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# Nevro Corp. **NVRO - \$156.75 - NYSE**

### **Recommendation: Sell Short**

#### Reasons For Short Sale Recommendation

- Insanely expensive, 14 x sales.
- Unprofitable for 9 straight years, soon to be 11 straight years.
- One product company, with a questionable product.
- New competitor with a better product to take major market share away.
- Small number of doctors perform the bulk of the implants.
- Top implant doctors paid "speaking fees", illegal bribes in our opinion.
- Insurance companies wising up, starting to refuse coverage.
- One state (Washington) has banned payments, more to come?
- Turnaround CEO hasn't/can't/won't turn it around for a quick sale.
- Product could be recalled, many injuries reported.
- Between 30% to 80% of implants need to be removed (explanted)!
- New product repudiates the old product?
- NVRO reps perform unauthorized practice of medicine.
- Little direct evidence/studies that these products even work (snake oil)?
- Has to continually issue debt and equity to survive.
- Much larger competitors, Medtronic, Abbott's, Boston Scientific, and St. Judes.
- NVRO valued at several times those competitors combined SCS sales, with only 15%+ of the market?
- Global SCS market is about \$2.5 billion, NVRO market cap is \$5.4 billion?



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### **Financials**

Market Capitalization	\$5.4B	Revenue/Shr (TTM)	\$10.56
Enterprise Value	\$4.99B	EBITDA (TTM)	-\$57.7M
Trailing P/E	N/A	Diluted Earnings/Shr	<mark>-\$2.55</mark>
		<mark>mrq)</mark>	
Forward P/E	N/A	Total Cash (MRQ)	\$576.43M
PEG ratio (5 Yr Expected)	N/A	Total Cash/Shr (mrq)	\$16.58
Price/Sales (TTM)	<mark>14.26</mark>	Total Debt (MRQ)	\$334.7M
Price/ Book (MRQ)	14.3	Current Ratio (MRQ)	3
Enterprise Value/Revenue	13.75	Book Value/Share (MRQ)	\$10.56
Enterprise Value/ EBITDA	-93.80%	<b>Operating cash Flow (TTM)</b>	-\$499 <b>K</b>
Profit Margin %	_	Levered Free Cash	6.66MM
	24.16%	Flow(TTM)	
Operating Margin (TTM)	-17.15%	52 Week Change	16.71%
Return on Assets (TTM)	-6.30%	Shares Short	2.81M
Return on Equity (TTM)	-30.19%	% of Float Short	10.62%
Revenue (TTM)	\$363.19M	Short Ratio	4.85

(TTM) = Trailing 12 months, (MRQ) = Most recent quarter, M = Millions, B = Billions, m = Thousands



**Report Date:** June 11, 2021 TomChanos@BadgerConsultantsLLC.com

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# What they do

Nevro is a one product company, it offers a **Spinal Cord Stimulator (SCS)**. This technology is not new. It has been around sine the 1960's. These products are used as a last ditch option to relieve chronic pain in patients after all else (drugs, physical therapy, surgery, etc...) has failed.

The product is a surgically implanted battery operated electric stimulator that delivers an electric current through electrodes that are attached to the spine. These electric currents are supposed to eliminate the pain the patient experiences in a certain area, hip, knee, foot, back, etc. It depends where you implant the electrodes on the spine to cover a certain area of the body for pain relief.

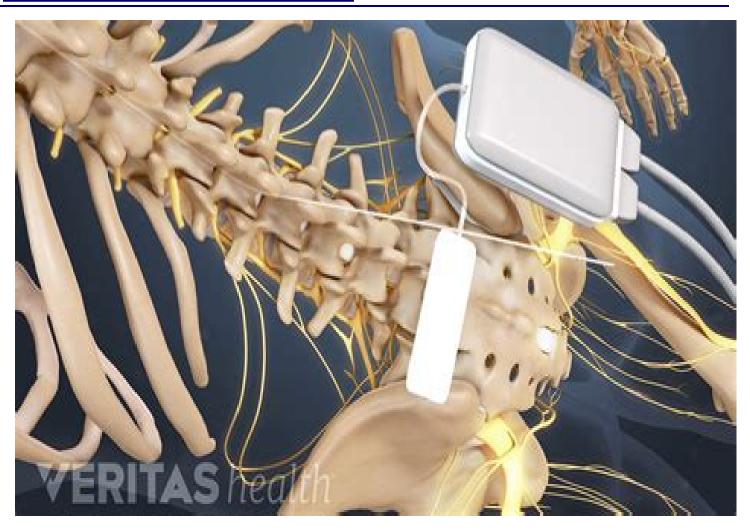
It is questionable whether the technology eliminates pain, or just masks it with a tingling sensation instead. There are few scientific studies that prove this technology actually works. Most studies are from the companies that make the devices themselves, that surprise, show that they work.

These devices cost between \$20-\$30K. Insurance companies are starting to wise up to this expensive treatment option and are beginning to deny more and more procedures. One state has outright banned coverage of SCS. We believe that this has opened the door for more and more states, insurance companies, and Medicare to refuse coverage. Needless to say this would be fatal to NVRO's business model.

All you need to know about SCS: What is SCS



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**NVRO** entered the US SCS market in 2015 with a "new and improved" product. Until then, most traditional SCS were low frequency (1kHz) models. NVRO claimed that their "high frequency" (10kHz) product was far superior to the low frequency models. They even claimed, for years, that the low frequency does not even work for pain relief. More on this later, (their "new product" uses low frequency)!

The product was called Senza, and was patented as HF10 technology, claiming that frequencies above 5kHz were far better at pain relief and that their study showed this to be true. For years, decades, this market had basically no innovation. The traditional SCS products did not work very well, so along came NVRO with a new and improved product and (some) doctors flocked to it, and



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NVRO quickly went from zero market share to above 15 percent. Much larger competitors were caught completely off guard. Now, when we say doctors all flocked to it, what is really happening is a small number of doctors that do the bulk of these procedures, all flocked to it. This is important, because if a new competitor comes along with a new and improved product, these same doctors could all flock to it, severely hampering NVRO sales. This is exactly what is about to happen. There is a new competitor with a new product.

### Launch

NVRO went public in November 2014 at \$18 per share. The Senza, high frequency device was launched in the middle of 2015. The product was an immediate hit for a couple of reasons. First, as NVRO says, low frequency does not work. Second, this gave doctors a legitimate reason to try the **Senza**. The patient was getting no pain relief from the other implanted traditional SCS, so now they could tell the patient that there is a "new" technology with promising results (according to NVRO) worth trying. Most patients with chronic pain, are willing to try anything. It doesn't hurt that the doctor gets to bill for a new procedure as well. Third, NVRO was smart and went out and recruited SCS salespeople from their competitors. These sales people could smell a huge opportunity going through their rolodex and pitching all the doctors with a new promising technology in a formerly slow mundane business. Sales went from \$70 million to \$327 million in 2017. The stock went to over \$100.

However, sales soon stopped zooming upward and by late 2017 went flat after only two years! The then CEO, blamed a slowdown in the overall SCS market, nothing company specific. The stock crashed 70% into the \$30's. The CEO was fired in March 2019, and replaced by "turnaround" expert Keith Grossman, a long time medical device executive. The new CEO blamed the slowdown, not on the overall market, but on "execution issues" from the former CEO. The market was fine he said. He blamed large numbers of



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poorly trained salespeople, high churn, not focusing on trials, Senza pricing missteps and lastly the high frequency only was alienating some customers! Wall street responded by upgrading the stock and assuming NVRO would return to to the hyper growth stage and possibly be bought out at a nice premium.

