The #1 Biotech Stock of the 2020s

Why the FDA Just Fast-Track the “King of Genetic Sequencing”

By Jeff Brown
Barbara Barnes seemed to be in perfect health. The 58-year-old homemaker’s mammograms had come back clean. And she had no symptoms of any illness.

But in 2016, Barbara sequenced her genome. All it took was a sample of blood.

A genome is the entire genetic makeup of a living organism. And we can think of “sequencing” a genome like creating a map, or blueprint, of our genetic code.

Barbara’s results were concerning. She had a DNA mutation that put her at a higher risk of developing breast and ovarian cancer. Armed with this knowledge, doctors conducted further studies. They found a golf ball-sized tumor in her fallopian tubes.

Genetic sequencing technology is saving lives. And it will save millions more in the years ahead.

Today, we’re investing in the single most important company behind this trend. This company has a 70% market share in this industry. And as you’ll see shortly, this company has also been providing the technology to “blueprint” the COVID-19 virus.

Genetic Sequencing for the Masses

Welcome to The Near Future Report. I’m Jeff Brown, your editor. I have nearly 30 years of experience working at and investing in high-tech companies. With this research service, we look for stable, mid- to large-cap companies with products enabling the newest technological trends. We can think of these as “sleep well at night” stocks with great growth potential.

In the past years, we’ve covered technology trends like 5G, artificial intelligence, and cloud-based software services.

In this report, we’ll be focusing on the precision medicine trend. This is an emerging approach to treat and prevent diseases by considering each person’s genetic makeup, environment, and lifestyle.

In other words, we won’t have to wait until we
present symptoms of a disease before seeking treatment. As Barbara’s story shows, our genes can alert us to a future condition years before symptoms manifest.

And if we get sick, we won’t use a “one size fits all” approach to treat the disease. Currently, many treatments just address the symptoms, not the underlying causes. That’s because scientists haven’t had the tools needed to cure the diseases. But now precision medicine, like gene therapies and CRISPR genetic editing, will cure the underlying cause of the disease.

And as I mentioned above, the company in this report is the single most important player in the world of genetic sequencing.

Genetic tests used to be something only the rich could afford. But the cost of genetic testing has declined considerably over the past two decades.

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 these tests are so cheap even some insurance companies are starting to cover a full genome sequencing for hard-to-diagnose patients.

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.

And 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.

And some people can even get free genetic sequencing through programs like the MyCode Community Health Initiative. This program sequenced Barbara’s DNA and saved her life.

This initiative has sequenced DNA samples from over 250,000 people. Scientists hope that by sequencing and analyzing a broad number of DNA samples, they can pinpoint the DNA
mutations of certain diseases. (And the lead partner in this initiative is a company I’ll discuss later in this report, Regeneron [REGN], which helps with the sequencing efforts.)

Governments and companies around the world are collecting the full genomes of residents. The United Kingdom, Iceland, and United States all have government-backed initiatives to sequence large numbers of DNA samples from a diverse set of people.

The goal is to use this information to develop new treatments to improve the lives of anyone suffering from a genetic disease.

All these initiatives have one thing in common. They use one company’s equipment to sequence patient DNA.

That company is **Illumina (ILMN)**...

**Illumina Dominates the Industry**

Illumina is the dominant player in the industry, and its sequencing technology is the backbone of precision medicine.

According to Morningstar, Illumina has over a 70% market share of the genetic sequencing industry. And it’s estimated over 90% of all the world’s sequencing data has come from Illumina sequencers.

No company sequences more DNA than Illumina.

And Illumina’s sequencers don’t just sequence human DNA. They also can sequence the genetic makeup of viruses like COVID-19...

As we saw on the previous page, it now costs under $1,000 to sequence an entire human genome. And sequencing is about to get cheaper now that Illumina has released its new sequencer, the NextSeq 2000.

The NextSeq 2000, pictured above, will retail for $335,000. And then Illumina receives about $20 per gigabase – one billion building blocks of DNA – to sequence a genome. It’s a classic “razor and blades” model.

I know $335,000 for a sequencer may sound like a steep price to pay. But as I showed earlier, the cost to sequence just one genome used to be as high as $100 million. With Illumina’s NextSeq 2000, physicians and researchers can sequence a genome for as low as 20 gigabases... meaning the cost to sequence a genome will decline to $400 with this machine. It will get to $100 over time.

If the cost per sequence is dropping so quickly, won’t Illumina’s revenues go down? The reality is that the opposite will happen. Lower sequencing costs only drive further adoption of genetic sequencing technology, which means more sales for Illumina... and more consumables revenue, as well.

And we can see this dynamic at work by looking at Illumina’s revenues over the last 20 years. As
we saw earlier, sequencing costs have been on a rapid decline over the last two decades. But Illumina’s revenue growth and free cash flow continue to increase year after year.

As I mentioned above, at these low prices, insurance companies are covering the cost to get genomes sequenced. It’s cheaper to pay the up-front cost in the hope of being able to completely cure a disease than to continually treat symptoms for years. Illumina’s sequencers will save the health care system billions of dollars.

Doctors will sequence patients’ DNA. Then they will be able to understand which mutations are causing symptoms, and physicians can put together a plan. They’ll know if they need to use a genetic therapy, RNA treatment, preventative surgery like a mastectomy, or another appropriate treatment.

But scientists can use Illumina’s sequencers for more than just sequencing human DNA...

