

A Positive Outlook for the Health Care Sector

This is an edited transcript of a January 31, 2023, webinar with Baron Health Care Fund Portfolio Manager Neal Kaufman and Assistant Portfolio Manager Josh Riegelhaupt. To access the video recording, please visit <u>our website</u>.

Executive Summary

- The Health Care sector had a strong fourth quarter, gaining 11.5%. The Fund underperformed somewhat, returning 9.1%.
- Portfolio companies discussed include:
 - o **Inhibrx, Inc.**, a biotech with expertise in single-domain antibody structures with a promising treatment for patients with an Alpha-1 antitrypsin (AAT) deficiency
 - o **HCA Healthcare, Inc.,** a leading provider of health care services
 - Option Care Health, Inc., the largest independent player in the \$15 billion U.S. home and alternate site infusion market.
 - Moderna Inc., which used mRNA technology to develop one of the four main COVID vaccines.
- Our long-term outlook for the Health Care sector is bullish. We think innovation and the
 themes we invest in are intact and the Fund owns competitively advantaged growth
 companies with strong management teams.

What drove Fund performance in the fourth quarter?

Neil Kaufman: The Fund returned 9.1%, better than the 7.6% gain for the S&P 500 index but not as much as the 11.5% gain for the Russell 3000 Healthcare index. The relative shortfall during the quarter was due mainly to adverse stock selection in biotechnology, health care equipment, and health care technology. In biotech, underperformance was partly due to a drop in the share price of **Inhibrx, Inc.** as a result of profit-taking after gains in the prior quarter and overall weakness in small-cap biotechs. Moderate gains from our high-conviction positions in **argenx SE** and **Vertex Pharmaceuticals Incorporated** along with lower exposure to stronger performing large caps **Gilead Sciences, Inc., Amgen Inc.**, and **AbbVie Inc.** presented additional headwinds.

Negative stock selection in health care equipment was due largely to sharp declines in **OpSens Inc.**, a fiber optic sensors manufacturer; **ShockWave Medical, Inc.**, an intravascular lithotripsy leader; and **Edwards Lifesciences Corp.**, a transcatheter aortic valve replacement leader.

Health care technology performance was pressured by a drop in the share price of **Schrodinger, Inc.** driven by lowered guidance due to foreign currency headwinds and lower adoption of its software than it had forecasted.

These negative effects were somewhat offset by favorable stock selection in life sciences tools, pharmaceuticals, and managed health care along with strength in McKesson Corporation and lower exposure to some health care supplies companies. In life sciences tools, Mettler-Toledo International, Inc. and Danaher Corporation outperformed. In pharmaceuticals, AstraZeneca PLC did well. These gains were partially offset by underexposure to Pfizer Inc. and Merck & Co., Inc. In managed care, shares of Elevance Health, Inc., a large managed care company, rose on raised guidance based on solid medical cost management, strength in its pharmacy benefit managers unit, and healthy enrollment growth.

Tell us about the investment thesis for Inhibrx.

Josh Riegelhaupt: We invested in Inhibrx in mid-October. Inhibrx is a biotech company with expertise in single-domain antibody structures. Antibodies have a canonical Y structure, the top of which binds to the "bad actors," like a bacteria or virus. The bottom is called the constant region because it is part of all antibodies. The constant region tends to have double domains and a very canonical biology. Inhibrx found a way to make the constant region a single domain rather than double. That means antibodies can be built in a different way.

Wall Street doesn't really care about this. It cares about the company's Alpha-1 antitrypsin (AAT) program, a replacement protein for patients with AAT deficiency. Patients with the worst outcomes, the ones who will be addressed first from a commercial perspective, have something called a Z mutation. There are about 100,000 Z patients in the U.S., or about 5% to 10% of total patients treated. There is another, much more common, lung disease called Chronic Obstructive Pulmonary Disease (COPD). It's likely that a good percentage of COPD patients are actually undiagnosed AAT patients.

AAT patients get augmentation therapy, in which donated blood is filtered for AAT. There are currently four approved products with about \$1.5 billion in sales. Sentiment is that the market is undersupplied. There are not enough donations. The drugs are weekly infusions with an annual cost of \$40,000 to \$50,000, carry the risk of infection, and do not get AAT levels up to normal, so are subtherapeutic.

Inhibrx dosing will likely be monthly. There is no infection risk because Inhibrx discovered a way to grow the recombinant ATT protein in cells. The cost will be \$20,000 or less. Most importantly, it can bring ATT levels to therapeutic range. To us, that seems straightforward -- a better product profile. Wall Street is concerned about the regulatory environment and FDA approval. The current blood-derived products were approved 15 to 30 years ago, and the standard of care and what we know about the disease has changed since then. There hasn't been an approval since. The market cares about timing when calculating valuations, particularly traders. That is usually a good setup for a long-term investor.

Can you tell us about any other names you've added to the portfolio?

