KARMIN CAPITAL

Informed Contrarianism

The most lucrative opportunities for investors generally arise when promising businesses become starved of capital. Those who are able and willing to provide financing during such draughts typically can do so on value extractive terms. Right now, though, an increasing portion of the investment universe is morphing into the equivalent of a seller's housing market. There is an overabundance of capital in public and private markets – aided by fiscal and monetary stimulus – seeking similar types of exposure. Unsurprisingly, this has had an upwards impact on valuations across multiple asset classes and industries. Speculation in some corners is running rampant. We are now living in a world where reproducible, digital copies of art – that are "tokenized" – have sold for tens of millions of dollars and a dog-themed cryptocurrency intended to be a joke – Dogecoin – has appreciated 6,500% year-to-date, despite having no supply constrictions like Bitcoin.[1,2] To be clear, we are still constructive on old-fashioned equity markets and suggest maintaining core, long-term positions. However, we advise applying increased scrutiny and selectivity when making new allocation decisions. For when investors are starved of compelling opportunities or herd into the same themes, it is the companies (or selling asset owners) that reap the extractive terms.

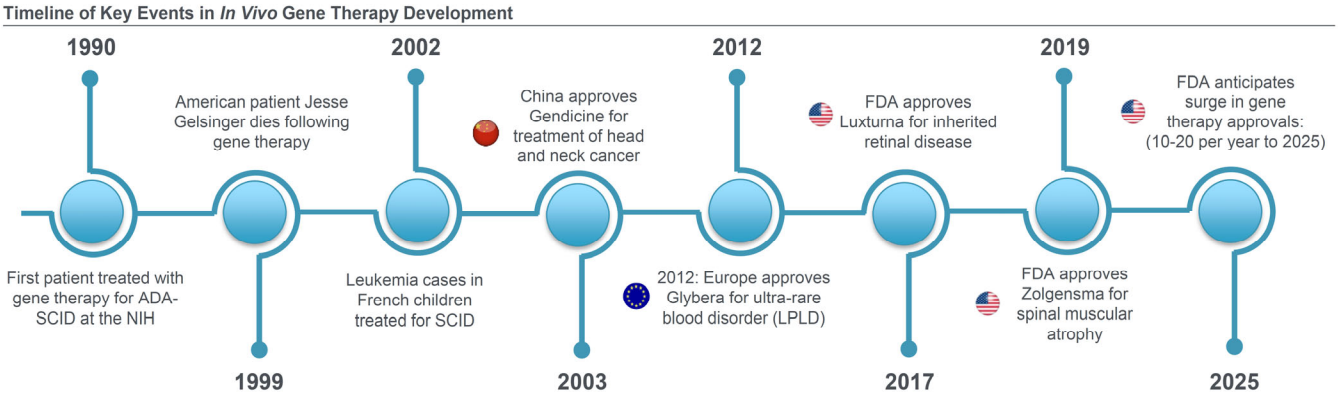
In our October 2020 letter, we wrote about the relationship between current sentiment and prospective returns. Briefly, investors risk losing the most when buying into peak expectations and can potentially gain the most when buying into troughs of disillusionment. This makes intuitive sense, but in practice can be psychologically challenging. We have evolved to seek comfort and safety in the herd rather than to go against it. And most of the time the herd is eventually right; errors are usually more a matter of timing and degree than direction. Even internet and technology investors in the late 1990s were right about the long-term trends. Identifying when expectations are elevated or depressed is difficult and far more an art than science. While valuation metrics are helpful indicators, they are not conclusive. Rather, one needs a holistic understanding of the factors driving a certain company or industry's trading and valuation backdrop to fully appreciate whether expectations are too optimistic or bleak.

