THE NEAR FUTURE REPORT

SPECIAL REPORT

The #1 Biotech Stock of 2021

By Jeff Brown

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By Jeff Brown, Editor, *The Near Future Report*

In 1991, IDEC Pharmaceuticals discovered a compound that would save millions of lives. It codenamed the drug IDEC-C2B8. Those in the lab knew IDEC was about to make a lot of money.

But even they couldn't have guessed how much.

Over the next 20 years, IDEC-C2B8 (or Rituxan, as it became known) grew to become the sixth-highest grossing drug in the world. According to Kiplinger, Rituxan generated over $82 billion during that time. In 2019 alone, sales were around $6.8 billion.

The secret to Rituxan's success? Its unique approach to fighting cancer.

Unlike other treatments, Rituxan attacked cancer in a different way. Instead of pumping the body full of chemicals through chemotherapy, Rituxan signals the body's immune system to attack the cancerous cells.

Using the immune system to fight cancer is a process known as immunotherapy. Doctors often use Rituxan in conjunction with chemotherapy as the first line of defense for several cancers including non-Hodgkin's lymphoma (NHL).

NHL is one of the most common forms of blood cancer in adults. Doctors diagnose nearly 70,000 new cases of NHL a year.

Over the years, Rituxan has had millions of patient exposures. And it has undoubtedly saved or prolonged the lives of thousands of people with NHL.

This helped propel IDEC Pharmaceuticals, which merged with Biogen in 2003, to a 12,020% run.

But Rituxan's reign as the first line of treatment for NHL (among other cancers) could soon end.

I've found a new drug that, based on early trial results, is more effective than Rituxan.

This company is much bigger than IDEC was back in 1998. In 2019, it had already reached $7.8 billion in revenue. However, the added revenue from this drug could double sales for the company.

And this company isn't a one-trick show. It has one of the most robust drug pipelines I have ever seen.

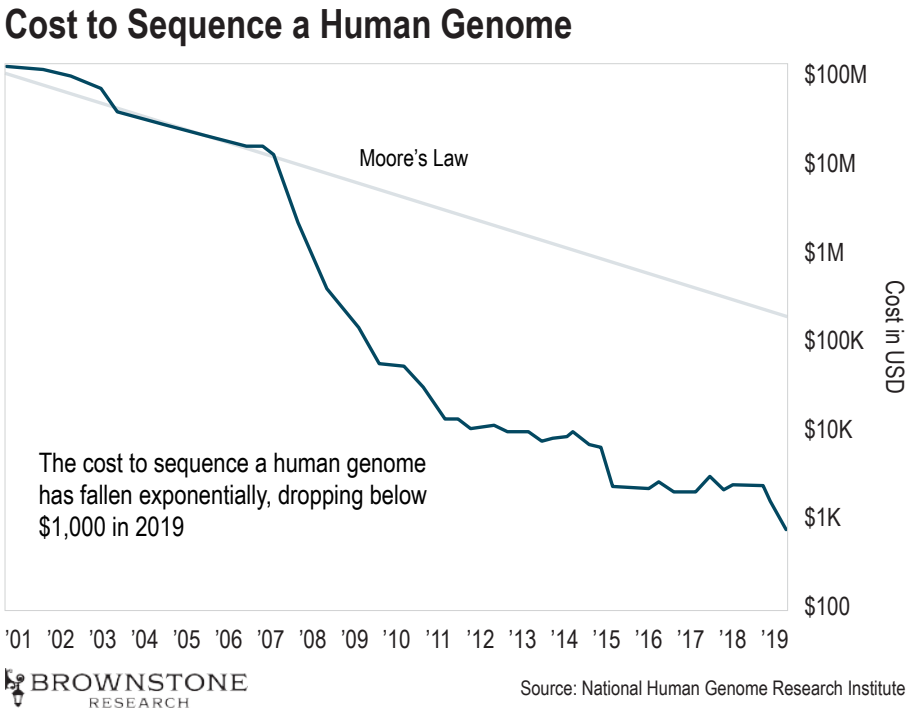
I'll explain more in a moment...

The Future of Precision Medicine

In 2001, it cost $100 million to sequence a human genome. Today, it's a tiny fraction of that cost – less than $1,000.

According to data published by the National Human Genome Research Institute, a division of the National Institutes of Health, the cost dropped to around $600 as of May 2019. It now costs less than a year's cell phone bill to sequence our entire genome.

And in fact, in early 2020, Chinese genetic sequencing company BGI Group announced that it can deliver full genome sequencing for a mere $100.



These tests are becoming affordable for just about anyone. And they are so cheap even some insurance companies are starting to cover a full genome sequencing for hard-to-diagnose patients.