Neal Kaufman: I'll highlight two. First is **HCA Healthcare, Inc.** a leading provider of health care services. It owns, manages, or operates 182 hospitals and approximately 2,400 ambulatory care sites in 20 states and the U.K. We think positive demographic trends coupled with its strong presence in attractive growth markets position HCA well for long-term sustainable growth. Prior to the pandemic, management targeted long-term top-line organic growth of 4% to 6% with pricing/mix in the 2% to 3% range and an increase in adjusted patient admissions of 2% to 3%. The pandemic has been disruptive to this framework, but management thinks organic revenue growth can return to its targeted 4% to 6% range along with positive margin leverage possible at the high end of the range. Recently, HCA has seen

contract labor costs and wage pressure start to moderate and volume trends improve. HCA also has a track record of returning capital to shareholders through special dividends and share repurchases.

The second is **Option Care Health, Inc.,** the largest independent player in the \$15 billion U.S. home and alternate site infusion market. We think Option Care is well positioned to capitalize on the ongoing shift to lower-cost care sites and the increase in new specialty drug treatments. Home infusions cost significantly less than hospital infusions, and, with over 150 locations, the company is positioned to serve roughly 96% of the U.S. population in a market growing 5% to 7% a year. Option Care has a diversified portfolio of therapies and provider relationships with no customer concentration, in-network status with all the large payers, and low direct government reimbursement risk as Medicare does not cover home infusion. We think the market would double if Medicare did provide coverage, which we think is a possibility. Given the company's geographic coverage and therapeutic expertise, we think it has the leverage to discuss new innovative payment models with payers. Its strong relationships with drug manufacturers facilitate early access to new drugs and preferred supply arrangements. Finally, its size and scale give it purchasing power. It currently projects high single-digit organic revenue and double-digit EBITDA growth. Finally, the company has a strong track record of successful acquisitions.

Can you update us on the Fund's investment in Moderna?

Josh Riegelhaupt: We see **Moderna Inc.** making a lot of progress. Most of its updates have been positive. Its balance sheet is still strong.

Moderna developed one of the four main COVID vaccines, using mRNA technology. The bookmark pricing is estimated in the \$40 to \$120 range per shot. The FDA's Vaccines Related Biologics Advisory Committee wants people to get annual shots. How many people will get it? We'll see what happens. But think about 500 million annual flu shots globally.

We believe mRNA technology has the potential to change vaccinations. Take, for example, respiratory syncytial virus (RSV). This is part of the "tripledemic" — flu, COVID and RSV — that has had a lot of attention in the press recently. Moderna has a long-term goal to buttress its business by combining vaccines. A person could potentially get an all-in-one vaccination for COVID, flu, and RSV. There's lots of precedent. Children's early life shots are administered as four or five vaccines all-in-one. Data show Moderna's RSV vaccine is 83% to 84% effective against respiratory tract disease, making it as good or better than its competitors' vaccines. It plans to file for approval in the first half of 2023.

Moderna also released data on its personalized melanoma vaccine. In the post-treatment adjuvant period for melanoma patients, the question is whether doctors should do nothing or continue to treat the patient when they don't know if the cancer is still present to prevent a relapse. It appears the drug potentially improves adjuvant therapy. The challenge is that melanoma is a very treatable disease. To show a reliable result will take years.

The potential market ranges from \$1 billion to \$2 billion. Some observers speculate it could work in every cancer, a \$20 to \$25 billion market. Wall Street's view is "let's just make sure we have the right lenses on to view the data." Then there is a real-world commercial issue. The patient's blood must be drawn first to create the vaccine with the patient's antigens for the infusion. If the oncologist works in a large metropolitan facility and provides infusions for a living, great. But an oncologist at a community center seeing many different patients can't do this. We are in a transition where more and more personalized medicine will become available, but we don't yet have the infrastructure to get this medicine to patients. It is happening, particularly because of cell therapies, but it's not the standard yet.

What do you feel sets Baron apart from other investors in the health care sector?

Neil Kaufman: Like all Baron Funds, we look for competitively advantaged growth companies that we

can own for many years. Baron Health Care Fund owns fewer stocks — roughly 40 to 50, with top 10 holdings typically representing more than 40% of assets — than our typical peer fund. We can invest across market caps and geographies. To help diversify the portfolio and manage risk, we loosely group our holdings into three categories: earnings compounders, high-growth, and biotech. Earnings compounders are companies we think can compound earnings at double-digit rates over the long term, like HCA and Option Care. High-growth stocks are companies we believe can generate mid-teen or better revenue growth. Some may not be profitable today; others are. An example is **Inspire Medical Systems, Inc.**, a company we have owned for a long time that sells a device for sleep apnea. While not yet profitable, it is growing fast with high gross margins. We are confident it has the ability to be highly profitable when it matures. Within biotech, we own Moderna, among others. Allocation among these categories changes depending on how we see the opportunity set and the overall market environment.