A further complication for those seeking to break away from the herd is that contrarianism as an investment strategy is often a losing proposition. Generally, markets are efficient at incorporating new information and, over long periods of time, rational in valuing businesses. If a company is suffering from a low valuation, there is usually a good reason for it. Thus, contrarianism has the best chance of working when markets get excessively carried away in the short-term due to broader trading dynamics or transitory events impacting a company or entire industry. When nearly every negative factor one can think of is reflected in asset prices and the possibilities for positive outcomes are ignored. When companies are simply punished by investors due to sentiment rather than actual operations. In these cases, there is a reasonable prospect of escaping from the trough of disillusionment and rewarding those investors who had the *informed* resolve to go against the prevailing narrative. We are writing this letter because we think we have identified one such opportunity worth considering for your portfolios.

In June 2017, we first wrote about advances in genetic sequencing, as well as a new gene editing technology called CRISPR and its potential applications in both human medicine and materials sciences (such as agriculture). At the time, publicly traded biotechnology companies providing exposure to CRISPR were valued on average at roughly 2x the levels of cash on their balance sheets due to concerns over safety and skepticism about how CRISPR gene editing, which showed proof of concept in labs and animal models, would translate to humans. We thought given the low valuations, due to questions surrounding the science and potential upside if it showed promise, that a small portfolio allocation (1-5%) made for a relatively attractive risk/reward proposition. Today, CRISPR is a household term, its foundational scientists have won the Nobel Prize and the publicly traded CRISPR stocks from 2017 – at their recent February peaks – returned between 6-14x (albeit partially driven by valuation insensitive thematic ETFs, such as those managed by ARK Invest). In the last two months, stock prices have justifiably corrected as expectations are still well ahead of actual progress. But other than the CRISPR firms, the broader

genetic medicine field – except for a handful of dedicated institutional biotech investors – has been mostly left for dead despite meaningful scientific progress.

It is those looked over companies – particularly ones developing gene therapies – that we think have a reasonable prospect of soon exiting the trough of disillusionment and providing investors meaningful returns. If there is anything that the Covid-19 pandemic has taught us, it is that cutting-edge medicine has immense value to society. Gene therapies are among a host of promising therapeutic approaches that scientists are advancing to treat a wide range of diseases. While newer techniques such as CRISPR and messenger RNA receive far more headlines and generalist investor attention (mRNA deservingly so), gene therapy – by which we mean the introduction, silencing or regulation of human genes to treat various disorders – is entering a maturation phase of its development, with an expected 10-20 drug approvals annually by the mid-2020s.[3,4]



Source: Goswami R et al. *Front Oncol*. 2019;24(9):297. Dunbar CE et al. *Science*. 2018;359:eaan4672. https://www.fda.gov/news-events/press-announcements/fda-continues-strong-support-innovation-development-gene-therapy-products. Piper Sandler Research.

Prior to outlining the gene therapy investment case, we wanted to provide a brief overview of the science. For a more detailed discussion and how gene therapy differentiates from other genetic medicine approaches, please reach out. To refresh, genes are a region of DNA that code for the production of proteins, which are vital for various biological functions. Every cell in the human body contains a full copy of our DNA and, thus, all of our estimated ~30,000 genes.[5,6] Different cells are responsible for different functions and use only the genes required to perform their specific tasks. Genetic mutations – whether inherited or developed over time – may cause a gene's failure to produce a normal level of protein, leading to numerous health ailments. Gene therapy is a therapeutic technique that uses genetic material (a strand of DNA) to remedy this class of disorders. This may involve delivering a copy of a healthy gene, inhibiting a faulty gene and/or regulating the degree to which a gene produces a certain protein.[7] Notably, gene therapy differs in its approach from gene editing, which seeks to repair genetic mutations by making changes at the actual cellular DNA level (a potentially higher reward, but higher risk method of treatment). In short, rather than attempting to manage the symptoms of a medical issue (which is the basis for most current medicines), gene therapies attempt to fix the source of the problem itself.