However, the large number of sales people were the top salespeople that they poached from their competitors? Suddenly these people can't sell the best product that is twice as effective as low frequency competitor products? Why was their a high churn rate in the sales force after the sales took off and then stalled? There was no new product from a competitor.

The reason is simple and logical. **The product DOES NOT WORK** as advertised, or at all, according to former sales reps, employees and doctors. After 6 months, doctors and reps started to notice that the implants were not working compared to the expected outcomes from the trials. After 18 months, not only were they not working, but many of them had to be REMOVED (explanted)! The company blamed the reps, that they missed something? What? Don't reps just sell the units to the doctors? Nope. The reps have to dial in the algorithm (program) on the unit for EACH patient, depending on what area is experiencing pain. They must be doing something wrong, according to the company, because they have data that shows the product works. **But wait,** that sounds like the rep is practicing medicine without a license. That is illegal.

Despite the reps trying all sorts of times to dial in the correct setting, nothing worked. It wasn't long before the reps talking amongst themselves, all figured out the same thing. The product didn't work and worse sometimes caused lots of problems.

After two years of selling a product that did not work, many sales reps left the company. Hence, the high churn rate. Many of these reps become friends with these doctors and could not knowingly deceive them, knowing that they were selling them something like "snake oil"



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### **Product drawback**

One drawback of the high frequency SCS is that it uses more energy. The patient has to Re-charge the unit once a day for 30 to 45 minutes! EVERY DAY! This re-charging can cause heating at the site and cause infections.

Since the product wasn't working, many patients got tired of re-charging every day, risking infections and they would get frustrated and just have the device explanted. One doctor implanted 13 devices and had to remove 10 of them within one year. According to our research, many doctors came to the same conclusion: The device seemed to work at first, but after 6 months there was no pain relief and the pain returned. Patients do not want to have to re-charge for 30-45 minutes every day for no reason. They demanded that their doctor remove the device. The explant rate that was experienced by doctors was between 30% to 80%! With many doctors at 70-80%. One doctor implanted 90 Senza's, after one year, only 2 still had them implanted.

Many doctors stopped implanting the devices. Hence, the stalled revenue. Many doctors started to compare notes, and they all had similar experiences. The product seemed to work at first but then stopped working and the pain returned and they were forced to remove the device.

However, some doctors were unaware the device was not working. This was because the follow-up care after the implant was handled by the NVRO rep. Many of these reps would just lie to the doctor and say everything was working. So, some of the doctors kept on implanting the devices assuming all was well. But soon, the story started to leak out and the doctors that actually followed up with their patients discovered it was not working, and that the rep had lied to them about it. This caused even more doctors to avoid the Senza unit.

Isn't the rep handing all the follow up care practicing medicine without a license? In our opinion, yes. It is illegal in Europe for the rep to program the machine. In the U.S. the rep usually does it, because it is very time consuming.



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Another SenZa drawback is that the product is "paresthesia-free", as there is no "tingling" sensation with the high frequency Senza unit as there is with competitors low frequency units. This at first seems like a product benefit, but what happens in the real world, is that the patient does not know if it is working or not. With the tingling sensation with the low frequency unit, the patient knows it is turned on and working, maybe not eliminating all the pain, but they know the unit is powered on and operating. With the Senza unit, the patient has no idea if it is working or not, and when the pain returns after a few months, many think the unit has malfunctioned. It hasn't, it just doesn't work as advertised.

## The SENZA-RCT Study

Before the Senza rollout, NVRO conducted a "landmark, first pivotal RCT in the history of SCS and the ONLY randomized study with a head to head comparison of SCS systems". - NVRO IPO prospectus.

The study found that NVRO's HF10 "was nearly twice as successful" for back pain and 1.5 times for leg pain over traditional SCS at 3 months.

Only, the **study was a sham**. It was **not randomized**, and ended at 3 months. Then NVRO claimed that the data showed tremendous, ongoing reduction in back at leg pain at the one year and two year mark versus traditional low **frequency SCS**. It was this study that green lighted the IPO and FDA approval.

The patients involved in the study knew which implant they were getting. It was **not a double-blind study**. If the patient was aware that they were getting an older technology, not the "new" technology, it is reasonable to assume that they would claim little to no improvement, while the patients that knew they were getting the "new" technology would claim better results. That is just human nature, and that is why you need to do double-blind studies, where the patients do not know which unit they are getting. Also, the patient had to



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describe on a scale of one to ten their pain level, with coaching from NVRO reps.

The problem was, this study was done in 2014. In 2010, NVRO used the HF10 unit in Europe. Doctors there after years of actual patient results found nowhere near the level of pain relief that NVRO was now claiming. One doctor called it "a meaningless gimmick".

In addition, the patients "chosen" for the study were not random either. NVRO hand picked each one, using criteria that was not the same as real world back pain patients. For instance, they ruled out anyone with more than one back surgery, any workers comp patients, prior spinal cord stimulation, significant opioid use, etc... The study was rigged to show the best possible outcome for **NVRO!** NVRO reps in the follow up care would ask leading questions to try and get the patient to claim 50% pain reduction. High frequency is just a marketing ruse!

What doctors in the real world found out is that **high frequency is actually** worse for the patient. The HF10 over a short period of time puts too much current on the spine leading to faster tolerance and less effective treatment than traditional low frequency SCS.

# **PROCO Study 2017**

In 2018 a study was presented at the annual NANS conference (North American Neuromodulation Society. It demonstrated that 1, 4, 7 & 10kHz frequencies all "provided equal pain relief". In addition, their study was a double-blind for both patients and doctors. This study also had a lot to do with the flatlining of NVRO's revenue. Not only were doctors not seeing results with actual patients, now there was a real study that showed why.

So, not only were doctors finding out that the HF10 was not working any better, and there was a study to prove it, the devices limitations made it not worthwhile



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to implant. The battery pack was far larger than competitors, it required far more recharging and far more reprogramming by NVRO reps in the doctors office. They need a lot more reps to support the doctors, a poor business model.

Compare this to Abbott's unit where the battery lasts 5-7 years! Patients at first don't realize what a pain in the ass it is to have to charge the battery EVERY DAY! After 6 months they get tired of it. When they find out that there is an alternative with the same results that requires far less charging, they ask their doctor why they didn't use that one in the first place? Many doctors are switching away from NVRO.

# Another drawback with HF10 being "paresthesia-free, is pain mapping.

Traditional low frequency stimulators are implanted with the patient awake. The doctor moves the stimulator leads along the spine until the patient feels the tingling in the area that they are experiencing pain. With the HF10 there is no tingling so the patient can not always tell if the leads are in the correct spot along the spine to affect the area of pain. Turns out, that doctors and patients prefer the tingling sensation. This is one of the reason that the HF10 needs so much reprogramming by the reps after implantation. It was common for the patient to have dozens of reprogramming sessions. There was a lot of frustration on the part of the patient and the rep, who was spending hours and hours reprogramming on one patient. This was another reason for reps quitting. The company kept claiming that the product works, but the reps were having a hard time actually making it work.

In addition, it wasn't long before the competition came out with their own "paresthesia-free" devices. Boston Scientific has Wavewriter and Abbot has Burst DR. So, NVRO no longer has any advantage here.



