One of the Fund's newer holdings is Moderna. Why is Moderna an interesting investment now?

Josh Riegelhaupt: The balance sheet is solid; we see no risk of default. That's in contrast to many companies in this space, particularly among the smaller caps.

The debate over **Moderna, Inc.** is about future COVID revenue, 2023 and beyond. There's a smaller side debate about what the pipeline is worth. What is mRNA as a drug modality? Is it useful? Can it do anything other than make a COVID vaccine?

Let's start with COVID. Consensus views are saying the opportunity for vaccinations will dry up. Moderna has created an expectation that in the future, once this vaccine is commercialized and paid for by commercial insurance, you won't have pandemic pricing, you'll have higher pricing. As a reference point, the pandemic price level is about $20-$25 per shot.

In 2024 and beyond, my personal belief is that people will be getting a shot every two to three years. Those over 65 or immune-compromised will be going for annual shots. If everyone in the U.S. got a shot every three years, with a population of 330 million people, that's 110 million doses annually. However, with some people exhibiting vaccine hesitancy, let's say compliance is 30%, we're down to 33 million shots a year. The biotech back-of-the-envelope math is whatever the U.S. is, just double it for the rest of the world. Let's say 66 million globally; maybe a little higher with Africa and non-Western countries, let's say 75 million. Now, at what price? Currently at $20 a shot, that's $660 million in revenue in the U.S., close to $1.5 billion globally. If prices increase to $60 a shot, that would bring us to $4.5 billion in annual revenue. And this would be perpetual essentially because COVID is not going away.

None of this considers that Moderna has $2.5 to $3 billion invested on research and development right now. That is a large-cap-pharma size budget. The company is working on vaccinations for the Epstein Barr virus, Respiratory Syncytial virus, HIV, cytomegalovirus, Nipah virus (an Ebola-type virus), and the Human pneumo virus. And it has mRNA for protein replacement. We'll get data in 4Q for two orphan indications. One's called propionic acidemia and if it works, it might start replacing part of protein replacement, which was what Sanofi bought Genzyme for back in the early 2000 for multi billions of dollars.

Any final thoughts about the broad outlook for Health Care?

Neal Kaufman: We think Health Care should do well in a recessionary environment because it's less discretionary and less cyclical. It should also do well in a higher-inflation environment because many of these companies have pricing power.

The potential for drug pricing reform could be a negative. We think the near-term impact would be limited, but the long-term impact could be substantial. One consulting firm estimated that Medicare negotiation could reduce drug manufacturer revenues by over $450 billion from 2026 to 2032. We're closely monitoring the situation as it develops.

Looking at other subsectors, we still like the life sciences tools group given these companies' stable, profitable growth characteristics. Once we get past concerns about peaking COVID-related revenues and the weak funding environment for biotech, we think these stocks can return to being good performers. This earning season, we saw stocks going up after companies cut their COVID revenue forecasts, which bodes well for the future.

As for medical devices, nursing and staff shortages are still constraining procedure volumes. In a recession, people may defer medical procedures. Longer term, we think medical device companies will see increased demand from an aging population and higher disease burden from chronic diseases. So, we have significant investments in companies with innovative devices for sleep apnea, diabetes, heart valve replacement, and blood clot removal.

Pressure on Health Care utilization provides an earnings tailwind for managed care companies, which also have pricing power and benefit from rising interest rates. In 2023, Medicare Advantage companies are set to receive the highest rate increase in the last decade. As a result, we believe the outlook for our managed care holdings is positive.

Overall, despite some headwinds and some uncertainty, our long-term outlook for the Health Care sector remains bullish.

Investors should consider the investment objectives, risks, and charges and expenses of the investment carefully before investing. The prospectus and summary prospectuses contain this and other information about the Funds.You may obtain them from the Funds' distributor, Baron Capital, Inc., by calling 1-800-99BARON or visiting www.BaronFunds.com. Please read them carefully before investing.