Scientists believe there are between 6,000 to 10,000 monogenic diseases (caused by defects in a single gene) that – while each rare on a population prevalence basis – in total impact approximately 30 million Americans and over 300 million people globally.[8,9] Many others suffer from polygenic disorders (meaning the underlying disease involves the interaction of multiple genes). To date, gene therapies have aimed at tackling the simpler to treat monogenic disorders, as well as several acquired health issues typically associated with aging for which the

normal protein expression by a certain gene may provide a meaningful benefit. The attraction of gene therapy is that it has the potential to (1) treat patients suffering from currently undruggable, severe disorders with a known, underlying genetic cause and (2) transform the medical care paradigms of some chronic conditions (such as Hemophilia and wet macular degeneration) from ones requiring regular dosing to possibly curative single drug administrations.

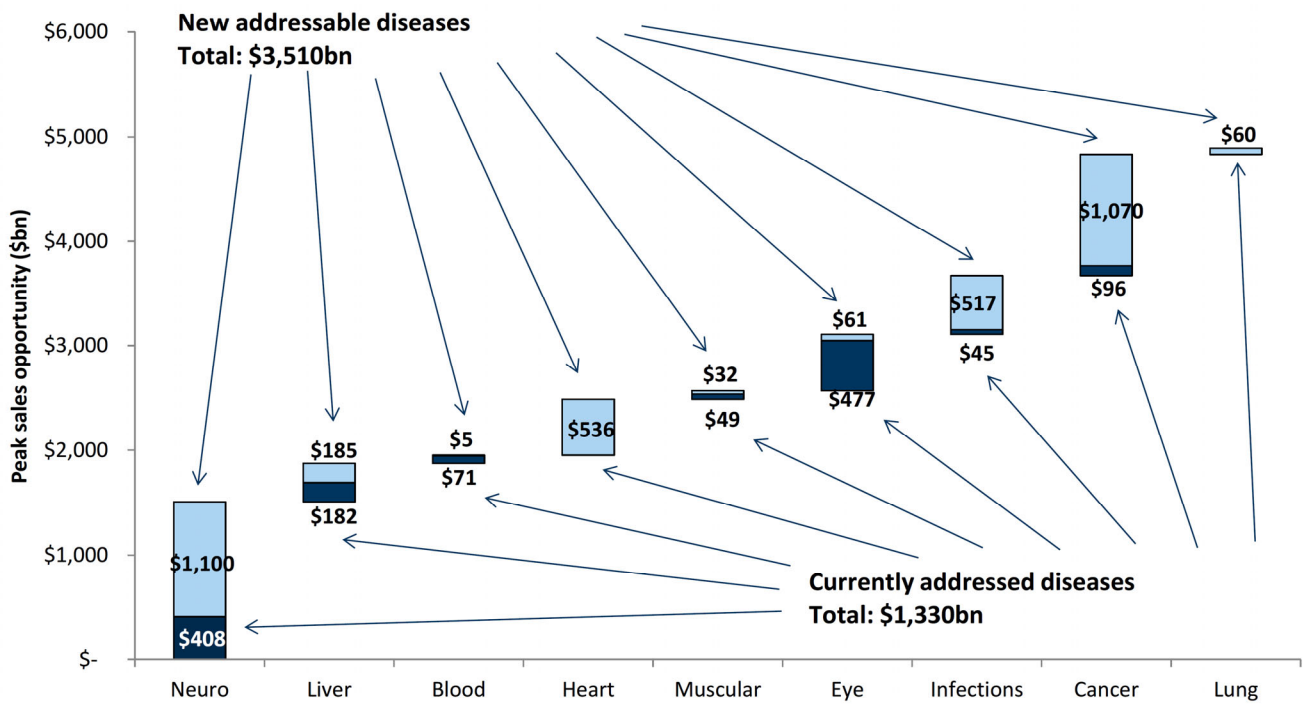
Gene therapies are typically administered by inserting genetic material into a modified, non-harmful and non-replicable virus (commonly, an adeno-associated virus), which once injected into a patient carries the genetic payload into the nucleus of targeted cells where – if effective –they have a functional and durable impact on protein production. The benefit of viral delivery is the efficient transfection (or entry) into target cells. The potential downside is the risk of an immune system response (especially at high doses) and difficulty in redosing due to the development of antibodies against the viral vector. Future generations of gene therapies may attempt to use synthetic gene delivery mechanisms which may avoid the potential for immune responses and permit redosing. If helpful, at the we have included at the end of this letter (page 9) a visual from the biotechnology firm uniQure describing the most common form of gene therapy administration.[10]