What are your near-term and long-term outlooks for health care?

Neil Kaufman: After two challenging years, we think the small/mid-cap biotechnology area is positioned for better performance, assuming interest rate hikes will slow, stabilize, or possibly even reverse. We have increased our exposure in this area.

In pharmaceuticals, our largest investment is **Eli Lilly and Company.** Its new diabetes drug, Mounjaro, is likely to be approved this year. It has also obesity drugs and a drug for Alzheimer's disease in the pipeline. It is not facing any significant near-term patent expirations, and we think the business can generate good growth in revenue and earnings through the end of the decade and beyond.

Life sciences tool stocks underperformed in 2022 due to declining revenues driven by COVID, weak capital markets, a weaker funding environment for biotech customers, an economic slowdown in Europe, foreign currency headwinds, and COVID lockdowns in China. Some of these headwinds are now in the rear-view mirror while others persist. Still, we think life sciences tools companies are good long-term investments because many have secular growth drivers, pricing power, recurring revenues, high margins, and low capital intensity. We're starting to see many of these stocks bouncing back.

Medical device companies have been impacted by reduced procedure volumes due to hospital staffing shortages. Long-term, we think many medical device companies will see increasing demand driven by an aging global population and a higher disease burden from chronic diseases. We are invested in companies with innovative devices for sleep apnea, diabetes, and heart valve replacement.

Managed care companies had a strong 2022 largely due to low health care utilization, higher interest rates, and lack of foreign currency exposure. Right now, investors are concerned about two issues. One is Medicare Advantage rates. The second, and perhaps larger issue, is the finalization of certain audit rules for risk-adjusted payments to participants in the Medicare Advantage program. We think there will be clarity soon on both issues, and unless there's a real negative surprise the stocks should recover. Over the long term, we think Medicare Advantage is an attractive market.

Overall, our long-term outlook for the Health Care sector is bullish. We think innovation and the themes we have been investing in are intact, and the Fund owns competitively advantaged growth companies with strong management teams.

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.

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 Fund expenses pursuantto a contract expiring on August 29, 2033, 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.

Baron Health Care Fund's annualized returns for the Institutional Shares as of December 31, 2022: 3 months, 9.08%; 1-year; -16.90%; 3-year, 12.41%; Since Inception (4/30/2018), 13.90%. 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 December 31, 2022: 3 months, 11.54%; 1-year, -6.10%; 3-year, 9.95%; Since Fund Inception (4/30/2018), 12.06%. The **S&P 500 Index's** annualized returns as of December 31, 2022: 3 months, 7.56%, 1-year, -18.11%; 3-year, 7.66%; Since Fund Inception (4/30/2018), 10.22%.

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.

The discussion of market trends is not intended as advice to any person regarding the advisability of investing inany particular security. The views expressed in this document reflect those of the respective writer. Some of ourcomments 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.

Portfolio holdings as a percentage of net assets as of December 31, 2022 for securities mentioned are as follows: Inhibrx, Inc. -0.8%; AbbVie Inc. -3.1%; OpSens Inc. -0.9%; ShockWave Medical Inc. -1.1%; Edwards Lifesciences Corp. -1.1%; Schrodinger, Inc. -0.2%; Mettler-Toledo International, Inc. -2.2%; Elevance Health, Inc. -2.8%; HCA Healthcare, Inc. -2.0%; Option Care Health, Inc. -1.0%; Moderna, Inc. -2.6%; Inspire Medical Systems, Inc. -2.2%; Eli Lilly and Company -6.0%; Vertex Pharmaceuticals Incorporated -3.2%; argenx SE -3.6%; Danaher Corporation -1.0%; Merck & Co., Inc. -3.7%.

Baron Health Care Fund did not hold **Amgen, Inc., Gilead Sciences, Inc.,** or **Pfizer Inc.** as of December 31, 2022.

Top 10 holdings as of December 31, 2022

Holding	% Assets
UnitedHealth Group Incorporated	9.5
Eli Lilly and Company	6.0
Thermo Fisher Scientific Inc.	4.2
Humana Inc.	4.0
AstraZeneca Plc	3.9

Merck & Co., Inc.	3.7
argenx SE	3.6
McKesson Corporation	3.5
Intuitive Surgical, Inc.	3.4
Vertex Pharmaceuticals Incorporated	3.2
Total	45.1

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

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. All rights in the FTSE Russell Index (the "Index") invest in the relevant LSE Group company which owns the Index. Russell® is a trademark of the relevant LSE Group company and is used by any other LSE Group company under license. Neither LSE Group nor its licensors accept any liability for any errors or omissions in the indexes or data and no party may rely on any indexes or data contained in this communication. The **S&P 500 Index** measures the performance of 500 widely held large cap U.S. companies. 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. Non-mutual fund products are available to institutional investors only.

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