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# **DeAndre study 2017**

In 2017 DeAndre did a blinded outcomes assessment with Nevro to Medtronic. They eliminated investigator bias, and had equal programming time. The study showed that there was **no difference between NVRO**"s HF10 and Medtronic.

A third study by a group of doctors compared high frequency stimulation in one arm, while the patients other arm had the same high frequency stimulator, only it wasn't turned on! There was no difference in 33 out of 40 patients that they had all the data for. In other words, **no better than a placebo!** 

## **Explants**

We know that in the real world, doctors are finding out that the HF10 does not work, real studies have shown that it doesn't work any better than low frequency devices. Many doctors are claiming high explant rates of at least 30% to **80%.** 

**NVRO claims that only 3.7% of their devices are explanted**. This is laughable.

Their 3.7% explant rate is **based on a study of 8 unnamed clinics**. The study was done by a medical writer for Nevro, Dr. Deborah Edgar. In addition, 10 of the doctors are "consultants" to Nevro and 3 others are employees of Nevro. This is another sham study as it also only looked at timeframes of 3, 6 and 12 months by biased authors/doctors, compensated by NVRO. A paper presented at the January 2020 NANS conference found explant rates of 22% within 2 vears and 33% within 3 years. They said "results of Nevro's SENZA study differ greatly from the results we have found in the real world". Many doctors say that even the 33% explant rate is underestimated, because some patients just turn the device off and don't want to go back to have it removed. One competitor claimed that his biggest clinic that he sells to refuses to use NVRO because they had an 80% explant rate. Another Medtronic manager said he had a doctor implant 25 HF10's and had to remove all of them.



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Another doctor said "The 33% explant rate for Nevro devices in the NANS paper is definitely low. It's significantly higher. Patients hate the Nevro device. That thing is a piece of shit. The explant rate could easily be 50-60%. It definitely doesn't work much more often than it does 6-12 months out. The high frequency is causing the nerves to become hypersensitive. The company just lies. They're full of it."

Another doctor said "For a while we all believed we had to have high frequency, like it was the holy grail. I'm not sure if it was just a placebo effect at the beginning with high frequency, because patients liked the idea of new technology. I don't expect device failure in the first 6 or 12 months. Nevro bragged about their 24 month success rate. I was dismayed after I got 3 to 4 failures within the first 2 to 3 months. I had never had that before."

Some doctors don't even know that the device failed because the rep does all the follow up care and does not tell the doctor and many of these patients go to a different doctor to have the device removed.

# **High volume Implanters**

So, after the Senza-RCT study and the HF10 launch in 2015, the honeymoon is over and by 2019 sales growth goes to near zero. Many of the high volume implanters started to switch to competitors devices. One doctor that can do over 100 implants per year can bring in \$2.5 -\$3.5 million, so it only takes 100 high volume doctors to account for 90% of the sales. However, NVRO is a one trick pony and now all the competitors have similar devices. So, when HF10 was launched, NVRO took the top sales reps from the competition and got the high volume implanters, but as the results failed, and the competitors woke up and refreshed their devices, many of these reps and doctors went back to the competition. If the device does not work, why do some doctors still implant **NVRO's HF10?** 



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# **Kickbacks To High Volume Implanters**

If it wasn't for payments made to doctors by NVRO for "consultants" or speaking fees, we believe that NVRO's sales would have collapsed not just stalled. Insys executives and high volume prescribers (of Fentanyl) went to prison for kickbacks disguised as Insys Speakers Bureau (speaking fees). In other words, doctors received speaker fees when they were really fees for prescribing Fentanyl. We believe NVRO is doing the same thing, giving doctors higher speaker fees the more implants they do. **Is it a coincidence that** the top 3 NVRO implanters are the 3 highest paid speakers? The number 5 implanter is the number 5 highest paid speaker (Kasra Amirdelfan, Leonardo Kapural, Sean U, Daywood Sayed) source: CMS Open payments.

After the Insys scandal, the US Department of Justice Office of the Inspector General issued a **Special Fraud Alert on November 16, 2020** that highlights the fraud and abuse risks associated with speaker fee programs by pharmaceutical and medical device companies." Speaker fraud

#### The Anti-Kickback Statute

Congress enacted the anti-kickback statute, in part, to protect patients from referrals or recommendations by HCPs who may be influenced by inappropriate financial incentives. The anti-kickback statute makes it a criminal offense to knowingly and willfully solicit, receive, offer, or pay any remuneration to induce or reward, among other things, referrals for, or orders of, items or services reimbursable by a Federal health care program.

When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. For purposes of the anti-kickback statute, the offer, payment, solicitation, or receipt of "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. By its terms, the statute ascribes criminal liability to all parties to an impermissible "kickback" transaction (i.e., those who solicit or receive prohibited remuneration as well as those who offer or pay the prohibited remuneration). Violation of the statute is a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Criminal conviction will also lead to mandatory exclusion from Federal health care programs, including Medicare and Medicaid



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### III. Fraud and Abuse Risks of Speaker Programs

Numerous investigations have involved allegations that drug and device companies organize and pay for speaker programs with the intent to induce HCPs to prescribe or order (or recommend the prescription or ordering of) the companies' products. Speaker programs typically involve an HCP who is not an employee of the company speaking in person to other HCPs about a company product or disease state using a presentation developed and approved by the company.

OIG is skeptical about the educational value of such programs. Our investigations have revealed that, often, HCPs receive generous compensation to speak at programs offered under circumstances that are not conducive to learning or to speak to audience members who have no legitimate reason to attend. Such cases strongly suggest that one purpose of the remuneration to the HCP speaker and attendees is to induce or reward referrals. Furthermore, studies have shown that HCPs who receive remuneration from a company are more likely to prescribe or order that company's products.

HCPs may skew their clinical decision making in favor of their own and the company's financial interests, rather than the patient's best interests.

Parties involved in speaker programs may be subject to increased scrutiny. These include any drug or device company that organizes or pays remuneration associated with the program, any **HCP who is paid to speak**, and any HCP attendees who receive remuneration from the company (e.g., free food and drink). **OIG has long expressed concerns** over the practice of drug and device companies providing anything of value to HCPs in a position to make or influence referrals to such companies' products.

OIG identified manufacturer compensation relationships with physicians connected directly or indirectly to marketing and sales activities, **including speaking activities, as an area of potential** risk under the anti-kickback statute.

We see "general payments" to doctors of about \$3.5 million per year. This is mostly the speakers program. Former employees and doctors describe NVRO's speaker fee program as "pay to play", where high volume implanters will only use your device if you pay them. Other comments were: kickback, throw money at you, reward system, etc...

In Europe, NVRO paid doctors \$10,000 per device implanted. This kickback scheme started in 2017 and was terminated by the company. It is unclear if

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NVRO will be prosecuted for this blatant kickback scheme, but if they are the penalties can be in the hundreds of millions of dollars range.



Source: NVRO doctor payments

# Some of these doctors were getting \$15-20K PER SPEECH!

How is this any different from the executives and doctors that went to prison for the same type of speaker fees in exchange for product use at Insys?



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#### Now What?

NVRO has spent years telling everyone that their high frequency stimulator worked twice as well as traditional low frequency devices. Then their competition came up with their own high frequency devices. What is NVRO to do now? Well, come up with a new device that does both low and high **frequency** of course!