Although generally well-tolerated by patients from a safety perspective, some gene therapies at high doses have resulted in significant adverse effects. Like any medicine, potential safety considerations must be weighed against alternative therapeutic options and the likelihood of reducing a patient's suffering. Generally, the fewer the alternative treatment options and the more severe the disease, the more comfortable both regulators and medical practitioners are in administering a medicine with potentially adverse side effects. Similarly, regulators and practitioners are more likely to endorse a new therapeutic approach such as gene therapy (even if for a disease with current treatment options), if clinical data validates its safety, effectiveness and durable impact.

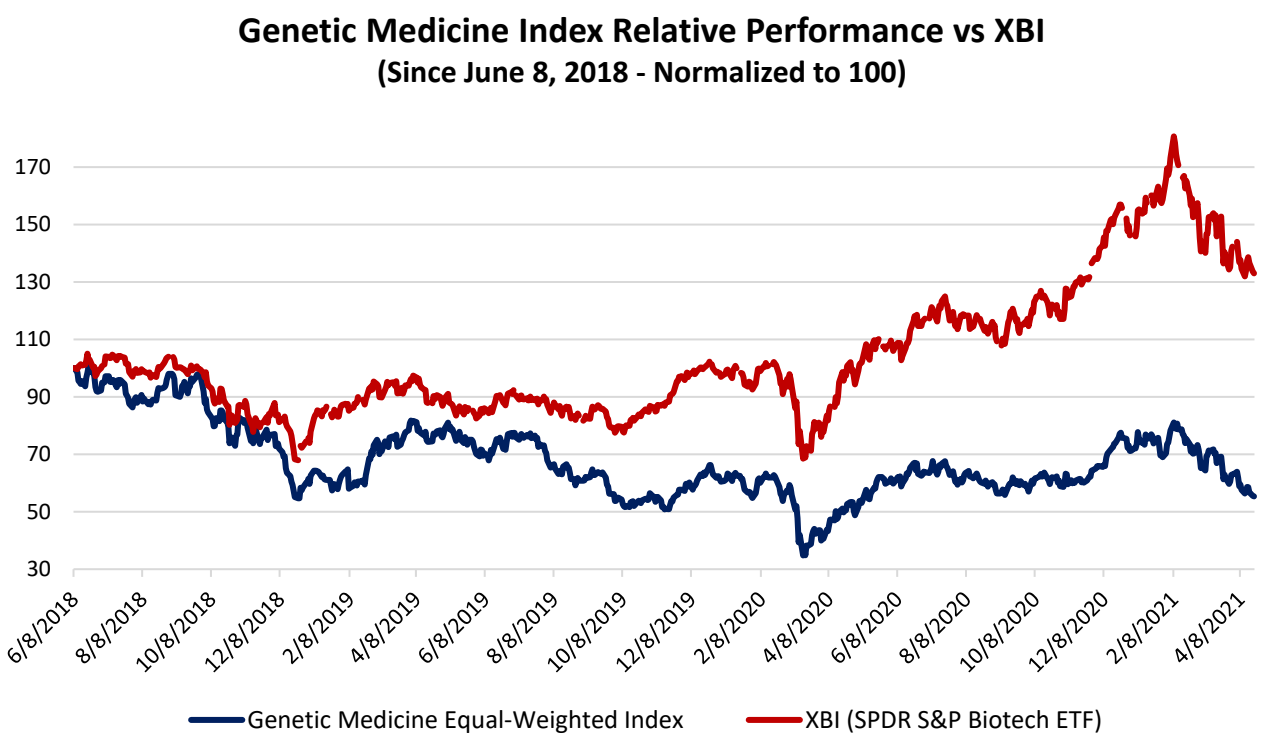
As of year-end 2020, there were 423 gene therapy trials in progress (182 in the U.S.) across phases 1-3 of clinical development, with conservative estimates for gene therapies to generate between $10-$15 billion in revenue by mid-decade.[11,12] Longer term, industry analysts anticipate gene therapies to have a significant impact on the medical landscape. Genetic medicine has the potential to usher in a third wave of healthcare innovation following in the footsteps of small molecule drugs (think simple compound, medicine cabinet drugs like aspirin) and biologics (far more complex medicines derived from biological sources, which include genetic medicines but to date have been dominated by monoclonal antibody drugs like the top-selling immunosuppressant Humira).[13,14,15]