For example, as of November 1, 2017, UnitedHealthcare began covering "whole exome sequencing for patients where clinical presentation is nonspecific and does not fit a well-defined syndrome."

In other words, if a physician knows something is wrong but can't figure out what it is, UnitedHealthcare would pay to have the patient's whole exome sequenced. (The "exome" consists of all the coding portions of genes.)

In late 2019, Cigna became in-network with direct-to-customer genetic testing screenings. This gave 16 million lives easy access to genetic sequencing.

And in March 2020, Blue Shield of California began covering rapid and ultra-rapid genome sequencing for critically ill children. That's right. We can even protect babies with this technology.

Think of how much time and pain can be saved when a genetic sequence can tell us almost immediately what is wrong… rather than spending years and potentially millions of dollars pursuing ineffective or sometimes lethal therapies.

And once we discover the genetic mutation causing the condition, there is already another technology capable of correcting that mutation.

The Power of Genetic Editing

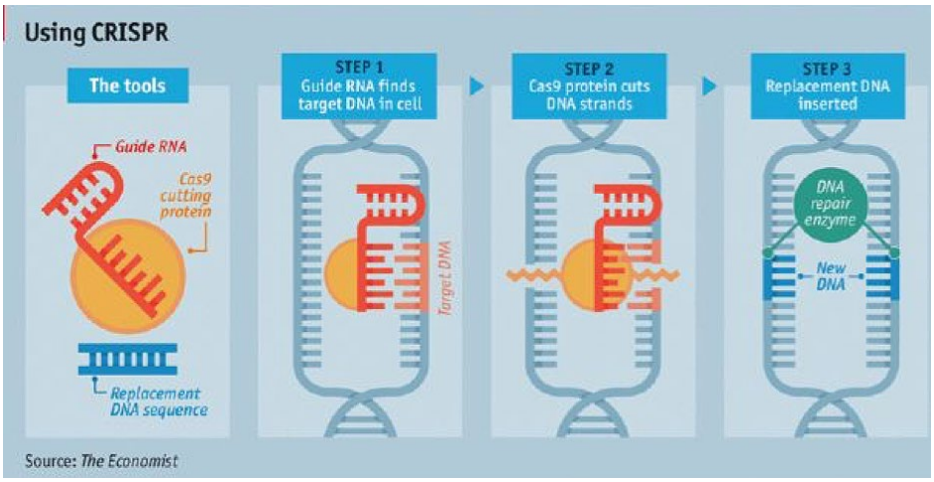
Regular readers know that I'm excited about the potential use of CRISPR-Cas9 genetic editing to eliminate the roughly 6,000 diseases caused by genetic mutations. Longtime readers know that CRISPR is a technology that can "edit" our DNA as if it were software code. 95% of these genetic diseases have no approved therapy or treatment.

And genetic diseases are fairly common…

- About 3–4% of all babies will be born with a genetic disease or major birth defect.
- 1% of all babies will be born with a chromosomal abnormality.
- Birth defects or genetic conditions cause

more than 20% of infant deaths.

- About 10% of adults in hospitals are there due to genetically related problems.
- About 30% of children in hospitals are there due to genetically related problems.



But scientists can use gene editing to "fix" or improve the genetics of plants, animals, and even humans. To say that this technology is revolutionary is an understatement. The possibilities include the following:

- We can provide human gene therapy for serious genetic diseases that have never had treatment.
- We can run screens for drug targets, accelerating new drug development.
- We can make pest-resistant crops to improve yields and feed the planet.
- We can improve the health of livestock.
- We can tackle major diseases like malaria at the source by effectively sterilizing mosquitos through genetically restricting their ability to carry disease.

Aside from what the technology enables, the beauty of CRISPR/Cas9 is in its simplicity.

Above, we can see a simple diagram of the CRISPR/Cas9 system at work.

First, the scientist or doctor finds the segment of DNA that contains a genetic mutation responsible for a disease or condition. Next, he or she programs a "guide RNA" (guide ribonucleic acid) to target the segment of the DNA that contains the genetic mutation.

The scientist or doctor designs the guide RNA to be complementary to the segment of the DNA that is targeted for repair. Put simply, the guide is drawn to it.

After the guide finds the target DNA, the Cas9 protein "cuts" the defective DNA and "inserts" the healthy replacement DNA. The replacement DNA has the potential to cure the disease that the genetic mutation originally caused. The doctor or scientist has "edited" the DNA. Hence the name genetic editing.

Now, we don't need to worry too much about the technical details. Just know that CRISPR can permanently "fix" faulty genetic material that causes disease.