**Illumina Sequenced the Genome of COVID-19**

Through a technology called Next-Gen Sequencing (NGS), companies can sequence a viral genome. It didn’t take long for scientists to sequence COVID-19. By January 24, 2020, the entire genome was published in the *New England Journal of Medicine*. You guessed it... This was made possible thanks to Illumina’s technology.

Knowing the genome sequence can help scientists in many ways. Researchers can understand the origin of a virus. We can also learn the epidemiology and transmission routes and help develop diagnostic and treatment strategies. We can even understand how a virus mutates over time with each genetic sequencing.

Having a diagnostic test can help track the progression of the virus. At the Cowen Annual Health Care conference at the beginning of March 2020, Illumina’s president and CEO, Francis deSouza, addressed COVID-19 concerns and opportunities.

He said, “There will be increased use for infectious disease monitoring. In fact, I think once we get through the COVID-19, I think you will see this potentially as a catalyzing event to say we truly do need a global surveillance network that will watch for naturally occurring viruses like we’re seeing right now.”

He went on to say it was a wake-up call for the infectious disease community...

In other words, it will be necessary to track viruses like COVID-19... or even look for things like antimicrobial resistance or maybe even bioterror. This could be a catalyzing event for the company. No company is better positioned to benefit from a global initiative like this than Illumina.

And there are many other uses for its sequencing technology. Those uses include the following:

- Screening parents before conception to
ensure there are no genetic diseases that might be transferred to the child

- Replacing amniocentesis for a prenatal test
- Immuno-oncology
- Therapeutic selection
- Data storage (yes, there is technology to enable us to store data on DNA!)
- Diagnosis of rare genetic diseases
- Embryo selection in IVF
- Oil and gas exploration

We will see explosive growth in these new applications because of the rapid increase in the speed of sequencing and the dramatic drop in the cost per sequence.

And this is a great time to get into Illumina...

In June 2020, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) to Illumina for the first COVID-19 diagnostic test utilizing its next-generation sequence technology. This is the sequencing that can determine the genetic sequence of a virus and help scientists understand if and how viruses mutate.

The FDA realized how critical Illumina’s technology was during the health care crisis. The EUA sped up the company’s ability to put its technology to work. We’ve been able to use this technology now rather than waiting months or years for it to go through the entire approval process. This shows the confidence the FDA has in Illumina’s work.

We want to make sure to build our position in this top biotech stock now. I expect Illumina will beat everyone’s expectations going forward.

**Action to Take:** For our current buy-up-to price for Illumina (ILMN), please see our [online model portfolio](#). At this time, we will not set a stop loss for this position. As such, let’s make sure to position size rationally. We don’t want to go “all in” on any single recommendation.

**Note:** My mission is to find the best technology companies trading at an attractive valuation. If this stock is trading above our recommended buy-up-to price, it means it is slightly higher than what I consider an excellent entry point. Technology stocks have natural volatility, and we almost always have an opportunity to establish a position at a great valuation.

That said, Illumina has great long-term prospects. If subscribers would like to begin building a position today, we could consider establishing a 25% position now and wait to complete our position at a later date.

As an example, if a reader would like to deploy $10,000 to this investment, we could invest $2,500 today and fill the rest of our position in the event of a pullback or a raise in the buy-up-to price.

If this stock is trading at or below our recommended buy-up-to price, then it means I consider it a good entry for a full position.

And remember, I’m constantly monitoring our portfolio. If I feel it’s appropriate to raise our recommended buy-up-to price, I’ll always notify readers.

**Bonus Pick: A Second Explosive Biotech Pick**

While Illumina may be my No. 1 biotech pick for
The Near Future Report, other companies are also revolutionizing the biotechnology industry. As a special bonus for my readers, I want to share a second biotech recommendation that we should be sure not to miss... It’s possible that this explosive stock could even top my first pick one day.

Let’s start off with some history...

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 bonus company is much bigger than IDEC was back in 1998. In 2020, it reported $8.5 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

As I mentioned above, precision medicine is an emerging approach to treat and prevent diseases by considering each person’s genes, environment, and lifestyle.

In other words, we won’t always have to wait until we present symptoms of a disease before we seek treatment. Our genes can alert us to a future condition years before symptoms manifest. This means we, as patients, will be able to proactively treat ourselves before those symptoms even exist.

And if we happen to get sick, we won’t use a “one size fits all” approach to treating the disease. Instead, with precision medicine, we will be treated with a personalized therapy designed specifically for us.

One of the biggest technologies enabling this trend is genetic sequencing. Think of genetic sequencing as creating a “blueprint” for an organism’s genetic material. Advances in technology have sent the costs to sequence a genome plummeting in recent years.

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. 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 the disease.

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

To the right, 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 bonus recommendation 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.

IDEC/Biogen’s Rituxan works much the same 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**

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 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 2020, Regeneron had $8.5 billion in revenue, and roughly 58% 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 when it 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 soon.

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 2020. 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.

This ensures that Regeneron will continue to generate increasing levels of free cash flow that it can use to fund both 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. Worldwide, sales of Dupixent reached over $4 billion in 2020. (That’s roughly half of the nearly $8 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.

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. Much like Illumina, Regeneron is trying to help fight COVID-19. Its antibody cocktail received FDA emergency use authorization last November. That’s great news.

This is too good of an opportunity to pass up.

**Action to Take:** For our current buy-up-to price for Regeneron Pharmaceuticals (REGN), please see our online model portfolio. 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*