In a 2018 analysis, Goldman Sachs healthcare analysts argued that genetic medicines (gene therapies, gene editing and cell therapies) not only could disrupt the current ~$1 trillion global pharmaceuticals market, but also had the long-term potential to target currently untreatable conditions (particularly gene therapies for neurological disorders) that could eventually lead to a $4.8 trillion addressable market opportunity.[16] While we think these estimates are far too aggressive (at least for any time in the near-to-medium future), we have included a graphic illustrating the analysis below. Let's just say for now that we are more comfortable with the closer to $10-15 billion sales estimate range by mid-decade and anticipate a ramp in growth over time as real-world results validate the approach and the technology improves.

Genome medicine represents a potential $4.8tn total addressable market



Despite impressive scientific advances, investors have largely shied away from genetic medicine stocks over the last several years. Since peaking in June 2018, a proprietary, equal-weighted index of genetic medicine companies we created (45 firms in total) has declined 44%.[17] The majority are gene therapy firms and those have suffered even sharper declines. After rallying last winter, this index is down approximately 30% since its February peak (on anemic trading volume suggesting to us it's not key institutional holders selling). The recent selloff has correlated with the performance of the XBI exchange traded fund, which tracks the S&P Biotechnology Select Total Return Index (-25% over the same period). This performance is consistent with many small cap growth stocks during the same period, as higher interest rates and a broader shift into large cap and value stocks has resulted in an exodus of liquidity that has punished quality firms along with more speculative stocks trading at exuberant levels. In any event, the performance for genetic medicine firms has been particularly dismal when compared to broader biotech: since June 2018, the XBI has returned 34% vs the 45% decline of our genetic medicine index (see below chart).



The poor market environment has resulted in many promising companies trading at valuations levels around 1.5-3x cash on their balance sheets (with market caps mostly in the $500 million to $1.5 billion range). Notably, the public market weakness has had little impact on private market financings and valuations – suggesting institutional investors are still constructive on the long-term potential. However, in a public market environment where extreme speculation on future technology has gone haywire (with many unproven electric vehicle and battery firms, for instance, trading at valuations in the $10s of billions) gene therapy firms have not joined in on the party. They are clearly out of favor and trading more like they are attempting to cause diseases rather than cure them.

Given advances in genetic medicine, its potential to make meaningful improvements in patients' lives and the large market opportunity, why are gene therapy stocks currently in a multi-year malaise? We think the following helps explains the underperformance:

- Like many new technological advances, the well-deserved hype around genetic medicines preceded actual progress (particular for CRISPR gene editing firms). Expectations for the pace of gene therapy commercial drug approvals and sales growth became too aggressive too early and have since corrected.

- Covid-19 significantly interrupted the ability to conduct clinical trials in 2020. The typical pathway to drug approval involves multi-year trials, with phase 1 ensuring safety, phase 2 focused on determining the proper dose required to elicit an effective response and phase 3 testing that dosage in a larger patient population. Understandably, many companies needed to pause or defer the initiation of critical trial work, most of which occurs at leading hospitals and medical research centers. Though trials have largely resumed, many stocks never recovered their pre-pandemic momentum.