And my recommendation in this report will give us more exposure to the precision medicine trend.

The Difference Between Gene Editing and Gene Therapy

Now, before I get to the exciting development in this sector and a great new way to play it, I need to explain a couple of things. Namely, that there is a difference between *gene editing* and *gene therapy*.

We use gene *editing* to literally alter our DNA and permanently change it… for the better, of course. Essentially, we return our DNA to what

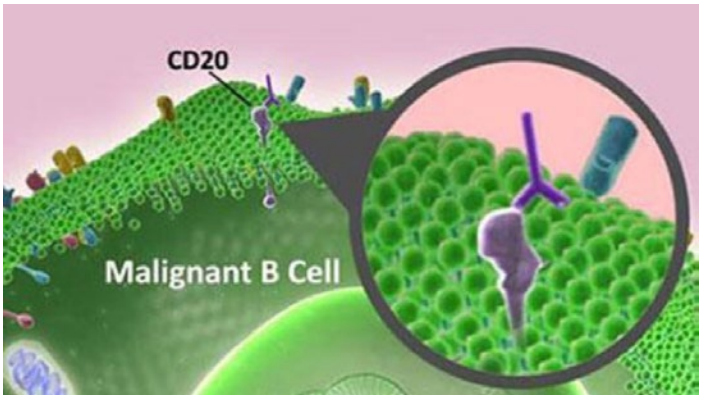
it should have been, without the disease-causing mutation.

Gene *therapy* delivers a new working gene into a cell in order to make it do what it's supposed to. With gene therapy, these cells occasionally need reminders of what they need to do. This requires ongoing treatment for the therapy to remain effective.

Rituxan works this way. NHL impacts B cells, which are immune cells responsible for producing antibodies to help fight infections.

Rituxan binds to the CD20 proteins, which are found on B cells, and triggers the body's T-cells (think of these as the foot soldiers that fight off evil diseases) to attack.

Rituxan Binds to CD20



Source: National Cancer Institute

Since we only find the CD20 protein on mature B cells (healthy and unhealthy), this can destroy the malignant cells that cause NHL. The groundbreaking finding was that immature B cells don't have CD20 proteins. So Rituxan kills off all the mature cells while leaving the healthy immature cells to grow back. Ideally, this returns the immune system back to normal.

But if all the cancerous cells don't leave the body, they will come back. And the patient will have to continue with the treatment.

This has been the best way to attack NHL for the past couple of decades. But I believe that's changing…

Rituxan's Replacement

Thanks to the research and development conducted by this company, a compound that has better efficacy numbers than Rituxan is in Phase 1/2 trials.

The company is **Regeneron Pharmaceuticals (REGN)**. And it codenamed its drug odronextamab (REGN1979). I'll get to the details in just a bit, but I want to provide some more context first.

Leonard Schleifer and George Yancopoulos launched Regeneron over 30 years ago. These two still lead the company today.

The first 20 years of the company involved writing a lot of academic papers and doing clinical testing. It kept the lights on by doing contract manufacturing for other drugmakers.

But in 2008, the Food and Drug Administration (FDA) approved Regeneron's first drug, Arcalyst. And after that, it approved Eylea, the big moneymaker for Regeneron, in 2011.

Eylea is a VEGF (vascular endothelial growth factor) inhibitor, meaning it stops the body's VEGF protein from forming abnormal blood vessels in the eyeball. A body with an overactive VEGF protein can form too many blood vessels in the eye, and those vessels can leak, causing vision loss.

After the FDA approval of Arcalyst and Eylea, Regeneron's sales really took off. From 2007, the year before the first approval, through 2015, revenue grew from $125 million to $4.1 billion. The compounded growth rate was 55% for that eight-year period.

In 2019, Regeneron had $7.8 billion in revenue,

and roughly 60% of that was just from Eylea. The remainder of its revenue was primarily from its collaborations with Sanofi and Bayer HealthCare, two pharmaceutical giants.

And the future revenues are going to come from REGN1979. REGN1979 is like Rituxan, but the difference is that it doesn't just bind with the CD20 protein and hope the T cells come and find it… It bonds with both the CD20 protein and the T cell. This ensures the T cells escort the mature B cells out of the body.

And as I said, results are amazing.

Relapsed Therapy

When a disease initially responds to therapy but stops responding after a period of months, we call it "relapsed." When a disease stops getting worse but remains present after a therapy or gets worse within months of the last treatment, we call it "refractory." In relapsed and refractory (the most difficult of cases) follicular lymphoma, REGN1979 had a 100% overall response rate. And in the notoriously difficult to cure large B cell lymphoma, it received a 60% response rate.