On November 5, 2020 CEO Keith Grossman announced the new product, the Omnia spinal cord stimulator. This would result in the turnaround that the street was expecting. But wait, didn't you just spend years saying that high frequency works twice as good as low frequency? Why, yes you did, it is right there in your 2020 10K: "Our proprietary paresthesia-free HF10 therapy, delivered by our Senza system, was demonstrated in our SENZA-RCT study to be superior to traditional SCS therapy, with HF10 therapy being nearly twice as successful in treating back pain and 1.5 times as successful in treating leg pain when compared to traditional SCS therapy."

"Traditional SCS therapy generates paresthesia, a sensation typically experienced as tingling, numbness and buzzing, which overlaps the pain area. Paresthesia is often considered unpleasant or uncomfortable[...] We believe the ability of HF10 therapy to deliver pain relief without paresthesia provides a substantial benefit over traditional SCS therapy to patients and physicians."

"Traditional SCS therapy is a long-established pain treatment that utilizes low frequency stimulation, typically between 40 Hz and 60 Hz (therapeutic pulses per second), to induce paresthesia that overlaps the distribution of pain with the intent of masking pain perception. Paresthesia is often considered unpleasant or uncomfortable, sometimes causes a shocking or jolting sensation with changes in posture and is a continuous reminder of the patient's chronic condition [...]Our HF10 therapy is designed to overcome many of the limitations of traditional SCS therapy, offering benefits to patients, physicians and hospitals."

So, never mind what we have been saying for years, we now have a new device that will also do low frequency even though we already told you that it doesn't work as good? Huh? This is desperation. They are a one product



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company, with a product that does not work. So, come up with a new product that directly contradicts everything that you said was good about your only product?

Turns out, even the company NVRO is still not sold on low frequency because CEO Grossman admitted that the Omnia is programmed for high frequency 85-90% of the time! In other words this is a desperate ploy to come up with anything and hope for a miracle. Basically, the Omnia is just another high frequency stimulator like the HF10.

Another doctor said "Abbott came out with a device you don't ever have to recharge for 10 years, or you implant Medtronic and it's MRI compatible. If the high frequency doesn't work, why would you use their low frequency device over someone else's? Nevro's entire campaign at launch was about how much better they were than low frequency, but now they're using low frequency to salvage themselves."

Another doctor correctly points out "It wasn't the best idea because it lets the competition undermine the high frequency technology that Nevro was built for. The competition is obviously saying, if high frequency wasn't a dud then why did they build Omnia? Because Nevro knows that high frequency doesn't work. It muddies the waters."

## **Another Dud Product?**

The Omnia is basically a high frequency stimulator. Why, because the leads are placed higher up on the spine, at vertebrates (T9/T10). But for low frequency, you need to place the leads lower down on the spine at vertebrates (T7/T8). So, the whole premise that the Omnia is something new and exciting is laughable and smacks of a company in desperation mode. With the leads placed high on the spine the low frequency is irrelevant! Wait, what? The Omnia is a "one system, all frequencies unit, but different frequencies require different lead placement making their one lead placement nonsensical!



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One doctor said "Omnia is just Nevro's old high device with different packaging: the handheld controller used by patients to adjust the stimulator is still tailored for high frequency and doesn't allow the proper adjustments for lower frequency stimulation.

# Painful Diabetic Neuropathy (PDN)

The bull case besides the dud Omnia is to branch into PDN with its high frequency stimulator. The company is looking for a 2021 second half launch.

As one doctor said "I don't know how they're going to do both high frequency and paresthesia (low frequency) with Omnia. In fact, I think they're lying. I think if you're going to go for PDN, you can't be in the T9/T10 spot. You're going to have to be somewhere else, which means that now you can't do the high frequency.

Once again this is not new technology. Doctors have been using stimulators for PDN since the 1980's. PDN is mostly in the lower limbs and feet. **It is almost** impossible to treat this with high frequency placed high on the spine.

One doctor stated "For diabetic neuropathy, Abbotts DRG is 100 times better than any other neuromodulation system. Without question. Nevro has one size fits all. It's not even a question — **DRG** is the answer, at least anything neuromodulation--related for neuropathy. At least with DRG you are going to have increased blood flow because it's a real system.

So, NVRO saying that they are doing both high frequency and PDN is nonsensical, the leads have to be in different spots. Getting stimulation to the foot is very difficult. It needs to be paresthesia by trial and error util the patient can feel the tingling in their foot, but the Omnia is high frequency without paresthesia with the leads up too high on the spine. This will never work for PDN.



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Also, the PDN client is different. Vascular surgeons hold on to their patients. A diabeteologist or endocrinologist is not going to refer their patient to a pain doctor. They feel that they can manage the patient themselves.

The PDN patient is almost all Medicare/Medicaid. They are not good commercial pay patients. They lack commercial insurance. Also, even if NVRO obtains approval for PDN, Medicare and other insurers would apply it to all other stimulators, not just NVRO. So, NVRO would not get the entire market share.

# Non-Surgical Refractory Back Pain (NSRBP)

NSRBP is another area that NVRO is targeting as a potential market opportunity. According to doctors, it is not realistic opportunity, as **insurance** companies will never allow a \$25,000 stimulator as a first line of treatment. SCS are a last line of treatment AFTER all other measures have been tried first. Another doctor said "Non-surgical back treatment will not be a big market for any stimulator company."

# Insurance companies cracking down on approvals

Many doctors, in fact most of them have said that it has never been more difficult to get stimulators approved for any treatment, much less NSRBP. Commercial insurers and the government are starting to realize that SCS are an expensive treatment with little evidence of long-term pain relief. One state has **ELIMINATED coverage for SCS completely!** 



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The state of Washington did a study in 2018. The study found:

- Complications ranged from 8 to 100%.
- Short-term device complications requiring revision ranged from 25% to 38%.
- Long-term device complications ranged from 42% to 60%.
- 54% of patients required battery replacement.
- Limited evidence overall of important patient outcomes.
- No evidence of longer term improvement for all outcomes.
- Significant risks, 33% revision and high removal rates.

The study concluded that with little evidence from previous studies on SCS and their study, that at best, weak evidence exists that SCS may provide temporary improvement in pain in some patients, but there is no evidence of mid or long term pain improvement.

This elimination of insurance coverage for SCS is a potential fatal development to NVRO. They are a one product company. If insurers won't cover the cost, they are out of business. The only thing worse that could happen is if other states and the government starts to deny coverage. Oh, wait...

California now requires a prior authorization, and workers comp only allows stimulators for Complex Regional Pain Syndrome (CRPS) and nothing else. The state of **Oregon** did a 6 year review of SCS outcomes and found little impact in reducing pain or opioid use, and found that 50% of patients needed revision surgery or device removal within about one year.

Some states are using American College of Occupational and Environmental guidelines. Those states are now refusing to cover stimulation. Once insurers and states deny coverage, it will spread to other states and insurers will refuse to pay. One doctor explained that the upfront cost is so high, at least \$25,000, that insurers will not recoup their cost for 5 years. If a patient is over 60, then goes



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on Medicare, the insurer will not recoup their cost. He said it is next to impossible to get anyone over 60 yers old approved now. **Doctors are now** seeing 50% of implants denied and it is getting worse. Some doctors have stopped implanting stimulators because it is not worth the trouble. Half of their claims get denied, there is little profit in it to the doctor, the surgery center has to shell out tens of thousands of dollars for the stimulators, they have to spend hours wresting with the insurers, it is just no longer financially worthwhile to do it. And to top it off, the situation is getting worse not better for denial of coverage. It is hard to see how NVRO can grow in this environment. The doctor that got Washington to eliminate workers comp reimbursement is now doing the same in California. Many doctors expect California to cut reimbursement rates, like they did with stimulator leads.