- As the number of gene therapy trials have increased, so has the demand for difficult to manufacture genetic material and delivery vectors. We won't bog you down with the details but creating both the genetic payload and viral vectors used to dose them is highly complex, strictly regulated, expensive and time consuming. There has been an industry-wide demand bottleneck for these products – and the problem is far more severe for firms that have outsourced their manufacturing processes to third-party specialists such as Lonza and Thermo Fisher. Many companies have faced lengthy and costly trial delays due to this gating factor. Firms that have incurred the substantial upfront capital costs to build out internal manufacturing centers and hire qualified personnel are meaningfully advantaged going forward.

- Investors are concerned that both regulators at the FDA and FTC are taking stricter stances when it comes to gene therapy trials and mergers. We think the FDA has been consistent in its requirements to companies,[18] but there have been notable, recent clinical holds and trial modifications due to FDA feedback. When it comes to new drug approvals the FDA is likely to consider the severity of disease, current care options and drug safety/efficacy. Importantly – and where companies have erred – the FDA will require reproducible manufacturing processes from early phase trials through commercial approval (hence the importance of internal manufacturing). Though too early to say, the FTC may take a harsher stance on mergers under the Biden administration. While the FTC has not blocked any gene therapy acquisition to date, the review process for some deals and even large-scale licensing agreements have gotten lengthier dating back to the Trump administration. Relatedly, merger and acquisition activity has slowed relative to several years ago. Potential acquisition premiums, once priced into stocks, have vanished.

- On the subject of regulation, drug pricing under a new administration is always a hot topic issue. Gene therapies are expensive. That is a reflection of their high cost to develop and risk of clinical failure, as well as the fact that they are intended to be one-time doses to treat either untreatable or chronic conditions that are a significant cost burden on the medical system. A $1m gene therapy, while costly, may substantially save the medical system millions in avoided costs over time. In addition to the always present political concerns over drug pricing, the payor systems in North America, Europe and Japan (key markets) will need to develop methods of accommodating high upfront costs.

- Clinical data integrity issues (from Novartis/AveXis) and several safety concerns have soured sentiment in the space. While the data integrity issues are company specific and unlikely to repeat, the safety concerns are broader to the industry. At extremely high doses, the viral vectors used to deliver genetic material inside patients' cells can elicit a harsh immune system response. This is of particular concern for systemic therapeutic routes of administration (such as IV drips) vs targeted administration to specific areas/tissues. While many gene therapies can dose effectively at safe levels without adverse effects, a few companies have pushed the boundaries of widely-considered dangerous dosage levels in attempts to deliver a higher therapeutic advantage to patients. In a small number of cases this has resulted in severe inflammatory reactions and even death. Though tragic, such results may be acceptable risks for medical indications where if left untreated the outcome will be a premature death. However, the reputation of the entire industry takes a blow when just one company pushes the limits on safety. In recent months, two gene therapy patients developed cancer in the years following treatment. This caused concerns across the industry as to whether the delivery vectors may have unintentionally integrated with cells and drove tumor growth. In each case, the companies whose trials were implicated have presented data convincingly showing the therapies were unrelated to each patient's tumor. Yet the fear of any correlation has hung over the sector.

- Though real world data has been robust and durable across many indications, investors are skeptical over the duration of therapies for a number of liver-related diseases such as Hemophilia A. Again, we can discuss details separately if interested, but the basic concern is that gene therapies dosed with the current vector technology can only be administered once as patients will develop antibodies to the vector post-administration. Many companies are doing promising work on redosable vectors, but the science is still at an early stage. If a patient can only receive one dose and that dose costs in excess of $1m, all interested parties (patients, clinicians, regulators, payors and investors) want to know that the therapy will be durable. Key to durability may be the specific genetic material and/or targeted tissue. For instance, liver cells have high turnover rates (meaning the natural cycle of cellular replacement) relative to cells in the CNS system or eye. Thus, the impact of newly introduced genetic material on protein production could theoretically wane over time in cells that divide with a higher frequency.