Remember, these are cancers that either came back or are difficult for other drugs to cure. And yet Regeneron's REGN1979 showed incredible response rates.

Regeneron did another study that included four people whose disease progressed after a first therapy. These four patients had CAR T cell treatments done, which is another common treatment method for NHL. But in these cases, it didn't work. But with REGN1979, two out of the four had complete responses.

The key point is that this drug has already demonstrated that it can treat previously untreatable cancer.

Stats like these are very exciting. REGN1979 has the potential to be a blockbuster like Rituxan.

And when it matches Rituxan's sales, it will double Regeneron's revenue.

This is a pivotal drug for Regeneron's future.

The FDA did put a partial hold on REGN1979 in December 2020 while waiting for further safety data, temporarily halting the enrollment of new patients. But we don't see any cause for concern with this minor delay. Regeneron has already responded to the FDA's concerns and expects the hold to be lifted later this quarter.

Still, it may be a couple years until the FDA potentially approves this drug… and a couple of years away from Regeneron earning revenue from it.

But when a drug has this much potential, we must get in before it's approved. Every positive announcement during the trials will push the stock price higher.

Regeneron's Drug Portfolio

As we saw earlier, the revenues from Eylea have been the cash cow for the company… literally. Regeneron reported over $2 billion in free cash flow for 2019. But fears of increased competition for Eylea have worried some investors.

These fears are overblown… First, Eylea has had competition from other drugs for years now. Second, the big threat of competition is coming from a drug from Novartis called Beovu that was approved in October 2019. This drug isn't as big of a threat as feared.

Beovu has shown strong efficacy – or effectiveness – on a once-every-12 weeks shot program. The results are marginally better than Eylea. But Beovu has higher rates of inflammation, immunogenicity (the effects may wear off before the next dose), and a lack of flexibility for more frequent dosing if needed.

It is going to be difficult for Novartis to crack this

well-established market with an inferior product.

It's true that sales of Eylea are likely to slow down and even decline a bit. But they won't fall off a cliff like some fear. We can expect steady and very high gross margin sales from Eylea for years to come. In Q3 2020, Eylea sales still increased 11% over the previous year.

This ensures that Regeneron will continue to generate increasing levels of free cash flow that it can use to fund clinical trials for REGN1979 and the rest of its product portfolio. And as I'm about to show you, Regeneron has two blockbuster drugs that the FDA recently approved.

Potential Blockbuster Drugs

Dupixent is the first drug. It's already approved for targeting type 2 inflammation problems. This includes atopic dermatitis, severe asthma, and chronic rhinosinusitis.

And it's already well on its way to becoming a blockbuster drug. Regeneron earned $2.32 billion for full year 2019 from sales of Dupixent. (That's roughly half of the $4.6 billion Eylea generated.)

And the drug has barely scratched the surface in terms of patient populations who could benefit from this drug. In addition to the three things it's already approved for, Regeneron is putting this drug through testing to help desensitize people to grass and peanut allergies. This way it can complete the allergy immunotherapy session and cure these allergy symptoms.

According to Bloomberg, Dupixent has "a peak estimate of $5.7 billion in five years to overtake Eylea as Regeneron's top product."

The second drug is Libtayo. This is Regeneron's first venture into oncology – the treatment of tumors. The FDA already approved Libtayo for a small type of skin cancer called cutaneous squamous cell carcinoma. And it's in trials for other cancer therapies. Combined, Libtayo is going after markets worth over $20 billion annually.

In addition to these two drugs, Regeneron has over 20 other drugs under development… any of which could end up being big.

Over the next few years, we could easily double our money on Regeneron. And if REGN1979 becomes the hit I believe it will and we see expansion in valuation multiples, we will have much more upside.

And that's not all. Regeneron is trying to help fight COVID-19. Its antibody cocktail received FDA emergency use authorization last November. Prospective Phase 2/3 results showed that REGN-COV2 significantly reduced virus levels and the need for further medical attention in non-hospitalized patients. That's great news.

This is too good of an opportunity to pass up.

Action to Take: Buy shares in Regeneron Pharmaceuticals (REGN) up to $650. We will not set a stop loss on this recommendation. As such, please be sure to position size rationally. We don't want to go "all in" on any single pick.

If this stock is trading above its recommended buy-up-to price when this research is published, we recommend readers wait for it to fall back within buy range.

Regards,

Jeff Brown
Editor, *The Near Future Report*

To contact us, call toll free Domestic/International: 1-800-681-1765, Mon-Fri: 9am-5pm ET or email memberservices@brownstoneresearch.com.