Many doctors and competitors say that the **normalized CMS market**, ex-Covid grows at about 3-5% per year. They say it is not high single digits or in the teens. A Medtronic manager said some of their doctors implants are down 30-40% after the doctors received a cannabis license.

# **Opioid Crisis**

Wall street is under the mistaken belief that the opioid epidemic in the U.S. will benefit NVRO. As states crack down on doctors prescribing opioids, NVRO will benefit because the SCS will be the only thing left to use. This sounds plausible but in the real world the opioid problem led to an increase in SCS. What happens is, that there a lots of sketchy pain clinics where patients go in search of opioids for their "pain". The doctor then has a whole new bunch of patients that can be pushed to use stimulators. The doctors can threaten to cut off the opioid prescription unless the patient agrees to a SCS trial or an implant. These patients are addicts and will basically do anything to get their fix. But with states cracking down on opioids, there are LESS patients now going to these pain clinics. So, there are less potential patients for SCS. **Doctors in** Florida have seen 50% reductions in SCS implants after Florida cracked



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**down** on opioids. Now, virtually every state and the federal government has cracked down on opioid prescriptions. And the number of opioid prescriptions a doctor prescribes is now monitored. When you had thousands of patients looking for opioids, a doctor could convert a good percentage of them to SCS. But now there are far less patients going to these pain clinics in the first place, knowing that they won't get an opioid prescription anymore, so less chance to convert them to SCS.

### **Trials**

CEO Grossman has talked about the **importance of increasing trials**. Insurers require that a patient undergo a trial period of a few days to a week or two before coverage is approved. The patient is outfitted with an external unit with leads attached externally. If the patient experiences at least a 50% reduction in pain, the insurer may cover the implant. This is the new scam.

Reimbursement rates for trials are very lucrative versus permanent **implants**. So, some doctors push patients into trials whether they need them or not and the rep wants to get as many of those trial patients converted to implants because that is how they are compensated. This leads to pressuring patients and overuse. An audit by Medicare is a highly likely outcome.

Before the patient can get a trial they are required to undergo a psychiatric evaluation. Many of these patients are looking at a SCS as a last resort. They have suffered with chronic pain for years, have had multiple surgeries, have used opioids and many are not mentally stable or good candidates for SCS. NVRO reps game the results of the examination, resulting in a near 100% pass rate, when the actual pass rate should be closer to 33%.

At these sketchy pain clinics, doctors would get \$1,000 to \$2,000 PER LEAD, so the doctor would put in 4 leads. Many times the doctor had no intention of ever doing an permanent implant. It was all about pumping bodies through.



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Some doctors have described this as straight out fraud. Medicare did not require an authorization so some doctors abuse the system and pump patients through, sometimes a dozen a day, to get paid by the lead, and never implant a permanent SCS. After that, the rep would take over and try an convince the patient that their pain relief was 50% and steer them to a doctor for an implant.

Doctors make more money (\$5,000 to \$8,000) doing a trial than a couple of hundred to couple of thousand for an implant. The government used to reimburse per electrode, so Boston Scientific came up with a 16 electrode lead! The government got wise and changed the reimbursement by lead not electrode.

Most of NVRO implants are done at doctor-owned ambulatory surgery centers (ACS's) rather than at hospitals. The incentive to push patients into trials is high and ripe for fraud and abuse. Doctors "always make money on trials". For implanted devices it is hit or miss depending on the payor. With private insurers, workman's comp or Medicare, the hospital will break even at best.

So, some doctors actually abandon the patient after the trial, knowing that they won't make any money on a permanent implant. Then the patient goes somewhere else to get the implant but the doctor/hospital does not want to do the procedure.

NVRO supplies leads for trials to doctors at very low prices \$100-\$500 per lead. Medicare reimburses a ASC \$4,686 per lead for a trial. So, the doctor puts in 2 leads, they can earn almost \$10,000 per trial, more than enough to offset making little to nothing on an implant.

# Repeat business from a permanent implant-Yes

A former NVRO rep estimates that 25-50% of NVRO revenue come from ASC's pushing patients into one stimulator, then another, then another. By changing the battery the doctor can earn another fee. That SCS didn't work for



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you? Lets try this new one, it is high frequency, maybe it will work better than your low frequency one. Studies show it to be very promising...

Repeated removals and implants at the same site can lead to infections and complications. Opening up the implant site automatically makes it not MRIcompatible, and most of these patients need MRI's. One doctor reportedly earned more than \$6 million in one year just by removing and implanting new stimulators. Some times Medicare will pay for the explant AND the new implant!

### **Price War**

After the launch of the Senza in 2015, the previous CEO kept prices high. But as sales growth started to slow, NVRO began cutting prices in 2Q18. They cut prices to stuff the channel. Once a company starts cutting prices, accounts get used to it and demand it. Then the competitor has to match it and the downward spiral in pricing begins. The new CEO Grossman also cut prices aggressively to gain market share. Their price was too high for ASC's. The Omnia pricing was too high. Then Medtronic cut prices by 20%, only to be undercut by Abbott. The problem also with cutting prices is that it lowers reimbursement rates as well.

After Covid, revenue starved surgery centers will be looking for even more price cuts. The market is dependent on a small number of high volume ASC's. The ASC's have very little loyalty and will be looking for the best deals. According to one high volume doctor, he was paying in the mid to high \$20,000's for NVRO. He is now paying in the upper teens for the same product.

ASC's account for over 70% of NVRO revenue. These ASC's are doctor owned which means that price cuts go right down to their bottom line. If you are a doctor at your own ASC, and you do 100 implants per year, a \$5,000 price cut, puts \$500,000 straight into your pocket. Since there is little differentiation



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of the product, do you actually care which one you use, or do you go with the cheapest one? There are only a couple of hundred major players that all the SCS companies are fighting over. Basically, price is the only difference. Once a doctor gets a price cut of a few thousand dollars from NVRO, he/she doesn't want to go back to paying the previous higher price. Then of course a competitor will match or beat that price because it is new business for them. Now, NVRO has to cut prices again to keep the business. It is a downward spiral in pricing. The only thing worse than insurers starting to deny coverage and a price war breaking out would be a new competitor with a better mousetrap. Oh, wait...

### Saluda

Remember, in 2015, it was NVRO with the new better mousetrap. They quickly went from zero market share to around 15%+ in three years. The high volume implanters all switched to NVRO because A). they have no loyalty, and B). the NVRO product was supposedly better. Well the exact same thing is about to occur again. This time it is a private company called Saluda, backed by Medtronic and Boston Scientific. Saluda's better mousetrap uses a new "closed" -loop stimulator technology called Evoke." Saluda is backed with clinical data showing how superior their technology supposedly is.

Existing stimulators force the patient into a single frequency, low or high (like NVRO) or waveform (like Burst). This results in too little or too much stimulation which leads to being not effective or to shocking the patient.

The Evoke monitors the spinal cord in real time and adjusts the current of each pulse! This is a personalized stimulation for each patient as opposed to NVRO's one fixed 10kHz frequency, one size fits all method. This is a game changer and is a serious threat to NVRO.