If you can articulate an investment theme's bear case in detail, you can fairly evaluate its strengths or shortcomings. In this regard, we think we may have some degree of an edge. In our view, the above briefly covers almost every negative factor one could come up with for gene therapy firms, short of a specific program's trial failure. Some companies in the space are deserving of low valuations for idiosyncratic reasons. But the above concerns are currently priced into the valuations of many promising companies working on cutting edge science with multiple clinical assets, validated technology, skilled management and advanced manufacturing capabilities. In our view the selloff has been indiscriminate as sentiment has sunk and all but specialist biotech investors have given up on the space. This creates an opportunity.

Our experience has taught us that stocks usually don't suffer precipitous falls (unless a business truly is falling apart) when valuations are low and pessimism has peaked. That is usually the environment conducive to a performance turnaround and attracting new investors. We firmly believe that genetic medicine and gene therapy, specifically, is not going away. It is just getting started. To believe otherwise is to essentially bet against scientific progress.

We don't know when sector performance will turn, but we think that it is likely to improve with (1) the resolution or relaxation of any of the factors above weighing on performance (particularly with more certainty surrounding the FDA and FTC regulatory landscape) and/or (2) positive clinical trial readouts (which have a better chance of occurring now than last year given the resumption of clinical work). If valuations do linger at low levels much longer, we think M&A is also likely to resume. For large cap firms seeking to gain a foothold into gene therapy or replenish stagnating pipelines, a $1-3 billion acquisition is a small price to pay – even if there are elevated risks to closing given the uncertainty as to the FTC's merger stance.

If you are interested in gaining exposure to gene therapy firms, we suggest a diversified approach and limiting your position sizing commensurate with your risk tolerance (as these are highly volatile stocks with large operating losses at early stages in their business development). In addition to company selection criteria (covered below) we think the number one advantage an individual investor can have in this space is time. We strongly believe in this investment theme, just as we did in renewable energy 4-5 years ago when those stocks were in the doldrums. We think we have a good understanding of the science, investment landscape and factors driving performance, but timing is impossible to predict. Who would have thought that last year – out of all years –renewable energy stocks would finally explode upwards? So, to reiterate, investors in the gene therapy space must have patience and a high tolerance for volatility.

When investing in gene therapy firms, key investment selection criteria we consider (in no particular order) include:

1) **Valuation** (the lower, the more intriguing. Also, consider how a firm trades relative to similarly situated peers or M&A comps).

2) **Cash runway to conduct clinical trial work** (the longer, the better. We like at least two years).

3) **Commercial viability of programs** (the fewer the current treatment options, the more likely a program is to get regulatory priority, assuming it demonstrates clinical efficacy and safety. Likewise, the higher a disease's patient population and the fewer competitors seeking to target the same indication, the more commercially viable the therapy).

4) **Technology/Science** (more attractive if differentiated vs competition, if there is strong preclinical data supporting the therapeutic methodology and if clinical proof of concept can apply to more than just one disease. Technologies that may enable gene regulation and vector redosing are particularly attractive).

5) **Internal genetic material and viral vector manufacturing capabilities** (even better if compliant with FDA and European regulatory protocols).

6) **Experienced and skilled management**.

7) **Ownership of intellectual property** (does the firm own, in-license or out-license its key assets and what are economics and cost sharing arrangements if it has a development partner? Wholly owned technology or clinical programs provide the most long-term upside potential and may be attractive to acquirors, but partnership arrangements with larger biotech companies can also bring in much needed cash and clinical development/commercialization experience).

8) **Quality of institutional investors** (more comfort in seeing top shareholders that are long-termed focused biotechnology investors with good track records).

9) **Identifiable catalysts** (while not a top selection criteria, it is important to understand for position initiation and sizing when a company may be providing key data readouts or investor updates).