Baron Health Care Fund's annualized returns for the Institutional Shares as of June 30, 2022: 1-year, -16.30%; 3-year, 15.40%; Since Inception (4/30/2018), 15.00%. Annual expense ratio for the Institutional Shares as of December 31, 2021, was 0.89%, but the net annual expense ratio was 0.85% (net of the Adviser's fee waivers). The **Russell 3000 Health Care Index**'s annualized returns as of June 30, 2022: 1-year, -5.14%; 3-year, 11.48%; Since Fund Inception (4/30/2018), 11.96%.

The performance data quoted represents past performance. Past performance is no guarantee of future results. The investment return and principal value of an investment will fluctuate; an investor's shares, when redeemed, may be worth more or less than their original cost. The Adviser reimburses certain Baron Fund expenses pursuantto a contract expiring on August 29, 2032, unless renewed for another 11-year term and the Fund's transfer agency expenses may be reduced by expense offsets from an unaffiliated transfer agent, without which performance would have been lower. Current performance may be lower or higher than the performance data quoted. For performance information current to the most recent month end, visit www.BaronFunds.com or call 1-800-99BARON.

Risks: In addition to general market conditions, the value of the Fund will be affected by investments in health care companies which are subject to a number of risks, including the adverse impact of legislative actions and government regulations. The Fund is non-diversified, which means it may have a greater percentage of its assetsin a single issuer than a diversified fund. The Fund invests in small and medium sized companies whose securities may be thinly traded and more difficult to sell during market downturns.

Non-mutual fund products are available to institutional investors only.

Portfolio holdings as a percentage of net assets as of June 30, 2022, for securities mentioned are as follows: argenx SE – 3.6%; **Eli Lilly and Company** – 5.3%; **Vertex Pharmaceuticals Incorporated** – 2.4%; **Bio-Techne Corporation** – 4.9%; **Intuitive Surgical, Inc.** – 1.8%; **Alexandria Real Estate Equities, Inc.** – 0.7%; **Thermo Fisher Scientific, Inc.** – 5.2%; **Novo Nordisk A/S** – 3.0%.; **Illumina, Inc.** – 1.0%; **Moderna, Inc.** – 0.9%.

Top 10 holdings as of June 30, 2022

Holding	% Assets
UnitedHealth Group Incorporated	9.4
Eli Lilly and Company	5.3
Thermo Fisher Scientific Inc.	5.2
Bio-Techne Corporation	4.9
AstraZeneca Plc	4.2
argenx SE	3.6
AbbVie, Inc.	3.5
McKesson Corporation	3.3
Novo Nordisk A/S	3.0
Dechra Pharmaceuticals PLC	2.9
Total	45.3

Portfolio holdings are subject to change. Current and future portfolio holdings are subject to risk.

The discussion of market trends is not intended as advice to any person regarding the advisability of investing in any particular security. The views expressed in this presentation reflect those of the respective speaker. Some of our comments are based on management expectations and are considered “forward-looking statements.” Actual future results, however, may prove to be different from our expectations. Our views are a reflection of our best judgment at the time and are subject to change at any time based on market and other conditions and Baron has no obligation to update them.

The **Russell 3000® Health Care Index** is an unmanaged index representative of companies involved in medical services or health care in the Russell 3000 Index, which is comprised of the 3,000 largest U.S. companies as determined by total market capitalization. The **S&P 500 Index** measures the performance of 500 widely held large cap U.S. companies. Russell Investment Group is the source and owner of the trademarks, service marks and copyrights related to the Russell Indexes. Russell is a trademark of Russell Investment Group. The indexes and the Fund include reinvestment of dividends, net of withholding taxes, which positively impact the performance results. The indexes are unmanaged. Index performance is not Fund performance; one cannot invest directly into an index.

Alpha measures the difference between a fund's actual returns and its expected performance, given its level of risk as measured by beta. **Beta** measures a fund's sensitivity to market movements. The beta of the market is 1.00 by definition. **Upside Capture** explains how well a fund performs in time periods where the benchmark's returns are greater than zero. **Downside Capture** measures how well a fund performs in time periods where the benchmark's returns are less than zero.