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Saluda comes armed with a study that shows 9 out of 10 patients experience long-term pain relief at 12 and 24 months. We expect the Evoke to rapidly take market share as did NVRO. But worse, we think that NVRO will lose even more than their competitors because we believe that the high volume implanters that currently use NVRO will switch over to the Evoke. Why do we believe that? Because, they all switched over to NVRO when the Senza first launched with their better mousetrap and worse, 4 out of the top 10 recipients of NVRO's payments and are high volume implanters of NVRO, were involved in (authors of) the double-blind, randomized, controlled Saluda study of the Evoke!

What did that study show? "A level of evidence that is unmatched in the **field."** You can bet, and we are, that these high volume implanters will switch over to Saluda. **NVRO could lose 30% of their revenue**. NVRO is not the new technology anymore. They have been around for 6 years and the doctors all know that the product doesn't really work anyway, so why wouldn't they try a new technology that they themselves tested and shows much better results?

The Evoke was launched in Europe on January 28, 2020 Evoke Europe It received its European CE mark, clearing it for sale in European Economic Area. They are still waiting for FDA approval in the U.S. It is limited to investigational use in the United States and not yet available for sale. We believe it will be late this year when they finally get approval. They have been waiting since 2019.

The FDA approved Mainstay Medical's ReActiv8 neurostimulation system to treat a form of intractable chronic low back pain, 19 months after ReActive8 FAILED a clinical trial. Mainstay wins FDA Approval



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### **Takeover**

A big part of the rise in NVRO stock has been investors hoping for a turnaround and a take-out. We believe that neither is going to happen. First of all, NVRO has never made a profit in 16 years, even with the hot new technology in the SCS market. They are a one product company, who's product doesn't work, about to be eclipsed by a new better product, during a pricing war, with insurers cracking down on approvals. How do they grow revenue to any degree or earn a profit? We just don't see it.

With a \$5.42 billion market cap and a \$156 stock price an acquirer can buy other SCS companies for far cheaper. There are many new smaller players entering the arena. This is adding to additional price challenges. NVRO is a one product money losing company. There is no diversification. Johnson & Johnson was a major investor in NVRO and never bought them.

Stryker is the name most mentioned as a possible buyer but they buy cheap bad companies, not expensive bad companies.

Abbot bought DRG at a huge discount and has not made a profit with them. Medtronic bought Stimgenics for a huge discount. They are big enough to buy anyone but they bought a new smaller player for cheap. Nobody is going to want to pay a huge premium for a money losing one product company.

Saluda was for sale for 18 months and could not find a buyer. They wanted \$1 billion for it and could not sell it. Why wouldn't you buy Saluda today for less than that, knowing that as soon as they get FDA approval their sales will quickly capture 15% market share. Because, they still will probably not be profitable. Nobody is profitable in this market. Then why is NVRO at \$5.4 billion? It's crazy.



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# But the CEO is a turnaround expert

CEO Kevin Grossman is viewed by wall street as a **medical company** turnaround expert. He was just the guy to take over and fix the problems and have a quick sale. But, is he an expert at turnarounds? For ten years, 1996 to 2006 he was the **CEO of Thoratec**, which sold a ventricular assist device for heart failure. In 2014 the stock collapsed after many instances of injuries and some fatalities. Grossman returned in 2014, trimmed some costs and quickly sold the company for double to St Jude. The revenue never increased, it was flat with 2012.

In late 2011 he became CEO of Conceptus, that sold a micro-catheter and guidwire system (Essure) that allowed physicians to access and navigate the fallopian tubes using a non-incisional approach. The company had hit a rough patch, and he did the same thing, trimmed some costs and sold it to Bayer AG for \$31 all cash offer, a 20% premium to the stock price for a \$1.1 billion deal. The deal closed June 5, 2013. From the time he joined until the time he left, revenue did not grow. CEO Grossman said Essure was a terrific product and the "safety and efficacy was uniquely compelling." A few years later sales declined 70% and Bayer had to pull Essure from the market. **Bayer had to pay** \$1.6 billion to settle all the lawsuits from patient injuries.

In neither case did he turnaround the business. He was able to turnaround the stock price. However, he has now been at NVRO for longer than either of those two flips. He has not turned the business around. 2019 was a year of record net income loss of \$103 million. He caught a break with Covid because it gave him a whole year of a free pass. At some point he will need to show results to justify the stock price rise. The stock has gone from \$35 at the end of 2019 to a high of \$188 in late 2020. The stock price has already priced in a buyout that is never going to come. We can see a round trip back to under a \$1 billion market cap, once the Evoke product hits the market.



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In the meantime they are a money losing one product, old technology, company in a price war, with payors increasingly denying approval, with some states outright banning payments. The company has never made a profit and most likely never will. Reality will return as sales falter and there is no financial support. It is likely that the day that the Evoke gets FDA approval, NVRO will be down 20%.

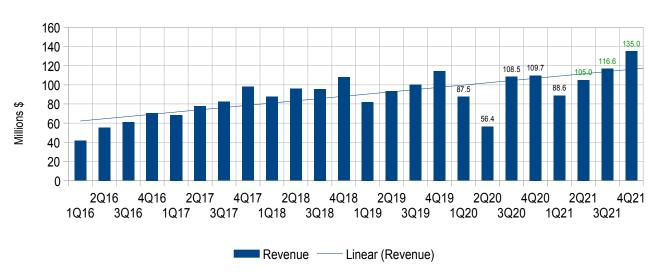
## **Price Targets:**

Short term (0-3 Mo): \$125-\$135 Medium Term (6-12 Mo): \$100-\$125 Long Term (1Yr+): \$50-\$80



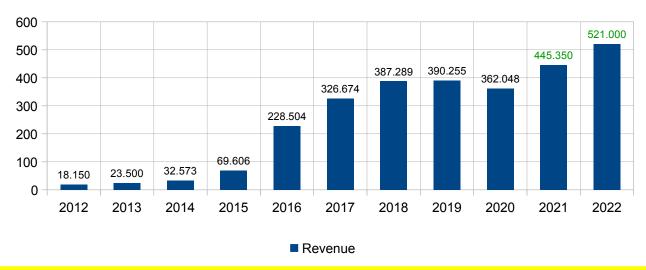
#### **NVRO** Revenue

2016 To 2021 Est.



#### **NVRO** Revenue

2012 To 2022 Est.



The street is looking for a big turnaround in 2021 and 2022. We don't see it with a price war going on and if Saluda gets approval.