After focusing on this space for four years, we think we have a workable understanding of the science, and a comprehensive grip on valuation drivers and key issues impacting sector performance. In a market environment where it is increasingly becoming harder to identify intriguing value opportunities, we believe this is one worth your consideration. Valuations for leading gene therapy firms have become low enough to compensate for the increased risks that come with early-stage biotech investing. This is admittedly a deeply contrarian investment idea, but we hope we have persuaded you that it is at least an informed one. The alleviation of any broader industry concerns is likely to create a more benign investor environment. And if concerns don't alleviate, we think our focus on specific company selection criteria can still help identify firms whose performance is poised to improve over the coming 1-2 years for idiosyncratic reasons.

The hardest thing to do as an investor is to position yourself against the herd. Doing so means venturing into the trough of disillusionment. In this case, though, we think there is a reasonable chance of exiting it on value

extractive terms. Please let us know if you would like to discuss genetic medicine investment opportunities and gene therapies, specifically, in more detail, as well as the broader market or your current portfolio. We hope you and your families are well.

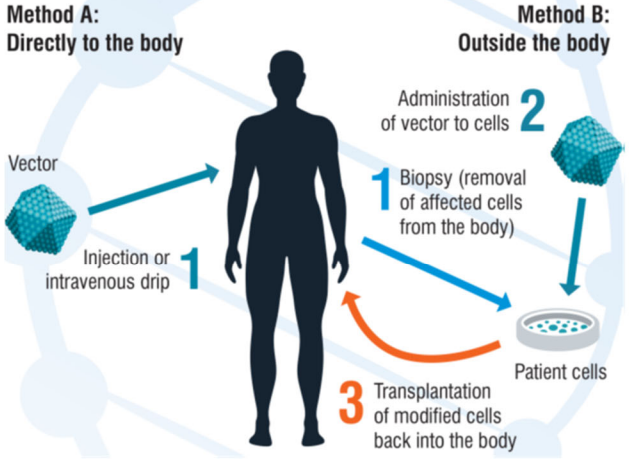
Sincerely,

Peter Karmin
Managing Member

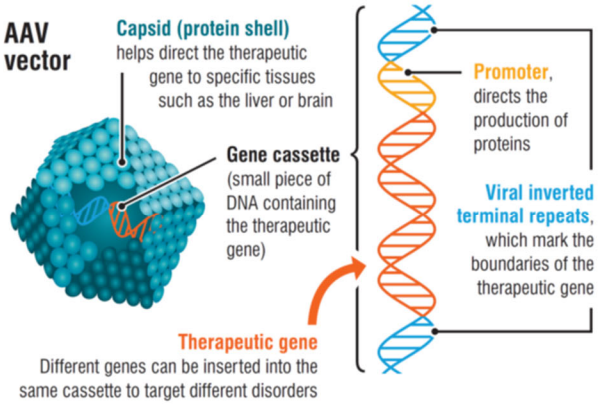
Stuart Loren
Director

Gene Therapy Delivery Overview

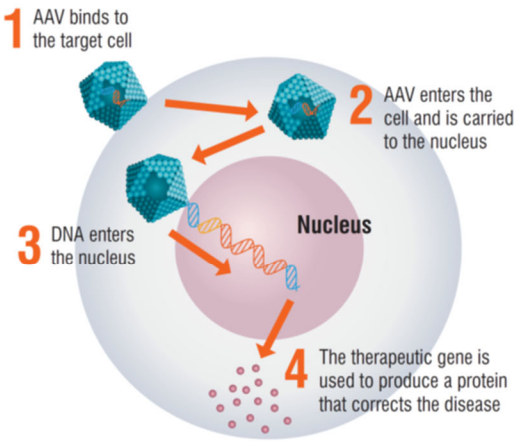
A healthy gene is inserted into a carrier, called a vector, and transferred to the affected cells, either inside or outside the body.



The most common gene therapy vectors are viruses (e.g. adeno-associated virus [AAV]) that have been modified to replace their disease-causing genetic material with a therapeutic gene; however, non-viral vectors are also available Different vectors target different cell types.



Once inside the cell, the healthy gene is carried to the nucleus, where the cell uses it to produce the therapeutic protein to improve or correct the disorder.



Citations and Disclosures

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