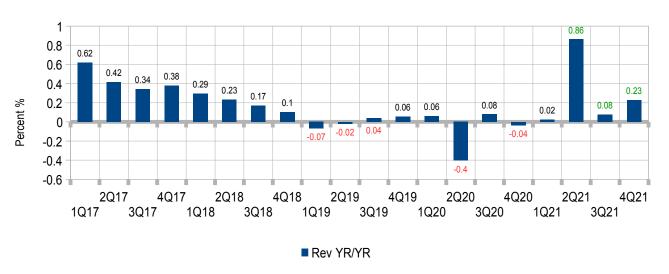
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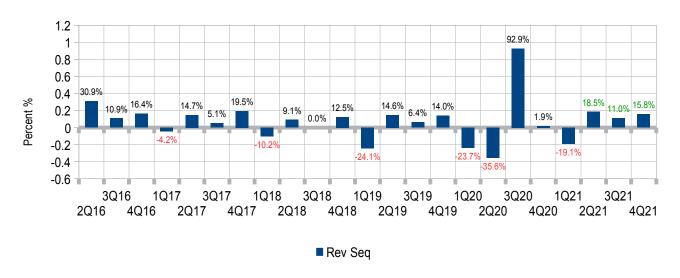
#### **NVRO Revenue Growth**

2017 To 2022 Est.



### **NVRO Sequential Revenue Growth**

2016 To 2021 Est.

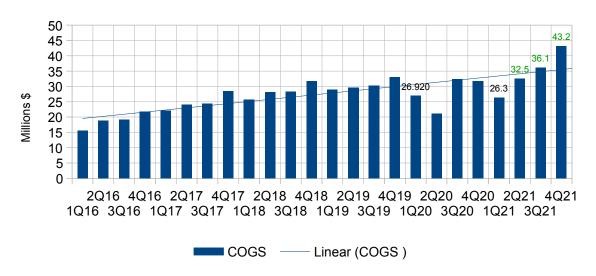


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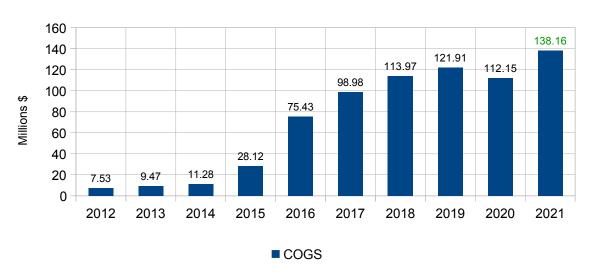
### **NVRO Cost Of Goods Sold**

2016 To 2021 Est.



#### NVRO Cost Of Goods Sold

2012 To 2021 Est.

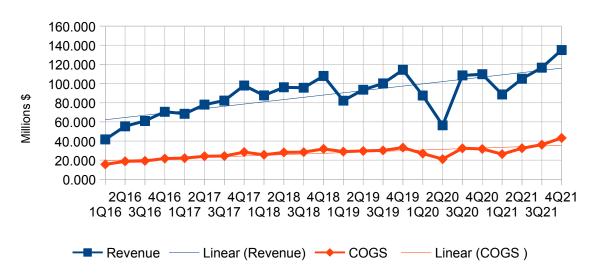


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June 11, 2021

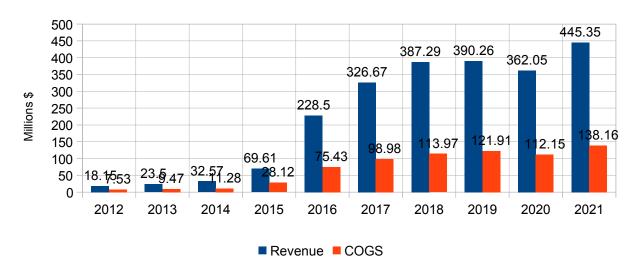
#### NVRO Revenue Vs COGS

2016 To 2021 Est.



#### NVRO Revenue Vs COGS

2012 To 2021 Est.



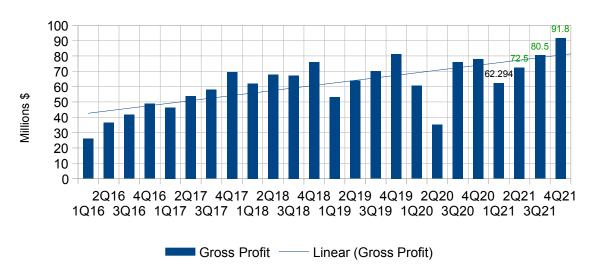
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#### **NVRO Gross Profit**

2016 To 2021 Est.



### **NVRO Gross Profit**

2012 To 2021 Est.



# Gross profit is expected to bounce back, like the market is fine. It's not.

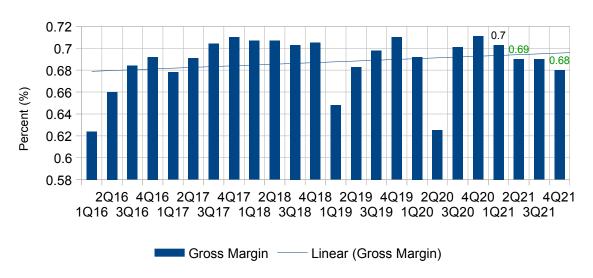
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### **NVRO Gross Margin %**

2016 To 2021 Est.



### **NVRO Gross Margin %**

2012 To 2021 Est.

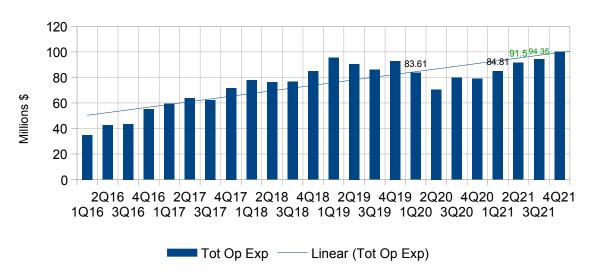


Gross margin has been flat for years as COGS matches revenue growth.

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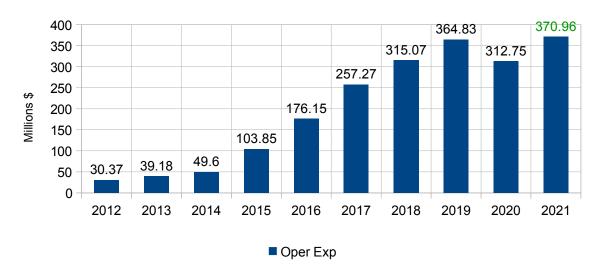
### **NVRO Total Operating Expense**

2016 To 2021 Est.



### **NVRO Total Operating Expense**

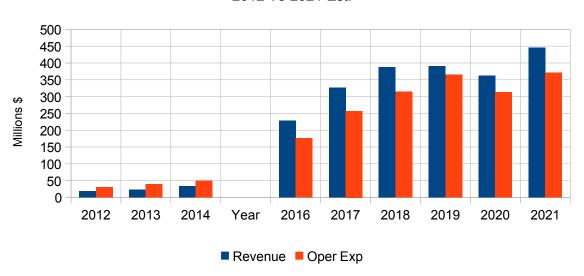
2012 To 2021 Est.



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## NVRO Revenue Vs Total Operating Expense

2012 To 2021 Est.



### NVRO Revenue Vs Total Operating Expense

2016 To 2021 Est.



# Total operating expenses rise just as fast as revenue. There is no scale in this business!

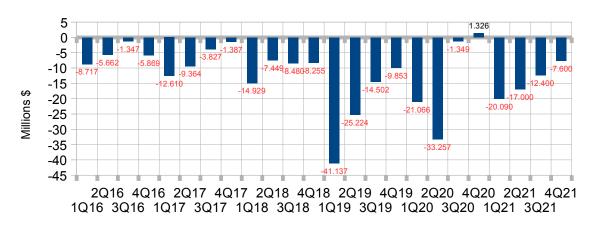
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#### **NVRO EBITDA**

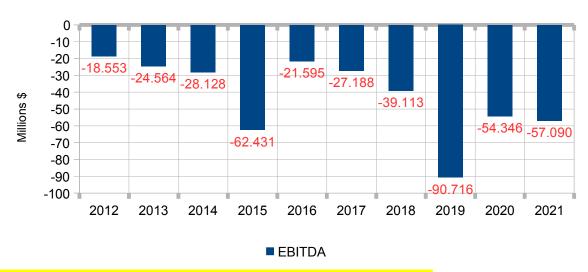
2016 To 2021 Est.



■ EBITDA

#### **NVRO EBITDA**

2012 To 2021 Est.



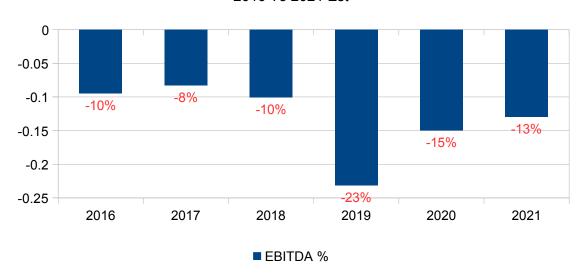
## We estimate EBITDA in 2021 to be worse than 2020!

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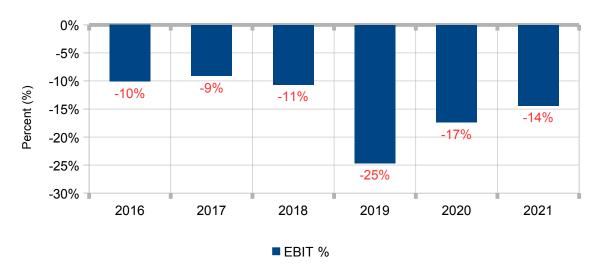
## NVRO EBITDA Margin %

#### 2016 To 2021 Est



### **NVRO EBIT Margin %**

#### 2016 To 2021 Est.



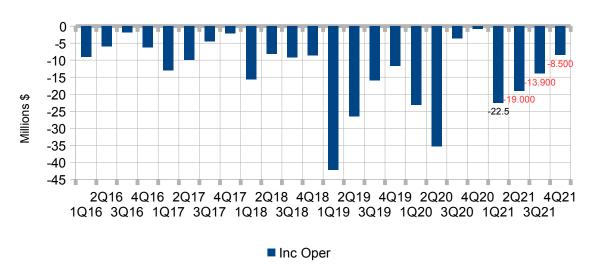
# Both EBIT and EBITDA margins are terrible.

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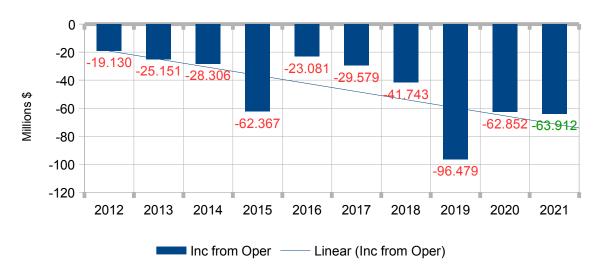
**NVRO Loss From Operations** 

2016 To 2021 Est.



### **NVRO Loss From Operations**

2012 To 2021 Est.



# This is worth \$5.4 billion, why?

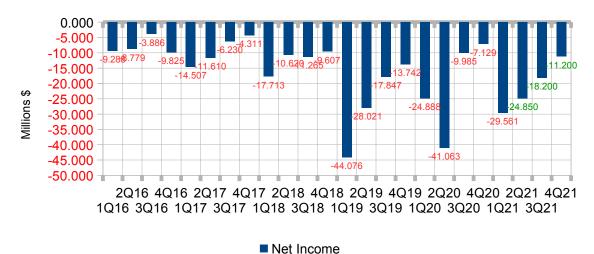
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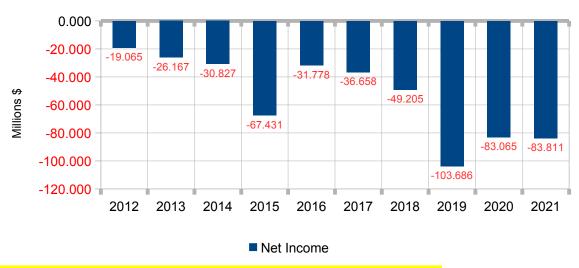
#### **NVRO Net Income**

2016 To 2021 Est.



# **NVRO Net Income**

2012 To 2021 Est.

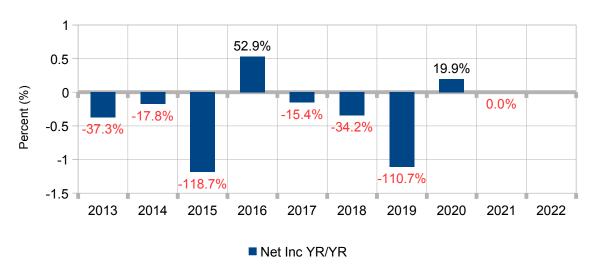


# Absolutely terrible, stock price went up 437% on this?

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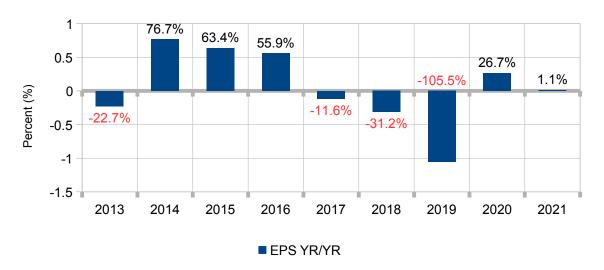
#### **NVRO Net Income Growth**

2013 To 2021 est.



#### **NVRO EPS Growth**

2013 To 2021 Est.



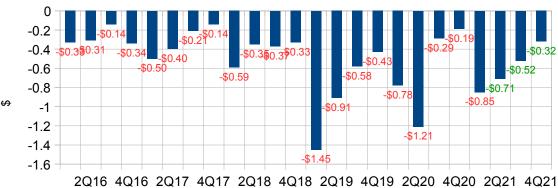
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### **NVRO Earnings Per Share**

2016 To 2021 Est.

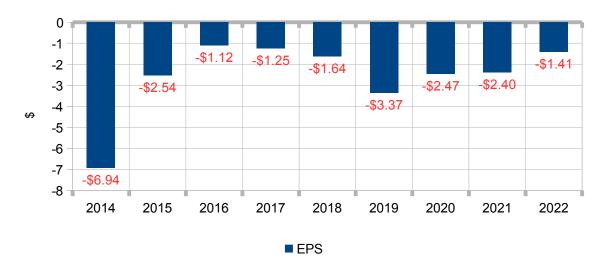


1Q16 3Q16 1Q17 3Q17 1Q18 3Q18 1Q19 3Q19 1Q20 3Q20 1Q21 3Q21

EPS

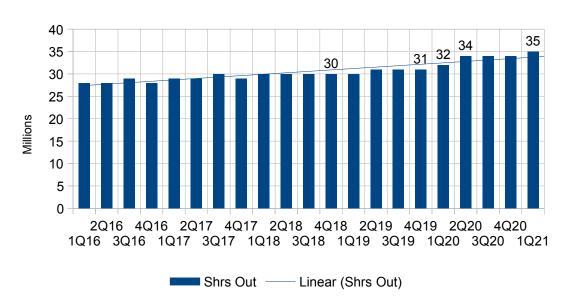
## **NVRO Earnings Per Share**

2014 To 2022 Est



EPS loss mostly improves only because of more shares outstanding.

### **NVRO Shares Outstanding**



### **NVRO Shares Outstanding**

#### 2012 To 2022 Est



Not only do they lose about \$86 million but you also get diluted by about 8% per year!

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